Section A Attachment

Attachment A.1: Non-Technical Summary

A.1 Non-Technical Summary

A.1.1 General

Regeneron Ireland, Raheen Business Park, Ballycummin, Raheen, Co. Limerick is applying to the Environmental Protection Agency (EPA) for an Industrial Emissions Licence (IEL) for the operation of a biopharmaceutical manufacturing facility at the former Dell EMF3 facility, Raheen Business Park, Ballycummin, Raheen, Co. Limerick. Notification of the application was posted at the site location; submitted in writing to Limerick County Council, and advertised in the Irish Independent, issue of 10th April 2014.

The site is bounded to the south by the business park road network and the established Dell EMF1 and Adhesives Research business premises. A Fás training centre is located to the north of the site, while to the east a series of four buildings accommodate a number of businesses including City Analyst and Freight Shift Services. Beyond the western boundary of the site is Greenfield in the ownership of Shannon Development.

To the North West is Roche Castle, a nineteenth century gothic revival style house and associated out buildings located on a mature wooded site. The castle is a listed building and currently unoccupied and in the ownership of Shannon Development.

The site and all immediate surrounding lands and properties are zoned for Enterprise and Employment under the Limerick County Council Southern Environs Local Area Plan 2011-2017. The nearest residential properties to the site are located approximately 400m to the east of the site along Ballycummin Drive, Raheen.

Regeneron has identified a need for additional manufacturing capacity to support the company's ability to supply growing demand for its medicines in Europe and other parts of the world. To fulfil this need Regeneron is proposing to develop a new state-of the-art manufacturing centre in Ireland. In Raheen, Regeneron intends to invest in the creation of new bulk manufacturing facilities for a range of biopharmaceutical derived medical products for patients worldwide, together with associated business support functions.

The facility will entail the installation of new biopharmaceutical manufacturing processes to the existing production area; this will involve a central production cleanrooms, warehousing, clean water and steam utilities, including boilers, heating ventilation and air conditioning systems and electrical switch rooms. A Quality Control Laboratory will be constructed on the site to accommodate quality control test procedures related to the proposed manufacturing process being developed within the Production Area. The proposed location for the laboratory is on the western side of the existing headblock within the existing site car park area.

The proposed development falls under Class 5.16 of the First Schedule of the Environmental Protection Agency Act 1992, as amended.

Class 5.16: The production of pharmaceutical products including intermediates

Planning Permission has been granted by Limerick County Council for the proposed development (Ref. No, 13/745). An Environmental Impact Statement was included in the planning package. These documents have been included in this IEL application as attachments.

The activity does not come under the EC (Control of Major Accident Hazards involving Dangerous Substances) Regulations (S.I. No. 74 of 2006).

A.1.2 Management of the Installation

Technical Competence & Site Management

The Directors of Regeneron Ireland will have responsibility for the operation of the proposed facility. The facility will be operated by a dedicated management team. The staff of the facility will be technically experienced and qualified in the areas of engineering; environmental management; waste; health and safety; finance; administration, human resources and maintenance.

Environmental Management System

An Environmental Management System (EMS) will be developed for the management of the environmental aspects of the proposed facility. The EMS will address the provision of all resources, human and otherwise, necessary to ensure control and continuous improvement in the environmental management of the facility. The EMS will be subject to an assessment for suitability (management review) by a member of senior management, at least on a yearly basis.

Hours of Construction and Operation

The proposed facility will operate 24 hours. Day staff will be on site from Monday to Friday, from 8 am to 5 pm each day. Site operatives will work over a 3 shifts:

- Shift 1 08:00 – 16:00
- Shift 2 16.00 – 00.00
- Shift 3 00.00 – 08.00

There will be a 24 hours security presence on site throughout the year.

Construction will occur for a period of 24 months. Normal construction working hours will be Monday to Friday 8:00am to 6:00pm however longer working hours and potentially shift working s envisage during peak construction periods.

A.1.3 Infrastructure & Operation

The manufacturing processes to be employed by Regeneron at the Raheen facility will follow what are now considered as industry standard techniques for the production of “medicines for patients” using biotechnology derived processes. Today, this approach is favoured over traditional organic chemistry routes used in the past because it is capable of yielding more complex molecules for medicinal applications, is more efficient in terms of productivity, poses lower safety risks to the surrounding community, and has less environmental impact in terms of hazardous chemicals used or waste generated for disposal.

This facility is intended to ultimately accommodate four production trains within the existing Production Building. The installation is being scheduled in two phases, each comprising two trains and associated support functions. The primary process steps in the Regeneron manufacturing scheme are;

- Cell Culture
- Harvest
- Purification
- Product Formulation

A.1.4 Emissions

The normal emissions from the facility will comprise:

− Emissions to air from boilers;

− Emissions to surface water sewer from site and roof runoff;

− Emissions to sewer from process effluent and sanitary effluent.

Emissions to Air

The emissions to atmosphere from the proposed facility are classified according to:

- Boiler Emissions
- Main Emissions
- Minor Emissions
- Fugitive and Potential Emissions

The proposed facility will consist of 5 No. 7.9 MW natural gas-fired steam boilers. These boilers will produce steam to service production operations and air handling units (AHUs) within the Production Building. For Phase 1 of the project (i.e. two production lines in operation plus associated services) 2 boilers will be in operation plus one on standby. With the facility in full operation i.e. four production lines plus associated facilities (Phase 2) four boilers will be operational plus, with the fifth on standby.

The proposed development will also consist of 2 No. 1.8 MW natural gas-fired boilers used for LPHW (low pressure hot water) generation servicing the QC Lab and Administration Buildings which will be operated on a duty/assist basis for Phase 2.

Of the substances listed in the schedule of S.I 394 of 2004, emissions from these gas-fired boilers will include the products of combustion, Oxides of Nitrogen (NO_2) and Carbon Monoxide (CO). As these boilers are natural gas-fired, the emission of particulates ($PM_{10\,/\,2.5}$) and of SO_2 is negligible.

Emissions to Sewer

It is planned that effluent arising from the development will undergo preliminary treatment on site, designed and sized to initially accommodate Phase I effluent only, before discharge to the Shannon Development foul sewer within Raheen Business Park, which ultimately connects to Irish Water's public foul sewer serving Limerick City and Environs. The on-site waste water management facility will be designed to allow for modular expansion for Phase II effluent and will include the following operations;

- Heat inactivation of streams potentially containing cells from the process (biowaste)
- Balancing and neutralisation of all process waste waters
- Cooling, odour management and monitoring

The biotechnology processes to be used at the Regeneron facility will generate a range of aqueous waste streams containing biodegradable organic components and nutrients. The utility equipment that will be provided at the facility to support the production process will also generate aqueous streams containing low levels of biodegradable organics. Sanitary waste water (sewage) will also arise due to approximately 300 full-time staff which ultimately could be employed at the facility.

The majority of waste water arising from the facility will be generated in the production areas, and in particular from the waters associated with vessel cleaning.

It is proposed that uncontaminated storm water run-off from the facility will discharge to the Shannon Development storm water sewer serving the Raheen Business Park, which ultimately drains via the Barnakyle stream to the River Shannon.

Noise Emissions

Construction noise will be generated for a limited period during the construction phase. The level of construction noise during the daytime will be minimised as much as practicable to limit the impact on ambient noise levels and noise sensitive locations (e.g. residential dwellings) in the vicinity.

There will be a small number of different noise sources associated with the operation of the facility. The main noise sources identified include cooling towers and associated pumps, chillers and condensers.

A.1.5 Control and Monitoring

Control of Emissions to Air

Boiler Emissions

The proposed facility will consist of 5 No. 7.9 MW boilers located in the Boiler Room and 2 No. 1.8 MW boilers located in the Utility yard, all of which will be naturally gas-fired. Each boiler will be designed for low NOx emissions (NOx emission concentration less than 80 mg/Nm^3 dry basis, 3% O_2). The low NOx emission design will be achieved through fuel-air ratio control.

No specific abatement will be in place for the minor emission points. Control of Minor Emissions will include the Standard Operating Procedures (SOPs) that will be part of the Environmental Management System for the facility.

There will be no anticipated odorous emissions from the facility.

Control of Emissions to Sewer

The proposed on-site waste water management system will provide preliminary treatment to the process/trade effluent only and will consist of the following component treatment steps:

- Heat Inactivation (biowaste or cell-contented waste only)
- Waste Water Balancing
- Cooling
- Neutralisation

Note: Sanitary effluent from the facility (from lockers, toilets and canteen) will combine with the process effluent downstream of the Waste Water Management System prior to entering the Shannon Development foul sewer in Raheen Business Park.

Control of Noise Emissions

Based on the existing noise levels and noise impact assessment (as detailed in the attached EIS and in Attachment I.7 of this application) it is predicated that the additional noise contribution from the facility will not cause a significant negative impact at the nearest noise sensitive locations.

The minimisation of noise will form an integral part of the detailed design. The various noise control and attenuation measures to be employed at the plant can be summarised as follows:

− As part of the detailed design and tendering process, stringent noise level criteria will be specified for all plant and equipment;

− Acoustic insulation / enclosures and attenuation will be provided on plant and equipment as necessary;

− Plant and equipment will be maintained and serviced on a maintenance schedule;

− Site access roads will be of smooth hard standing surface to reduce vehicular noise.

Air Monitoring and Sampling

Boilers

The boiler emission points will be monitored in line with BAT. Sampling and analysis will be carried out on an annual basis for oxides of nitrogen and carbon monoxide.

This periodic sampling and the associated laboratory analysis will be undertaken by an accredited laboratory.

Sewer Monitoring and Sampling

Monitoring will be carried out on the effluent at emission point, SEMP1, discharge from the process waste water balancing tanks, in line with BAT. Parameters that will be monitored, either continuously or on a monthly basis, will be flow, pH, temperature, Biological Oxygen Demand (BOD), and Chemical Oxygen Demand (COD).

A monitoring chamber will be installed at surface water sewer monitoring point (SEMP2) to enable continuous monitoring of Total Organic Carbon (TOC).

Groundwater Ambient Monitoring and Sampling

Groundwater will be monitored from 3 existing boreholes and 1 proposed borehole on site.

Noise Ambient Monitoring and Sampling

An ambient noise survey will be carried out annually at the site boundaries and noise sensitive locations. The results will be reported annually to the EPA and included as part of the Annual Environmental Report (AER). Ambient monitoring will be carried out in accordance with the EPA NG4 Guidance Note.

A.1.7 Resource Use and Energy Efficiency

Resource Use

All materials and products are listed in Tables G.1(i) and G.1(ii) of this application.

Energy Efficiency

As part of the proposed development, the measures described below are being carried out in order to reduce site energy demand:

- Use of Vapour Compression WFI (Pure Water for Injection) generation as opposed to multi-effect distillation reduces steam usage.
- Minimise clean room area and volume through reduction of footprint and ceiling heights where possible to reduce the HVAC heating, cooling and electricity demands.
- Introduce some level of recirculation with the air handling units on select ISO 8 areas in lieu of once through air to reduce volume and energy usage.

- Use of De-humidification in lab building cold-rooms to reduce frost induced inefficiencies in the refrigeration systems.
- Engineering out the need for liquid nitrogen back-up on lab building -70ºC resulting in saving on Liquid Nitrogen venting. Liquid Nitrogen production is energy intensive.
- Laying out QA/QC labs to minimise the solar heat gain into the building, thus reducing the cooling demand.
- The site proposes to use best available technology for steam generation with direct digital combustion control, oxygen trim and heat recovery through economisers and flash steam recovery. A high level of condensation recovery will also be implemented.
- The Heating demand for the lab building and Admin block will be carried out using low pressure hot water boilers as opposed to inherently less efficient steam/LPHW heat exchanger system.
- VSD technology will be deployed where appropriate to ensure that electrical drives operate efficiency over their demand range.
- Use of electronic expansion valves in lab building cold-rooms and refrigeration systems.
- Use of VSD's on Air Compressors to reduce electricity demand.

A.1.8 Materials Handling

Raw Materials, Intermediates and Product Handling

Raw materials and products are listed in Tables G.1(i) and G.1(ii) of this application.

All raw materials and packaging components are received though the Goods In/Out area in the warehouse.

Waste Management

Anticipated wastes and the management of these wastes are outlined in Table H.3(i) of this application. Waste management at the facility will be carried out in accordance with the Waste Management Acts 1996 to 2013.

Improvements in environmental performance will encouraged in the EMS associated with the IEL by setting a series of objectives and targets commonly associated with reducing resource material use (e.g. water, energy, paper) and waste production generally. Regeneron will undertake the establishment of meaningful targets for improvements in the areas of waste reduction throughout the lifetime of the operation of the facility.

Food waste will be managed in accordance with the Waste Management (Food Waste) Regulations 2009.

A.1.9 Existing Environment & Impact of the Activity

The facility has been designed to ensure that the emissions which will arise from the facility do not have an adverse impact on human health or the environment.

A description of the existing environment (air quality, water quality, noise levels, ecology) is included in the Environmental Impact Statement (EIS) that accompanies this application. Further to the impact assessment detailed in the EIS and Attachment I of this application, a summary of the impact of emissions is included as follows:

Impact of Air Emissions

Based on the detailed information contained in Attachment I, and with reference to the Schedule of the Environmental Protection Agency (Industrial Emissions) (Licensing) Regulations 2013, there are no potential significant emissions from the proposed development.

The emergency generators will only be operational for short test and maintenance periods or during an electricity supply failure, and not under normal operating conditions therefore it is considered that emissions from it will have no significant effect on air quality.

Impact of Emission to Surface Water

It is proposed to continue to use the exiting arrangements for discharge of storm water run-off from the proposed development. Storm water from the site arises from run-off from buildings, car-parks, road-ways, service yards and other developed areas of the site which discharge via a petrol interceptor to the main Raheen Business Park storm water system. The storm water discharge from the Raheen Business Park exits the estate and follows the route of a culvert and pipe to Loughmore Common canal, which enters the Barnakyle River, which in turn flows into the Maigue River, which ultimately discharges to the River Shannon Estuary.

Impact of Emission to Sewer

It is proposed that process waste waters (non-sanitary) arising from the proposed development will undergo preliminary treatment on-site which will render the waste water amenable for discharge to the local municipal sewer and subsequent downstream treatment at the Limerick City & Environs Waste Water Treatment Plant (WWTP) in Bunlicky which discharges into the River Shannon estuary.

Shannon Development and Limerick Local Authorities have confirmed that sufficient hydraulic capacity is available in the sewerage system, from the point of discharge from the Regeneron site via Raheen Business Park and the city network, to Bunlicky WWTP, without compromising spare capacity for other future development in the city catchment. Limerick Local Authorities have also confirmed that the municipal WWTP at Bunlicky has the capacity and scale to treat the waste water (with some modification for Phase 2), without impacting on its ability to comply in full with its EPA issued discharge licence and the Urban Waste Water Treatment Regulations.

The Fourth Schedule of the 1994 Urban Waste water Treatment Regulations (as amended) specifies particular requirements for industrial waste water entering public collection systems and Urban Waste water Treatment Plants.

Impact of Emissions to Groundwater

There are no emissions to ground or groundwater as part of the proposed facility and therefore there is no predicted impact to the groundwater environmental due to the proposed facility. There will be an underground drainage network on site for process wastewaters, foul sewerage and storm waters.

Impact of Noise Emissions

In order to determine the indicative noise impact on the nearest noise sensitive locations noise from the proposed facility was modelled using Bruel & Kjaer Predictor Type 7810, V9.10 software package. No Impact from the Regeneron facility was predicted at the noise sensitive locations. For full details of the developments noise model please refer to Attachment I of this application (Section I.7-2).

Environmental Considerations and BAT

The proposed development has been assessed against a number of European Union Reference Documents on Best Available Techniques (BAT).

BAT is a key principle in the Industrial Emissions Directive where emphasis is placed on pollution prevention techniques, including cleaner technologies and waste minimisation, rather than end of pipe treatment. Regeneron will subscribe fully to the principles of BAT in the design and operation of the facility.

The following documents have been reviewed in order to detail the relevant BAT conclusions to the proposed development. Each identified BAT conclusion is assessed in terms of applicability to the proposed development, implementation of BAT, timeline for implementation, and a justification where BAT is not relevant (in the case of the BAT Guidance Note on Best Available Techniques for Pharmaceutical and other Speciality Organic Chemicals and the BAT Reference (BREF) document for the Manufacture of Organic Fine Chemicals):

− BAT Guidance Note on Best Available Techniques for Pharmaceutical and other Speciality Organic Chemicals, 2008

− BREF Document for the Manufacture of Organic Fine Chemicals, August 2006

− Reference Document on Best Available Techniques in Common Waste Water and Waste Gas Treatment / Management Systems in the Chemical Sector, February 2003

− Reference Document on Best Available Techniques for Energy Efficiency, February 2009

− Reference Document on Best Available Techniques on Emissions from Storage, July 2006

− Reference Document on the General Principles of Monitoring, July 2003

A.1.10 Accident Prevention & Emergency Response

The proposed facility is not currently in existence, so a site Accident Prevention and Emergency Response Procedure is not currently in place for the site. Regeneron regards the prevention of accidental emissions from its sites to be an integral part of the efficient production of high quality products. The prevention of accidental emissions and spills will be facilitated by the correct design of equipment and operations at the site in the following areas:

− Bunding and Collection

− Storage and Transport

− Training

− Procedural Control

− Emergency Response

− Site Drainage

− Containment of Firewater

A.1.11 Remediation, Decommissioning, Restoration & Aftercare

The proposed facility is in the process of being designed in accordance with Best Available Techniques and best practice to minimise the potential for adverse effects on the environment during preconstruction, construction, operation and closure.

An Environmental Liabilities Risk Assessment (ELRA) has been prepared by PM Group in accordance with the new EPA Guidance on Assessing and Costing Environmental Liabilities, and is included in this application (Attachment K).

A detailed Closure Plan will be developed and submitted to the EPA within six months after proposed grant of licence, or as otherwise agreed with the EPA, in accordance with the recent EPA Guidance on assessing and costing environmental liabilities. The plan will be reviewed annually as part of the Annual Environmental Report (AER). Decommissioning of all aspects of the facility will be validated by the EPA prior to IEL surrender.

A.1.12 Statutory Requirements

This application and the proposed development has taken due regard to the statutory requirements outlined in this section of the application. The proposed facility will comply with or not contravene the statutory requirements, as outlined in Attachment L of this application.

A.1.13 Declaration

This application includes the formal, signed declaration of Regeneron Ireland for the making of an application to the EPA for an IEL.

Section B Attachments/Drawings

Attachment B.1: Certificate of Incorporation

Drawing 1: Site Location Map

Drawing 2: Site Layout Plan

Attachment B.6-1: Limerick County Council grant of permission

See Attachment B.6-2: Environmental Impact Statement

Attachment B.6-3: Previous Planning Permissions

Attachment B.6-4: Appropriate Assessment Screening Report

Attachment B.7-1 – Water Discharge Supporting Information

Attachment B.7-2 – Irish Water Agreement

Attachment B.7-3 – Shannon Development Agreement

Attachment B.9-1: Site Notice

Drawing 3: Site Notice Locations

Attachment B.9-2: Newspaper Advertisement

Attachment B.9-3: Copy of Notice given to Limerick County Council

Attachment B.12: Supporting information on Regulations Controlling Fluorinated Greenhouse Gases and Ozone Depleting Substances

Attachment B.1: Certificate of Incorporation

Number 519550

Certificate of Incorporation

I hereby certify that

REGENERON IRELAND

is this day incorporated under
the Companies Acts 1963 to 2012.

We hereby certify that this document is a true copy of the original.

Dated this 3 **day of** April **2014**

Arthur Cox

ARTHUR COX
Arthur Cox Building,
Earlsfort Terrace,
Dublin 2.

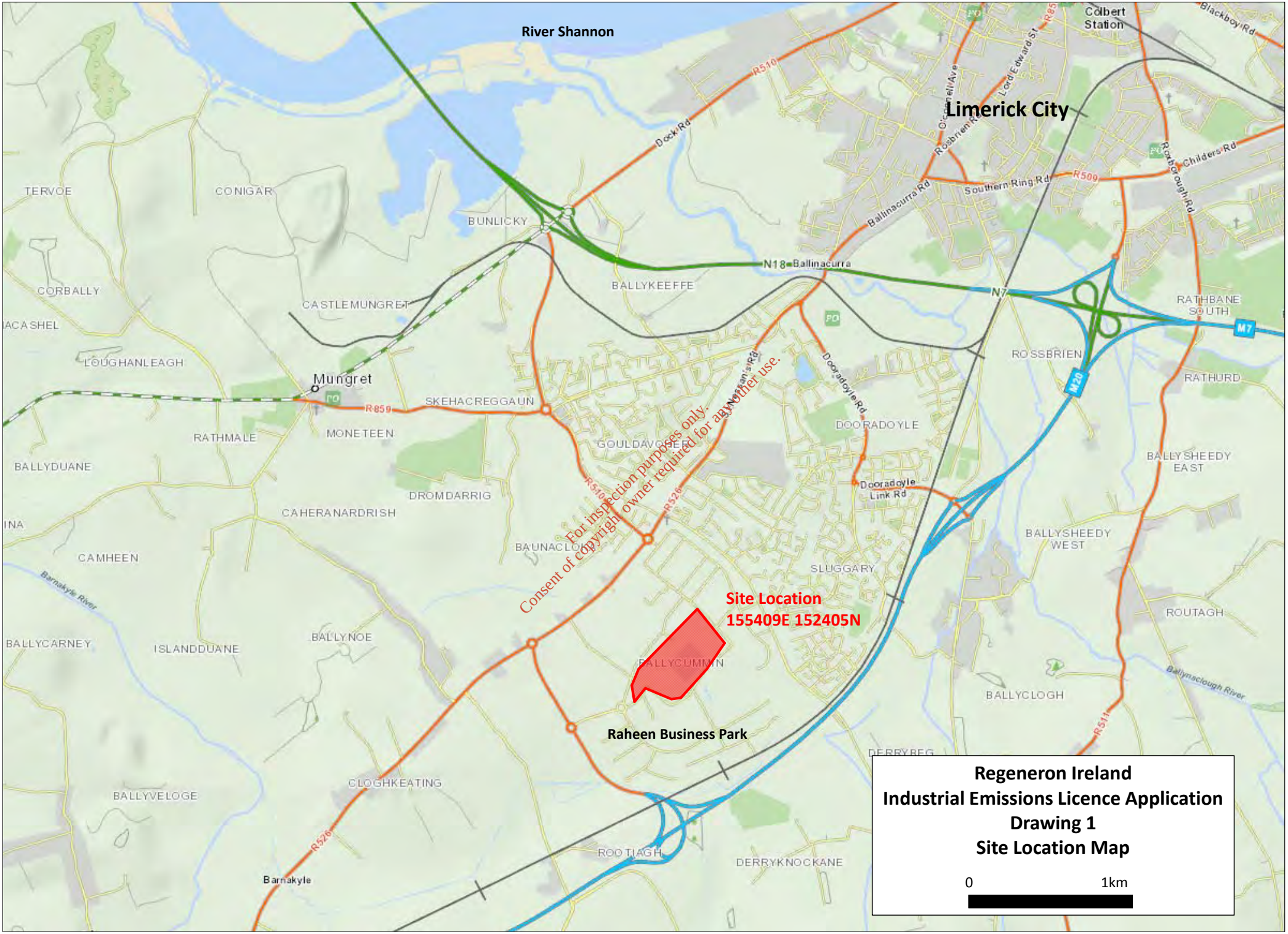
Given under my hand at Dublin, this

Friday, the 2nd day of November, 2012

Par Del

for Registrar of Companies

Drawing 1: Site Location Map



Drawing 2: Site Layout Plan

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EXISTING TRUCK ENTRANCE

ROCHES AVE.

WASTE WATER MANAGEMENT AREA

EXISTING WASTE MANAGEMENT YARD

WAREHOUSE EXTENSION FFL 22.00

GAS TANK YARD

COLD & AMBIENT STORAGE

ELEC. SUBSTATION FFL 22.00

ELEC. SUBSTATION FFL 22.00

UTILITY YARD

NEW PRODUCTION PLANTROOM ROOF

E 155409
N 152405

FIRE WATER TANK

PUMP HOUSE

PROCESS WATER TANKS

AGI

ELEC. SUBSTATION FFL 22.00

DIESEL TANK

SCREEN WALLS

SCREEN WALL

COURT YARD

NEW QC LAB FFL 22.00

PROPOSED SITE SECURITY HUT AT MAIN ENTRANCE

ESB 38kV COMPOUND

CLIENT 38kV COMPOUND

PROPOSED CARPARK

OVERHEAD CABLES TO BE RE-ROUTED UNDERGROUND

0 20m 100m

THIS DRAWING WAS CREATED USING: AutoCAD

NOTES

1. THIS DRAWING IS TO BE READ IN CONJUNCTION WITH ALL RELEVANT ARCHITECTS AND ENGINEERS DRAWINGS AND SPECIDICATIONS
2. DO NOT SCALE DRAWING. USE FIGURED DIMENSIONS ONLY.
3. ALL DIMENSIONS ARE IN MILLIMETRES
4. ALL LEVELS INDICATED ARE IN METERS AND RELATIVE TO ORDNANCE DATUM : MALIN HEAD.

LEGEND

SITE BOUNDARY

PROPOSED BUILDING

PROPOSED UTILITIES

FORMAL ISSUE
20140410.091349 – CHITL

ISSUE	DESCRIPTION	DRN	ORIG	AUTH CHK	APP	DATE
A	FOR IEL APPLICATION	LRC	BT	TMcG	TMcG	07/04/14

REGENERON

CLIENT: REGENERON IRELAND

PM GROUP

PROJECT: BIOPHARMACEUTICAL MANUFACTURING FACILITY

TITLE: INDUSTRIAL EMISSIONS LICENCE APPLICATION
DRAWING 2:
SITE LAYOUT PLAN

DRAWINGS PREPARED BY: PM GROUP
LOUGHMAHON TECHNOLOGY PARK
BLACKROCK
CORK

ON BEHALF OF: REGENERON IRELAND IE0311171_22_SK_0001

CLIENT REF.

PROJECT No. IE0311171

A3 SCALE 1:2000

CLIENT DRG No.

PM DRG No. IE0311171-22-DR-0002

Attachment B.6-1: Limerick County Council grant of permission

LIMERICK COUNTY COUNCIL

PLANNING AND DEVELOPMENT ACTS, 2000 - 2013

NOTIFICATION OF GRANT OF PERMISSION

Regeneron Ireland
c/o PM Group
Loughmahon Technology Park
Blackrock
Cork

PLANNING REGISTER NUMBER : 13/745

APPLICATION RECEIPT DATE: 19/12/2013

Permission for the change of use of the former computer manufacturing facility to a biopharmaceutical manufacturing facility which will require the alteration and extension of the existing building, the installation of ancillary external utilities in the existing yards and all associated site development works. The proposed change of use of the existing 40,538 m.sq. building includes; internal alteration of the existing single storey production area to accommodate the installation of a new biopharmaceutical manufacturing process; the addition of 23,679 m.sq. of floor area to be provided by a 1st floor plant room over the existing production area, single storey warehouse extension, 3 No. 2 storey electrical room extensions; all resultant alterations to the existing elevations and the installation of 5 no. additional boiler flues. The proposed development also provides for the construction of a new 3 storey, 4,440 m.sq. laboratory building which will be linked to the existing building at ground and 1st floor levels. The ancillary external utilities have a total floor area of 247 m.sq. and consist of a single storey gate house, a single storey generator electrical room, a single storey pumphouse, 5 no. emergency generators, 5 no. bunded cooling towers, 3 no. water chillers, 2 no. process water storage tanks, a fire water storage tank, a gas storage area, a pipe rack, a natural gas pressure reducing station and 6 no. bunded tank areas holding chemical tanks, waste water holding tanks and diesel storage tanks. The facility works include a 38kV electrical substation housed in 2 no. single storey buildings of 116 m.sq. and 122 m.sq. with a new underground electrical supply. The works include the demolition of existing structures and the diversion of existing utilities. Site works include external fencing and boundary stone walls, access gates, landscaping, a bicycle shelter and modifications to the existing car park. The applicants are seeking a 10 year permission (an Environmental Impact Statement (EIS) has been prepared and will be submitted to the Planning Authority with the application. The proposed development is for the purposes of an activity requiring an Integrated Pollution Prevention and Control Licence (now Industrial Emissions Licence) at Ballycummin Raheen Business Park Raheen.

Further to the Order dated: 04/02/2014

A PERMISSION has been granted for the development described above subject to the 21 condition(s) set out on the Schedule which accompanied the Notification of the Council's Decision dated 04/02/2014 and amended by revised Schedule amending Condition No. 2 of the 07/02 2014

Signed on behalf of the said Council

(for) Director of Services
Economic Development & Planning
Date: 31st March 2014

Please note that the provisions of Planning & Development Acts, 2000 - 2013 limits the duration of this planning permission to a period of ten years from the date hereof.

LIMERICK COUNTY COUNCIL

PLANNING AND DEVELOPMENT ACTS 2000-2013
NOTIFICATION OF DECISION TO GRANT

Regeneron Ireland
c/o PM Group
Loughmahon Technology Park
Blackrock
Cork

Planning Register Number: 13/745
Valid Application Received: 19/12/2013
Further Information Received Date:

In pursuance of the powers conferred upon them by the above-mentioned Act, Limerick County Council has by Order dated **4th February, 2014** decided for the reason set out in the First Schedule hereto, to GRANT **PERMISSION** for development of land in accordance with the documents submitted namely:-**the change of use of the former computer manufacturing facility to a biopharmaceutical manufacturing facility which will require the alteration and extension of the existing building, the installation of ancillary external utilities in the existing yards and all associated site development works. The proposed change of use of the existing 40,538 m.sq. building includes; internal alteration of the existing single storey production area to accommodate the installation of a new biopharmaceutical manufacturing process; the addition of 23,679 m.sq. of floor area to be provided by a 1st floor plant room over the existing production area, single storey warehouse extension, 3 No. 2 storey electrical room extensions; all resultant alterations to the existing elevations and the installation of 5 no. additional boiler flues. The proposed development also provides for the construction of a new 3 storey, 4,440 m.sq. laboratory building which will be linked to the existing building at ground and 1st floor levels. The ancillary external utilities have a total floor area of 247 m.sq. and consist of a single storey gate house, a single storey generator electrical room, a single storey pumphouse, 5 no. emergency generators, 5 no. bunded cooling towers, 3 no. water chillers, 2 no. process water storage tanks, a fire water storage tank, a gas storage area, a pipe rack, a natural gas pressure reducing station and 6 no. bunded tank areas holding chemical tanks, waste water holding tanks and diesel storage tanks. The facility works include a 38kV electrical substation housed in 2 no. single storey buildings of 116 m.sq. and 122 m.sq. with a new underground electrical supply. The works include the demolition of existing structures and the diversion of existing utilities. Site works include external fencing and boundary stone walls, access gates, landscaping, a bicycle shelter and modifications to the existing car park. The applicants are seeking a 10 year permission (an Environmental Impact Statement (EIS) has been prepared and will be submitted to the Planning Authority with the application. The proposed development is for the purposes of an activity requiring an Integrated Pollution Prevention and Control Licence (now Industrial Emissions Licence) at Ballycummin Raheen Business Park Raheen** subject to the 21 condition(s) and the reasons for the imposition of the said condition(s) as set out in the Second Schedule.

Signed on behalf of said Council _____
for DIRECTOR OF SERVICES
PLANNING & DEVELOPMENT

Date: **4th February, 2014**

/P.T.O.

Under Article 20 of the Planning & Development Regulations 2001 - 2013 the applicant shall remove the notice in respect of the application following notification of the Planning Authority's decision.
In deciding the planning application, the Planning Authority, in accordance with Section 34(3) of the Planning & Development Acts 2000 – 2013 has had regard to submissions/observations received (if any) in accordance with the Planning & Development Regulations 2001 – 2013.
If there is no appeal to An Bord Pleanála a grant of permission shall be issued as soon as may be but not earlier than 3 working days after the expiration of the period for making of an appeal (see footnote).
THIS NOTICE IS NOT A GRANT OF PERMISSION AND WORK SHOULD NOT COMMENCE UNTIL PLANNING PERMISSION IS GRANTED.

NOTE:
An appeal against a decision of a planning authority under the provisions of the Planning & Development Acts, 2000-2013 may be made to An Bord Pleanála at any time before the expiration of the appropriate period and on payment of the appropriate fee, by an applicant for permission or any person who made submissions or observations in writing in relation to the planning application. An appeal by a person who made submissions or observations must be accompanied by the acknowledgement of receipt of the submissions or observations from the planning authority. Any such appeal must be made in writing and received by the Board within 4 weeks beginning on the date of the making of the decision by the planning authority. The appeal must be fully complete from the start otherwise it will be invalid. It is very important to note that any appeal referrals under the 2000 to 2013 Planning & Development Acts which are not accompanied by the correct fee will be invalid.

The scale of fees payable to An Bord Pleanála in respect of appeals is set out hereunder:

Case Type	Appeal received on or after 5th September 2011
Planning Acts	
a. Application for strategic infrastructure development or a request to alter the terms of such development already permitted or approved.	€100,000
b. Appeal against a decision of a planning authority on a planning application relating to commercial development, made by the person by whom the planning application was made, where the application included retention of development.	€4,500 or €9,000 if *EIS or **NIS involved
c. Appeal against a decision of a planning authority on a planning application relating to commercial development, made by the person by whom the planning application was made, other than an appeal mentioned at (b).	€1,500 or €3,000 if *EIS or **NIS involved
d. Appeal against a decision of a planning authority on a planning application made by the person by whom the planning application was made, where the application relates to retention of development, other than an appeal mentioned at (b) or (c) (non-commercial development).	€660
e. 1st party appeal solely against contribution condition(s) – (2000 Act Section 48 or 49).	€220
f. Appeal other than an appeal mentioned at (b), (c), (d) or (h)	€220
g. Application for leave to appeal.	€110
h. Appeal following a grant of leave to appeal.	€110
i. Referral.	€220
j. Reduced fee (payable by specified bodies).	€110
k. Submissions or observations (by observer) on strategic infrastructure development applications, appeals and referrals.	€50
l. Request from a party for an oral hearing.	€50
*EIS - Environmental Impact Statement **NIS - Natura Impact Statement	

Sub[illegible]ssions or observations on appeals made by third parties must be received by the Board within 4 weeks from the receipt of the appeal by the Board and the fee in this case is €50. Development consisting of the provision of two or more dwellings is classed as commercial development for the purposes of an appeal.
Should you wish to make an appeal, the following documents are available on www.pleanala.ie

- A Planning Appeal Form/Checklist and
- A Guide to making a Planning Appeal.

Appeals should be addressed to An Bord Pleanála, 64 Marlborough Street, Dublin 1.

PLANNING REGISTER REFERENCE NUMBER: 13/745

FIRST SCHEDULE

Having regard to the nature of the proposed development, it is considered that subject to compliance with the conditions as set out in the Second Schedule, the proposed development would be in accordance with the proper planning and sustainable development of the area.

SECOND SCHEDULE

1. The development shall be carried out in accordance with the plans and particulars lodged with the application and the E.I.S., on the 19th December 2013 except as may otherwise be required in order to comply with the following conditions.

   Reason - In order to clarify the development to which this permission applies.

2. The developer shall pay to Limerick County Council a financial contribution of €1,000,160 (one million one hundred and sixty thousand euro) in respect of public infrastructure and facilities benefiting development in the area of the Planning Authority that is provided or intended to be provided by or on behalf of the Authority in accordance with the terms of the Development Contribution Scheme made under Section 48 of the Planning & Development Acts, 2000 - 2013. The contribution shall be paid prior to the commencement of development or in such phased payments as the Planning Authority may facilitate and shall be subject to any applicable indexation provisions of the Scheme at the time of payment.

   Reason - It is a requirement of the Planning & Development Acts, 2000 - 2013 that a condition requiring a contribution in accordance with the Development Contribution Scheme made under Section 48 of the Act be applied to the permission.

3. Taking audible tonal and impulsive components of noise into account, the rating level of noise from the site during the construction phase shall not be greater than +5dB above measured background noise levels at 3.5m from the façade of any noise sensitive building, when assessed in accordance with B.S. 4142:1997: Method for Rating Industrial Noise Affecting Mixed Residential and Industrial Areas. Noise monitoring shall be carried out on request by the Local Authority.

   Reason - In the interest of amenity and the proper planning and sustainable development of the area.

4. Prior to construction works commencing on site, details of a dust minimisation plan for the construction phase shall be submitted for the written agreement of the Planning Authority.

Reason - In the interest of amenity and the proper planning and sustainable development of the area.

5. Prior to installation of the grease trap, details shall be provided to clarify if effluent from the kitchen is proposed to be discharged to a grease trap. The proposed hydraulic loading to the grease trap shall be estimated and details of how the grease trap has been sized shall be submitted, ensuring that it meets the requirements of IS EN 1825. This information shall be submitted for the written agreement of the Planning Authority.

Reason - In the interest of public health.

6. A Class 2 interceptor which meets BS EN 858 and is adequately sized shall be installed on site.

Reason - In the interest of public health.

7. Within two months of the operation phase of the development a revised Mobility Management Plan defining staffs travel arrangements shall be submitted for the written agreement of the Planning Authority.

Reason - In the interest of traffic safety and the proper planning and sustainable development of the area.

8. A revised Waste Management Plan containing the waste types with estimated quantities together with details of the Authorised Waste Collectors to be used to transport each type of waste shall be submitted for the written agreement of the Planning Authority prior to commencement of development.

Reason - In the interest of proper planning and sustainable development.

9. All planting shall take place on or before the first appropriate planting season after the commencement of development. This planting shall consist of trees of native broadleaf species. The planting shall be staked and tied and adequately maintained. All unsuccessful or damaged trees shall be replaced without delay.

Reason - In the interest of biodiversity and to protect the visual amenities of the area.

10. Pollution prevention measures including regular maintenance of the upgraded petrol interceptor shall be carried out.

Reason - To enhance the wildlife value of the site.

11. Bat friendly lighting shall be installed and no lighting of Roche Castle or the surrounding vegetation is permitted.

Reason - To enhance the wildlife value of the site.

12. A Bird survey and a Bat survey shall be carried out at an appropriate time of the year if possible. Should bats be encountered during construction works, works shall cease and the National Parks & Wildlife Service shall be informed.

Reason - To minimise possible disturbance to both birds and bats.

13. Prior to commencement of development proposals for mitigating threats to all features of special interest in the fabric, fixtures and features of Roche Castle, a Protected Structure, (which by legal definition includes the outbuildings complex and the lands comprising the curtilage), during the course of the works, shall be submitted and agreed in writing with the Planning Authority. Any shields or protective barriers erected or installed shall be wholly reversible without loss of material, or damage to the structure, in accordance with the Principles of Conservation.

Reason – To protect the architectural heritage in the interests of the proper planning and sustainable development of the area.

14. a. Prior to commencement of development revised drawings shall be submitted for the written agreement of the Planning Authority to provide for Boundary Fence Type 1 to a maximum height of two metres.
    b. Prior to commencement of development detailed specifications and methodologies for the construction of Boundary Fence Types 1 and 4, shall be prepared by an accredited conservation architect who shall also supervise the works.

Reason – To protect the architectural heritage in the interests of the proper planning and sustainable development of the area.

15. Proper records shall be kept of all works undertaken, insofar as they pertain to the curtilage boundaries, landscape features, and amenities of Roche Castle. These records shall include: Archival Standard Photographs taken before, during and after the completion of each stage of the work; Specifications, Schedule of Works undertaken, Difficulties encountered and their resolution, Modifications to Method Statements and so forth. Two Copies of the final report, including photographs and records, shall be submitted to Limerick County Council upon completion of the work.

Reason – To protect the architectural heritage in the interests of the proper planning and sustainable development of the area.

16. Prior to commencement of development a palette of materials and proposed colour finishes to the building shall be submitted for the written agreement of the Planning Authority.

Reason - In the interest of visual amenity and to protect the architectural heritage in the interests of the proper planning and sustainable development of the area.

17. Prior to commencement of development the final height of the proposed first floor plant room extension to the existing building along with roof profile and finishes shall be submitted for the written agreement of the Planning Authority.

Reason - In the interest of clarity and orderly development.

18. No material change of use of the areas identified for plant shall take place without a prior specific grant of permission.

Reason - In the interest of orderly development.

19. No advertising signs, symbols, structures or nameplates, other than those shown or indicated on the drawings submitted, shall be erected on the premises, or within its curtilage, without a prior specific grant of permission from the Planning Authority.

a. Individual mounted lettering is permitted, lettering shall only be painted, raised plaster or fixed individually and directly to the building.
b. Plastic, neon, internally light signs or internally illuminated fascias are not permitted.
c. Lighting shall comprise of spot light, short arm flood lights or traditional style lamps

Reason - In the interest of visual amenity.

20. The developer shall preserve, protect or otherwise record archaeological materials or features that may exist within the site by ensuring that all ground disturbances associated with the site development is archaeologically monitored. In this regard, the developer shall –

a. Notify the Planning Authority in writing at least four weeks prior to the commencement of any site operation (including hydrological and geotechnical investigations) relating to the proposed development.

b. Employ a suitably qualified archaeologist who shall monitor all site investigations and other excavation works.

c. Submit the name of the suitably qualified archaeologist to the Planning Authority four weeks in advance of the commencement of any site works (including site investigations).

d. Should archaeological material be found during the course of monitoring, the archaeologist may have work on the site stopped, pending a decision as to how best to deal with the archaeology. The Development Applications Unit, National Monuments Service, Department of Arts, Heritage and Gaeltacht and the Planning Authority Archaeologist shall be informed immediately. The developer shall be prepared to be advised by the Department of Arts, Heritage and Gaeltacht and the Planning Authority with regard to any necessary mitigating action.

e. Provide satisfactory arrangements for the recording and removal of any archaeological material which may be considered appropriate to remove.

f. Submit on completion an archaeological report detailing the works to the Department of Arts, Heritage and Gaeltacht and the Planning Authority.

Reason - In order to conserve the archaeological heritage of the site and to secure the preservation of any remains which may exist within the site.

21. This permission shall be for a period of ten years from the date of the final grant of planning permission.

Reason – In order to further assess the visual, traffic safety and other consequences of the development in the interest of proper planning and development and in the light of changing circumstances.

Attachment B.6-2: Environmental Impact Statement

See Separate Document

Attachment B.6-3: Previous Planning Permissions

Attachment B.6-3: Previous Planning Permissions

Planning permission was first established on this site in 1998 when Limerick County Council granted permission to Dell Products(Europe) B.V. for a development with the following description 'Major-Construction of computer manufacturing plant to include single storey production area, two storey office area, utility building, loading bays, car parking spaces for 1606 vehicles', Planning Reference 98/1139 refers. This application included an Environmental Impact Statement.

Subsequent to this parent permission a number of applications were submitted and granted on the site for minor alterations to the site and building between 1999 and 2006. These included an application for 'retention of alterations to computer manufacturing plant consisting of elevations and roof profile, car park layout, office layout, attic plan, boundary lines, security cabin, signage and construction of data centre' which was granted in December 1999, Planning Reference 99/2221 refers.

In 2001 Dell Computer Corporation lodged 2 planning applications the first was for 'retention of extension of existing canteen, fitting of double doors, internal alterations and associated site works' Planning Reference 01/2372 and the second for the 'construction of a single storey extension to existing production area, a two storey extension consisting of open plan office area at first floor level, a canteen, kitchen, toilets, locker room, entrance at ground floor level and a revised road layout', Planning Reference 01/2430. Both these application were granted in December 2001.

The last planning activity on the site was in 2006 when Dell Products applied for retention for a 'Waste management building and pallet storage yard and hard standing area currently used for collection of waste by- products from production process' which was granted in October 2006, Planning Reference 06/45.

No substantive planning issues arose in any of the planning applications submitted on the site to date principally due to the fact that the site is appropriately zoned for industrial development.

See the following table for a description of each planning application and the relevant planning reference number:

Planning Ref. Number	Description
06/45	Retention permission granted to Dell Products for waste management building and pallet storage yard and hard standing area currently used for collection of waste by-products from production process.
01/2372	Permission granted to Dell Computer Corporation for retention of extension of existing canteen, fitting of double doors, internal alterations and associated site works.
01/2430	Permission granted to Dell Products Europe B.V. for the construction of a single storey extension to existing production area, a two storey extension consisting of open plan office area at first floor level, a canteen, kitchen, toilets, locker room, entrance at ground floor level and a revised road layout.
99/2221	Permission granted to Dell Products Europe B.V. for retention of alterations to computer manufacturing plant consisting of elevations and roof profile, car park layout, office layout, attic plan, boundary lines, security cabin, signage and construction of data centre
99/44	Live application by S.F.A.D. Co for development of lands to include roads, sewers, watermains, public lighting, electrical and telecommunications of ductwork, 2 no submersible pumping stations and interlinking rising main, provision of rising main to discharge sewage and 2 no surface outfall.
98/1139	Permission granted to Dell Products B.V. Europe for Construction of Computer manufacturing plant to include single storey production area, two storey office area, utility building, loading bays, car park.

Attachment B.6-4: Appropriate Assessment Screening Report

APPROPRIATE ASSESSMENT SCREENING STATEMENT

FOR A PROPOSED BIOPHARMACEUTICAL MANUFACTURING FACILITY, RAHEEN BUSINESS PARK, LIMERICK

PREPARED FOR

PM GROUP

Rev.	Status	Author	Reviewed By	Approved By	Issue Date
00	Draft	AC	AC	AC	28.11.2013
01	Draft	AC	AC	AC	12.12.13

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FIGURES

1. Introduction

It is proposed to develop a Biopharmaceutical Manufacturing Facility on the site of a former Dell facility in the Raheen Business Park, Limerick.

This report contains information required for the competent authority (in this instance Limerick County Council) to undertake a screening exercise for Appropriate Assessment (AA), and has been prepared by Scott Cawley Ltd on behalf of the applicant. It provides information on and assesses the potential for the proposed development to impact on any European sites[1] within its zone of influence.

It is necessary that the proposal has regard to Article 6 of the *Council Directive 92/43/EEC of 21 May 1992 on the Conservation of Natural Habitats and of Wild Fauna and Flora* (as amended) (hereafter referred to as the Habitats Directive). This is transposed in Ireland by the Bird and Natural Habitat Regulations 2011 (Statutory Instrument 411 of 2011) and the Planning and Development (Amendment) Act, 2010 as amended.

The information in this report forms part of, and should be read in conjunction with the documentation being submitted to Limerick County Council in connection with the application for planning permission.

It is the responsibility of the competent authority to make a decision as to whether or not the proposed development is likely to have significant effects, either individually or in combination with other plans or projects, upon European sites. If likely significant effects cannot be ruled out then it would be necessary for Limerick County Council to undertake an Appropriate Assessment of the implications of the proposed development on the integrity of the European Site(s) in question in view of the sites(') conservation objectives.

Following the preparation of this report it can be objectively concluded that there is no likelihood of any significant negative effects on any European sites arising from the proposed development either alone or in combination with other plans or projects. Therefore it is our view that an Appropriate Assessment will not be required in this instance. The information in the tables below provides a summary of the information gathered for this screening exercise and the conclusions made.

2. Methodology

This Screening Statement for Appropriate Assessment has been prepared with regard to the following guidance documents, where relevant:

- *Appropriate Assessment of Plans and Projects in Ireland - Guidance for Planning Authorities.* (Department of Environment, Heritage and Local Government, 2010 revision).
- *Appropriate Assessment under Article 6 of the Habitats Directive: Guidance for Planning Authorities.* Circular NPW 1/10 & PSSP 2/10.
- *Assessment of Plans and Projects Significantly Affecting Natura 2000 sites: Methodological Guidance on the Provisions of Article 6(3) and (4) of the Habitats Directive 92/43/EEC* (European Commission Environment Directorate-General, 2001); hereafter referred to as the EC Article 6 Guidance Document. The guidance within this document provides a non-mandatory methodology for carrying out assessments required under Article 6(3) and (4) of the Habitats Directive.

[1] The Term European sites refer to all Natura 2000 sites that form part of the EU-wide network of nature protection areas established under the EU Habitats Directive. The aim of the network is to assure the long-term survival of Europe's most valuable and threatened species and habitats. It is comprised of Special Areas of Conservation designated by member states under the Habitats Directive, and also incorporates Special Protection Areas designated under the EU Birds Directive.

- *Managing Natura 2000 Sites: The Provisions of Article 6 of the Habitat's Directive 92/43/EEC* (EC Environment Directorate-General, 2000); hereafter referred to as MN2000.
- *Guidance Document on Article 6(4) of the 'Habitats Directive' 92/43/EEC. Clarification of the Concepts of Alternative Solutions, Imperative Reasons of Overriding Public Interest, Compensatory Measures, Overall Coherence.* Opinion of the European Commission (European Commission, January 2007).
- Guidelines for Good Practice Appropriate Assessment of Plans under Article 6(3) Habitats Directive. *Findings of an international workshop on Appropriate Assessment in Oxford, December 2009. http://www.levett-therivel.co.uk/AAguidelines.htm*

The above referenced guidance sets out a staged process for carrying out Appropriate Assessment. To determine if Appropriate Assessment is required, documented screening is required. Screening identifies the likely effects on a European site, if any, which would arise from a proposal, either alone or in combination with other plans and projects, and further considers whether these effects are likely to adversely affect the integrity of any European sites.

If it can be concluded at the end of the screening exercise that there is no likelihood of significant impacts occurring on any European site, then there is no requirement to proceed to an Appropriate Assessment.

However, even if the screening exercise makes a finding of no significant impact, and therefore concludes that an Appropriate Assessment is not required, these findings must be clearly documented in a Screening Statement for Appropriate Assessment in order to provide transparency of decision-making, and to ensure the application of the 'precautionary principle'[2].

Screening for Appropriate Assessment involves the following:

1. Determining whether a project or plan is directly connected with or necessary to the conservation management of any European sites (this is not the case in this instance);
2. Describing the details of the project / plan proposals and other cumulative plans or projects that may affect any European Sites (see Table 1);
3. Describing the characteristics of relevant European Sites and identifying the potential for the proposed development to result in effects on any European Sites. This may involve a desk study and/or field survey and/or primary research as necessary (see Table 2); and
4. Assessing the likelihood and significance of any likely effects on any relevant European sites

This screening exercise was based on a desktop study alone. Sources of information relied upon include the following:

- Ordnance Survey of Ireland mapping and aerial photography available from www.osi.ie;
- Online data available on European sites as held by the National Parks and Wildlife Service (NPWS) from www.npws.ie;
- Information on land-use zoning from the online mapping of the Department of the Environment, Community and Local Government http://www.myplan.ie/en/index.html;
- Information on water quality in the area available from www.epa.ie;
- Information on the Shannon International River Basin District from www.wfdireland.ie;
- Information on soils, geology and hydrogeology in the area available from www.gsi.ie;

[2] One of the primary foundations of the precautionary principle, and globally accepted definitions, results from the work of the Rio Declaration. Principle #15 declaration notes:
"In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation."

- Information on the compliance of Waste Water Treatment facilities in Limerick City with licence discharge limits from the EPA's online waste licence search facility http://www.epa.ie/terminalfour/wwda/wwda-view.jsp?regno=D0013-01#.UozJgeKa-kj Accessed November 2013; and from the EPA directly;
- Information on the status of EU protected habitats in Ireland (National Parks & Wildlife Service, 2013);
- Information on the conservation status of birds in Ireland: (Lynas *et al*, 2007);
- *Limerick County Development Plan 2010-2016.*
- Information on the location, nature and design of the proposed development as supplied by the applicant's design team

3. Screening Matrix

Table 1 Overview of the Application to extend duration of permission its Receiving Environment	
Brief Site Description	The proposed development site is approx. 11.88 hectares located in the Raheen Business Park, Limerick. Raheen Business Park is located within the town land of Ballycummin to the south west of Limerick City. The Business Park is bound to the north and west by the R526 and to the south and east by the M20 motorway. The proposed development site is the former Dell EMF3 facility and is taken up almost entirely by buildings and hard standing. It consists of a large assembly area, a warehouse and manufacturing support area, a utility building, a two storey office building, service yards, car parking spaces for c.1,050 vehicles and an access road linking the site to the M20 and R526. The area comprises hard standing underlain by predominantly made ground material. There are small areas of landscaping (tree planting and shrubs) scattered throughout the site. There is one field of agricultural/amenity grassland with a few scattered trees located in the western part of the proposed development site which is enclosed by landscape planting/shrubs and by an area of broadleaved woodland. There is an area of rough grassland in the eastern part of the site. An existing access entrance on the western boundary of the site is lined by two remnant field hedgerows. There is no significant semi-natural vegetation within the site boundary, nor any visible watercourses or other wetland features.
Features of the Surrounding Environment	The existing Dell EMF1 facility and Adhesives Research Ltd. are located adjacent to the south and south eastern boundary of the proposed development. Additional industrial/commercial development within the Raheen Business Park is located in the surrounding area to the north and east of the proposed development site. The remaining surrounding lands are currently in use for agriculture. A protected structure, Rocke Castle, along with a number of associated farm buildings, are located outside of but adjacent to the proposed development site on its north western boundary. An area of mature broadleaved woodland is also located outside of but adjacent to the proposed development site on its western boundary. A turlough proposed National Heritage Area (Loughmore Common Turlough pNHA) is located approximately 650m to the west of the proposed development site, to which there may be connectivity from the proposed development site via local drainage ditches. The online EPA database of watercourse mapping does not indicate any watercourses within the proposed development site. The closest referenced watercourse is the Barnakyle, approximately 450m to the south. The Barnakyle falls within the River Maigue Water Management Unit, which is part of the River Shannon catchment. The River Shannon is designated as both Lower River Shannon cSAC and River Shannon and River Fergus Estuaries SPA. At its nearest point, as the crow flies, the proposed development lies approximately 3km from the cSAC and approximately 3.5km from the SPA. However the distance from the proposed development site to these European sites via water catchment linkage is in fact 8.5km and 9 km respectively.
Description of the planning application	Full details of the proposed development are included in the drawings and information accompanying the planning application but are summarised here.

Table 1 Overview of the Application to extend duration of permission its Receiving Environment	
	It is proposed to convert the former Dell computer manufacturing facility at Ballycummin, Raheen Business Park, Raheen, Co. Limerick to a biopharmaceutical manufacturing facility. The proposed development will require the alteration and extension of the existing building, the installation of ancillary external utilities in the existing yards and all associated site development works. The proposed works to the existing building includes a) internal alteration of existing production area to accommodate the installation of a new biopharmaceutical manufacturing process; b) extension to the existing building to accommodate warehousing and electrical rooms; c) construction of new 2 storey Laboratory Building including ancillary service area and which will be linked to the existing building at ground and 1st floor levels; d) increase in height of the roof over part of the existing production area and installation of 5 no. boiler flues; e) all resultant alterations to the existing elevations. It is proposed to continue to use current arrangements for discharge surface water run-off from the proposed development. Surface water from the site arises from run-off from buildings, car-parks, road-ways, service yards and other developed areas of the site which discharge via a petrol interceptor to the main Raheen Business Park storm water system. The surface water discharge from the Raheen Business Park exits the estate and follows the route of a culvert and pipe to Loughmore Common Canal, which enters the Barnakyle River (Water body Code IE_SH_24_1704), which in turn flows into the Maigue River (which is designated under SAC 002165 and SPA 004077), and finally discharges into the Lower River Shannon SAC and the River Shannon and River Fergus Estuaries SPA. The proposed development will include for the upgrade or replacement of the existing site petrol interceptor, and the installation of an actuated valve on the outlet of the surface water drainage system to facilitate greater control on the release of surface water from the site. Therefore discharge of surface water run-off from the proposed development will be to at least the existing standard or better. The former Dell facility catered for 1100 cars whereas the proposed development will give rise to in the region of 350 cars. Therefore the quantities of hydrocarbons and other potential contaminants that the proposed development could give rise to will be lesser than when the former Dell facility was operational. A key feature of the proposed development is the fact that the overall impermeable area of the site will reduce as a result of the project. The reduction will be in the order of 5% which will be achieved mostly by the replacement of excess parking area with permeable landscaped areas. This reduction will have a positive impact on off-site downstream drainage capacity. Waste water generated from the proposed development will arise from a number of sources, namely process/manufacturing, labs, utilities and sanitary. It is proposed that waste waters arising from the proposed development will undergo preliminary treatment on-site which will render the waste water amenable for discharge to the local municipal sewer and subsequent downstream treatment at the Limerick WWTP in Bunlicky which discharges into the River Shannon estuary, within both SAC 2165 and SPA 4077 boundaries. In consultation with Shannon Development and Limerick County Council the capacity of the public sewer has been confirmed as being adequate to accommodate the projected loading associated with the proposed development. Water supply will be provided by an existing public water main. In consultation with Shannon Development and Limerick County Council the capacity of the public water main has been confirmed as being adequate to accommodate the projected

Table 1 Overview of the Application to extend duration of permission its Receiving Environment	
	demand associated with the proposed development.
Other development nearby which may lead to cumulative impacts upon local ecology	**Existing habitat loss pressures** The site is dominated by existing hard standing and industrial units. There will be no loss of habitats supporting or associated with any European sites. There is therefore no potential for cumulative effects relating to habitat loss. **Existing pressures on Water Quality of European sites in proximity to the site** Water pollution is a known threat[3] to some of the aquatic Qualifying Interests of the Lower River Shannon cSAC (e.g. Otter and Atlantic Salmon), and several Special Conservation Interests of the River Shannon and Fergus Estuaries SPA (e.g. Teal, Cormorant and other wetland birds). *Surface Waters* The site and environs is within the catchment of the River Shannon (River Maigue Water Management Unit), which is designated as the Lower River Shannon cSAC and River Shannon and Fergus Estuary SPA. There are no watercourses within or immediately adjacent to the proposed development site, however the Barnakyle stream is located approximately 450m to the south. Surface waters arising from the site will continue to discharge via a petrol interceptor to the River Shannon via the surface water system outlined in the previous row. There therefore will be no change in impact on the receiving surface water environment. However, as the proposed development itself is unlikely to generate any significant risk to water quality, there is no requirement to account for background pollution from surface water sources in the surrounding area. This judgment has been informed by the location of the development on hard standing away from any watercourses, the limited requirement for earthworks as part of the development which is located predominantly on made ground, and the inclusion of secondary containment bunding of all potentially polluting materials within the site in accordance with the requirements of an Industrial Emissions Licence from the EPA which will ultimately govern the site operations. *Foul Waters* It is proposed that waste waters arising from the proposed development will undergo preliminary treatment on-site which will render the waste water amenable for discharge to the local municipal sewer and subsequent downstream treatment at the Limerick WWTP in Bunlicky which discharges into the River Shannon estuary. Bunlicky WWTP discharges effluent within the tidal reach of the River Shannon at the eastern limit of Limerick City within both the Lower River Shannon cSAC and the River Shannon and River Fergus Estuaries SPA. EPA data indicates that water quality in this transitional estuarine reach of the River Shannon into which the WWTP discharges is primarily of "unpolluted" status. The most recently available Annual Environmental Reports for Bunlicky WWTP (Limerick City Council, 2011 and 2012) indicate that the WWTP has met the emission values set out in the

[3] NPWS, 2013; Birdlife, 2013

Table 1 Overview of the Application to extend duration of permission its Receiving Environment	
	discharge licence and that there were no exceedances of discharge limits. The project design team, in consultation with Limerick Local Authorities, has confirmed that the Limerick WWTP in Bunlicky has adequate capacity to receive and adequately treat waste waters from the proposed development site to the extent that there will not be any significant cumulative effect from the proposed development on the European site designations covering the River Shannon estuary.

Table 2 Analysis of European sites within 15km. No sites are "Relevant" to the Proposed Development. (European sites are "Relevant" where a relevant source-pathway-receptor link[4] exists between proposed development and European site)			
Site name and code	**Distance from Proposed Development**	**Reasons for designation[5] (*= Priority Habitat)** (Sourced from NPWS online from Conservation Objectives Version 1.0 unless otherwise stated).	**Relevant source-pathway-receptor links between proposed development and European site?**
Lower River Shannon cSAC (002165)	3km (but 0km from Bunlicky WWTW outfall)	**Annex I Habitats:** • Sandbanks which are slightly covered by sea water all the time [1110] • Estuaries [1130] • Mudflats and sandflats not covered by seawater at low tide [1140] • *Coastal lagoons [1150] • Large shallow inlets and bays [1160] • Reefs [1170] • Perennial vegetation of stony banks [1220] • Vegetated sea cliffs of the Atlantic and Baltic coasts [1230] • Salicornia and other annuals colonizing mud and sand [1310] • Atlantic salt meadows (Glauco-Puccinellietalia maritimae) [1330] • Mediterranean Salt Meadows [Juncetalia maritimi [1410] • Water courses of montane levels with the Ranunculion fluitantis and Callitricho-Batrachion vegetation [3260] • Molinia meadows on calcareous, peaty , or clayey-silt laden soils	Whilst pathways via surface and waste water discharge were identified, neither has been identified as giving risk to significant effects on the European site. The nature, scale and duration of the works will not result in significant effects on the European site, either alone or in-combination with other plans or projects. During the period of construction works, which predominantly comprise modifications to existing buildings, there will be no substantive site clearance or earthworks. There will therefore be no likelihood for significant amounts

[4] For significant effects to arise, there must be a risk enabled by having a 'source' (e.g. construction works at a proposed development site), a 'receptor' (e.g. a cSAC), and a pathway between the source and the receptor (e.g. a watercourse connecting a proposed development site to a cSAC). The identification of a pathway does not automatically mean significant effects will arise. The likelihood for significant effects will depend upon the characteristics of the source (e.g. duration of construction works), the characteristics of the pathway (e.g. water quality status of watercourse receiving run-off from construction) and the characteristics of the receptor (e.g. the ecology including conservation status of the cSAC Qualifying Interests). When expert judgment determines, following analysis of these characteristics, that significant effects are likely to rise, both the pathway, and the European site are considered "Relevant", and an Appropriate Assessment (i.e. Stage 2) is triggered

[5] "Qualifying Interests" for cSACs and "Special Conservation Interests" for SPAs. Based on relevant Statutory Instruments for each SPA, and NPWS Conservation Objectives for cSACs downloaded from www.npws.ie on 20th November 2011. The version or date of Conservation Objective document downloaded from the NPWS website has been provided following the recommendations of the NPWS.

Table 2 Analysis of European sites within 15km. No sites are "Relevant" to the Proposed Development. (European sites are "Relevant" where a relevant source-pathway-receptor link[4] exists between proposed development and European site)			
		(Molinion caeruleae) [6410] • *Alluvial forests with Alnus glutinosa and Fraxinus excelsior (Alno-Padion, Alnion incanae, Salicion albae) [91E0] **Annex II Species:** • *Margaritifera margaritifera* [1029] • *Petromyzon marinus* [1095] • *Lampetra planeri* [1096] • *Lampetra fluviatilis* [1099] • *Salmo salar* (only in fresh water) [1106] • *Lutra lutra* [1355] • *Tursiops truncates* [1349]	of suspended solids or other contaminants to enter the cSAC via existing surface water sewers (i.e. there will be no significant amounts of stock-piled soil that could be washed into drains following heavy rain). During operation, waste waters arising from the proposed development will undergo preliminary treatment on-site before discharge to the municipal sewer which will render the waste water amenable for discharge to the local municipal sewer and subsequent downstream treatment at the Limerick WWTP in Bunlicky which discharges into the River Shannon estuary. The project design team, in consultation with Limerick Local Authorities, have confirmed that the Limerick WWTP in Bunlicky has adequate capacity to receive and adequately treat waste waters from the proposed development site to the extent that there will not be any significant cumulative effect from the proposed development on the European site. Further information supporting the

Table 2 Analysis of European sites within 15km. No sites are "Relevant" to the Proposed Development. (European sites are "Relevant" where a relevant source-pathway-receptor link[4] exists between proposed development and European site)			
			ruling out of significant effects is provided in Table 1. This assesses all these pathways with regard to potential cumulative effects.
Glenomra Wood cSAC (1013)		**Conservation Objectives without "Version" number (Dated 18th July 2011)** **Annex I Habitats:** • Old sessile oak woods with Ilex and Blechnum in the British Isles	No. There are no relevant pathways linking the proposed development and the European site. There is no likelihood for significant effects, wither alone or in combination with other plans or projects.
Tory Hill cSAC (00439)	12.5km	**Conservation Objectives without "Version" number (Dated 18th July 2011)** **Annex I Habitats:** • Semi-natural dry grasslands and scrubland facies on calcareous substrates (Festuco Brometalia)(*important orchid sites) [6210] • Calcareous fens with Cladium mariscus and species of the Caricion davallianae [7210] • Alkaline fens [7230]	No for the same reasons outlined under Glenomra Wood cSAC above.
Glenstal Wood cSAC (001432)	15km	**Conservation Objectives without "Version" number (Dated 18th July 2011)** **Annex I Habitats:** • Old sessile oak woods with Ilex and Blechnum in British Isles [91A0] **Annex II Species:** • Killarney fern (Trichomanes speciosum) [1421]	No for the same reasons outlined under Glenomra Wood cSAC above.

Table 2 Analysis of European sites within 15km. No sites are "Relevant" to the Proposed Development.

(European sites are "Relevant" where a relevant source-pathway-receptor link[4] exists between proposed development and European site)

Special Protection Areas

Site name and code	Distance from Proposed Development	Reasons for designation	Do any source-pathway-receptor links exist between the proposed development and the Natura 2000 site?
River Shannon and River Fergus Estuaries SPA (4077)	3.5km (but 0km from Bunlicky WwTW outfall)	**Annex 1 Species** • *Cygnus cygnus [wintering]* • *Pluvialis apricaria [wintering]* • *Limosa lapponica [wintering]* • *Tringa nebularia [wintering]* **Non-Annex 1 Migratory Populations** • *Phalacrocorax carbo [breeding + wintering]* • *Branta bernicla hrota [wintering]* • *Tadorna tadorna [wintering]* • *Anas penelope [wintering]* • *Anas crecca [wintering]* • *Anas acuta [wintering]* • *Anas clypeata [wintering]* • *Aythya marila [wintering]* • *Charadrius hiaticula [wintering]* • *Pluvialis squatarola [wintering]* • *Vanellus vanellus [wintering]* • *Calidris canutus [wintering]* • *Calidris alpina [wintering]* • *Limosa limosa [wintering]* • *Numenius arquata [wintering]* • *Tringa totanus [wintering]* • *Chroicocephalus ridibundus [wintering]*	Whilst pathways via surface and waste water discharge were identified, neither has been identified as giving risk to significant effects on the European site, for the same reasons as already outlined under the Lower River Shannon cSAC (002165) above.

Table 2 Analysis of European sites within 15km. No sites are "Relevant" to the Proposed Development. (European sites are "Relevant" where a relevant source-pathway-receptor link[4] exists between proposed development and European site)			
		Habitats • *Wetlands*	
Slievefelim to Silvermines Mountains SPA	14.5km	**Conservation Objectives without "Version" number (Dated 16th April 2012)** **Annex I Species** • *Circus cyaneus* (breeding)	No for the same reasons outline under Glen Bog cSAC above.

All other designated sites have been excluded from Table 1 due to distance over 15km from the proposed development site, but sites within the wider area are illustrated in Figure 1 below.

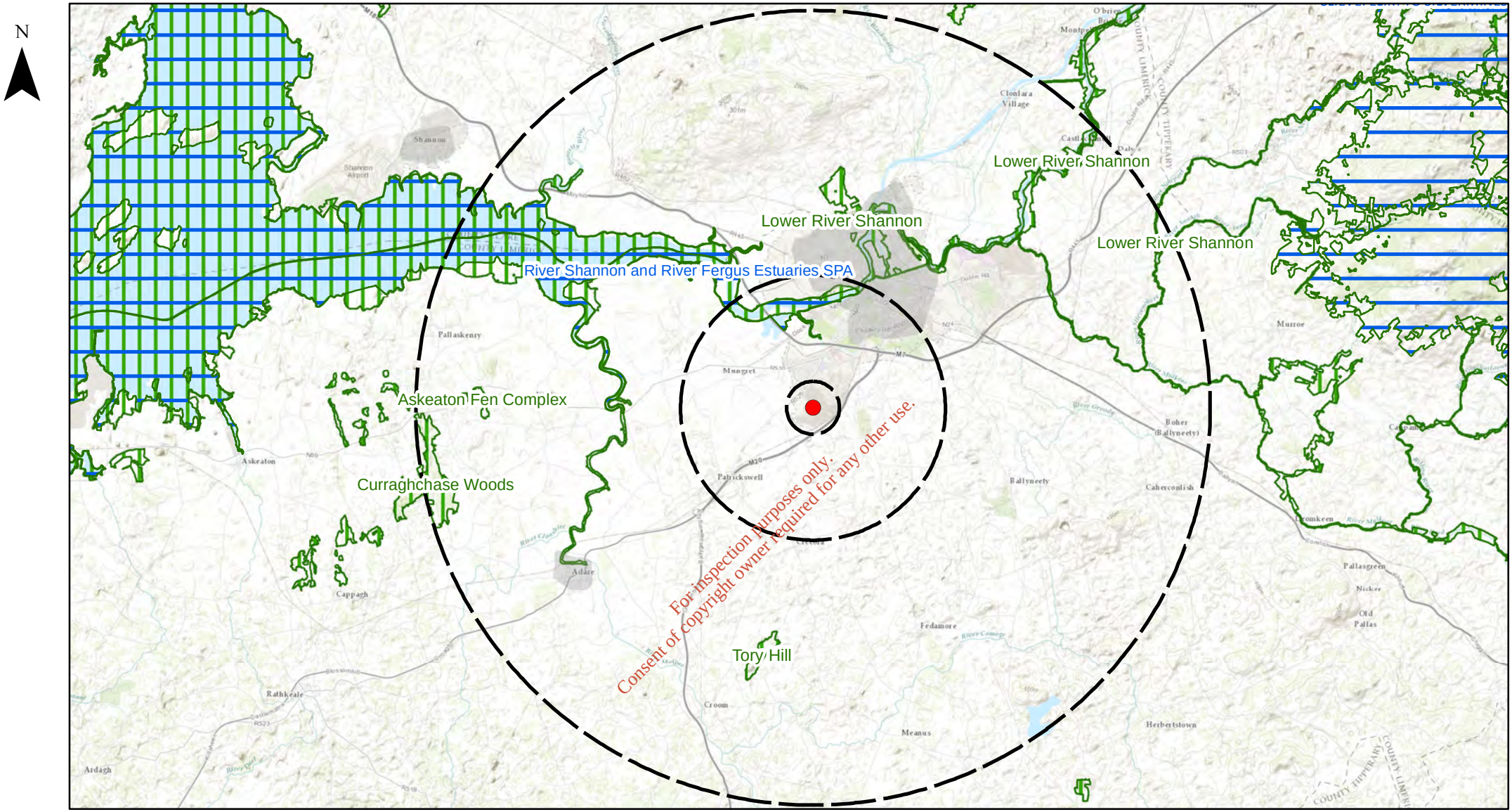

Figure 1: Designated Sites within 1, 5 and 15km of the Proposed Development Site

4. Conclusions of the Screening Assessment

Following an analysis of the proposed development, and any potential relationships with European sites, it was concluded that there would be no likelihood of significant effects, direct or indirect, either alone or in combination with other plans or projects, on any European Sites, and no impacts to the integrity of any European sites. Therefore it is our view that an Appropriate Assessment of this proposed development is not required.

5. References

BirdLife International (2013) *IUCN Red List for birds.* Downloaded from http://www.birdlife.org in November 2013

Department of the Environment, Heritage and Local Government (2010) *Appropriate Assessment of Plans and Projects in Ireland - Guidance for Planning Authorities* (Department of Environment, Heritage and Local Government, Rev Feb 2010)

DoEHLG (2010) Shannon International River Basin Management Plan. Available online at http://www.wfdireland.ie/docs/1_River%20Basin%20Management%20Plans%202009%20-%202015/ Accessed July 2012.

European Commission (2000). *Communication from the Commission on the precautionary principle*

European Commission (2000) *Managing Natura 2000 sites: The Provisions of Article 6 of the Habitat's Directive 92/43/EEC* (EC Environment Directorate-General, 2000)

European Commission (2001) *Assessment of Plans and Projects Significantly Affecting Natura 2000 sites: Methodological Guidance on the Provisions of Article 6(3) and (4) of the Habitats Directive 92/43/EEC* (European Commission Environment Directorate-General).

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Environmental Protection Agency (2011). EPA ENVision Service (internet-based environmental information portal). Available online at: http://maps.epa.ie/internetmapviewer/mapviewer.aspx [Accessed November 2012]

Limerick City Council (2011) Annual Environmental Report. Waste Water Discharge Licence Register No. D0013-01. Limerick City and Environs Agglomeration.

Limerick City Council (2012) Annual Environmental Report. Waste Water Discharge Licence Register No. D0013-01. Limerick City and Environs Agglomeration.

Lynas, P., Newton S., Robinson, A. (2007). The status of birds in Ireland: an analysis of conservation concern 2008-2013. Irish Birds 8: 149-167

NPWS (2013) *The Status of EU Protected Habitats and Species in Ireland***.** Habitat Assessments Volume 2. Version 1.0. Unpublished Report, National Parks & Wildlife Services. Department of Arts, Heritage and the Gaeltacht, Dublin, Ireland.

NPWS (2013) *The Status of EU Protected Habitats and Species in Ireland*. Species Assessments Volume 3 , Version 1.0. Unpublished Report, National Parks & Wildlife Services. Department of Arts, Heritage and the Gaeltacht, Dublin, Ireland.

National Parks & Wildlife Service (2010). Circular NPW 1/10 & PSSP 2/10 *Appropriate Assessment under Article 6 of the Habitats Directive: Guidance for Planning Authorities.* (Department of Environment, Heritage and Local Government, March 2010);

Attachment B.7 – Water Discharge Supporting Information

Attachment B.7-1: Water Discharge Supporting Information

(a) the name and address of the owner(s) of the sewer and the waste water treatment plant to which the sewer discharges (e.g. IDA, SFADCo or private undertaker) and who are responsible for the quality of the treated effluent discharging to waters

The sewer to which the trade effluent from the site discharges is in the ownership of Shannon Development (SFADCo);

Shannon Development,
Town Centre,
Shannon,
Co. Clare

The Shannon Development sewer, which serves the Raheen Business Park, then discharges to a public sewer formerly owned by Limerick County Council but now in the ownership (since 1st January 2014) of Irish Water. The public sewer discharges to the Limerick City and Environs municipal wastewater treatment plant located at Bunlicky, which is also now in the ownership of Irish Water.

Irish Water
PO Box 6000,
Dublin 1

Responsibility for the quality of treated effluent discharging to water is defined under the terms of the EPA Wastewater discharge Licence for Limerick City and Environs Wastewater Treatment Plant (Reg. No. D0013-01) as issued to Limerick City Council and now the responsibility of Irish Water.

(b) a copy of the effluent regulations and the agreement between the applicant and the aforementioned.

Details of the agreement between Irish Water and Regeneron Ireland are attached as Attachment B.7-2. Also attached is a letter from Shannon Development (Attachment B.7-3) consenting to Regeneron utilising the existing connections to their storm and foul water sewer collection systems in Raheen Business Park. Separate formal applications for these connections have since been made to Shannon Development.

Attachment B.7-2 – Irish Water Agreement

PM Group,
Lough Mahon Technology Park,
Blackrock,
Cork.

Uisce Éireann
Bosca OP 6000
Baile Átha Cliath 1
Éire

Irish Water
PO Box 6000
Dublin 1
Ireland

T: +353 1 602 1000
F: +353 1 602 1330
www. water.ie

09th April 2014

By Email & Post

Re: Regeneron Water Services Connection Application to Limerick

Dear Mr. McGrath,

Irish Water (IW) wishes to confirm receipt of your recent application for a Water /Waste Water Service connection on behalf of your client Regeneron Ireland, at Raheen Business Park, Limerick. Irish Water wish to advise that your application is currently being considered and IW anticipate being in a position to provide you with a formal connection offer in the coming weeks. The connection offer will be based on the parameters provided by PM Group as part of the connection application ref: email 11th of March 2014 to Limerick County Council, (see copy attached).

Subject to your client's acceptance of the connection offer, IW will provide the client with a connection agreement setting out the commercial and technical terms and conditions associated with the connection. IW is committed to delivering the necessary capital upgrade to the Bunlicky Wastewater Treatment Plant to meet your client's water service requirements in line with the agreed and executed Connection Agreement.

We trust that this letter provides you with sufficient comfort to Irish Water's commitment to the proposed connection.

Yours Sincerely,

John O'Shaughnessy
Regional New Connections Management Lead
E: joshaugh@water.ie

Attachment B.7-3 – Shannon Development Agreement

Shannon Development
Ag Feabhsú na Todhchaí
Delivering a Better Future

Ceannoifig
Lár an Bhaile, Sionainn
Co. an Chláir, Éire

Head Office
Town Centre, Shannon
County Clare, Ireland

t: +353 61 710000
f: +353 61 361903
e: info@ShannonDevelopment.ie

www.ShannonDevelopment.ie

Limerick County Council
County Hall,
Dooradoyle,
Co. Limerick

Re: Proposed Biopharmaceutical Manufacturing Facility at Raheen Business Park, Ballycummin, Raheen, Co. Limerick

We, Shannon Development, confirm that we consent to Regeneron Ireland making a planning application within Raheen Business Park which includes taking a new water supply connection to the facility from our existing watermain within the park, and utilising the existing site connections to our storm water and foul sewer collection systems within the park.

This consent is subject to the necessary application for connection to services being made to Shannon Development (or our successors in title) at the appropriate time.

Yours sincerely,

David Neylon
Shannon Development

Attachment B.9-1: Site Notice

SITE NOTICE

APPLICATION TO THE ENVIRONMENTAL PROTECTION AGENCY FOR A LICENCE

Regeneron Ireland, Ballycummin, Raheen Business Park, Raheen, Co. Limerick is applying to the Environmental Protection Agency (EPA) for an Industrial Emissions Licence for the operation of a Biopharmaceutical Manufacturing Facility under *Class 5.16: The production of pharmaceutical products including intermediates,* of the First Schedule of the Environmental Protection Agency Act 1992, as amended. The site is located at the former Dell Computer Manufacturing Facility, Ballycummin, Raheen Business Park, Raheen, Co. Limerick (National Grid Reference 155409E 152405N).

The application is accompanied by an Environmental Impact Statement (EIS) which will be submitted to the Agency and which has previously been submitted to Limerick County Council (Planning Reference 13/745) on 19th December 2013. The Environmental Impact Statement, and any further information relating to the effects on the environment of emissions from the activity which may be furnished to the Agency in the course of the Agency's consideration of the application, will be available for inspection at the headquarters of the Agency.

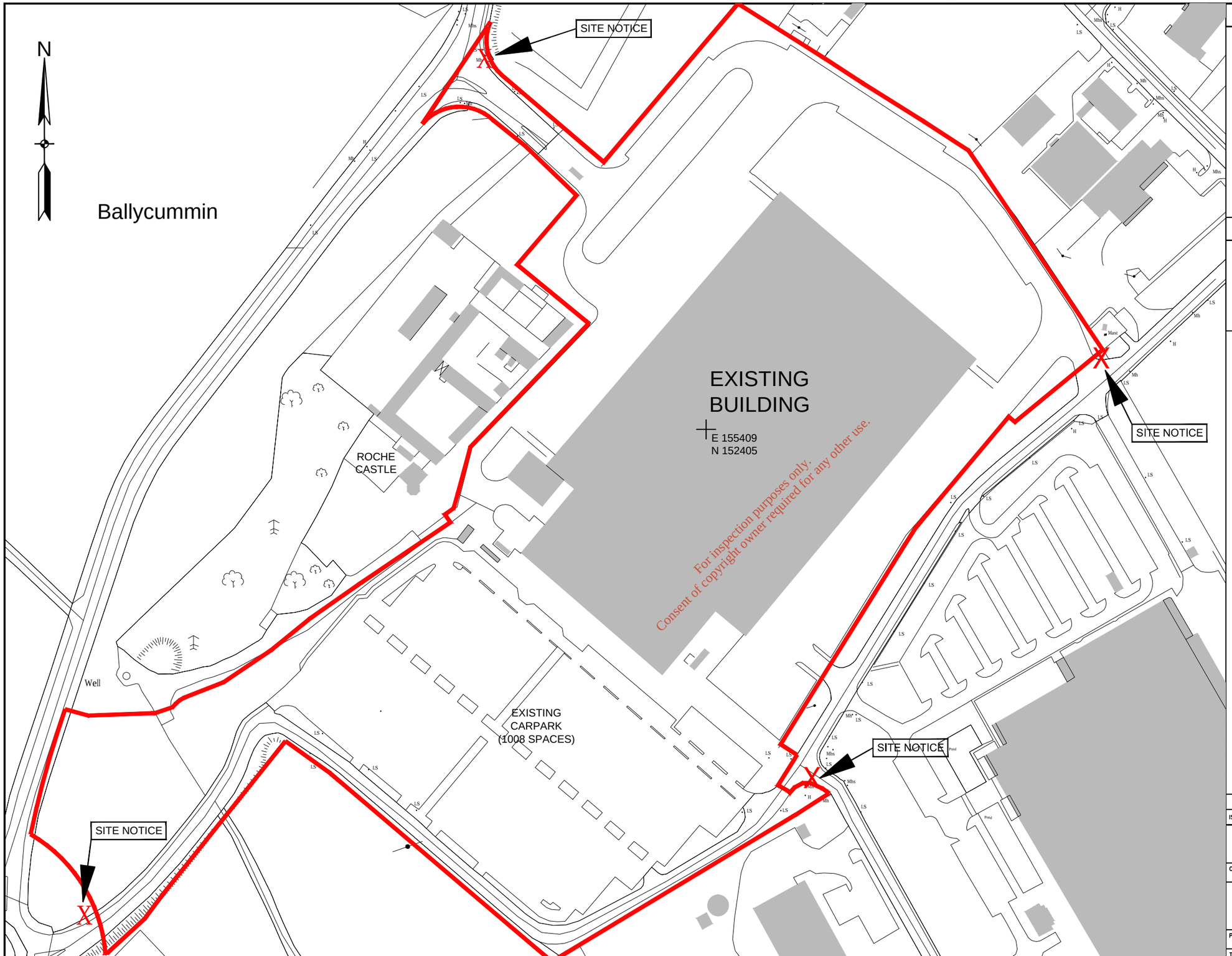
A copy of the application for the licence may be inspected on the Agency's website www.epa.ie or inspected at or obtained from the headquarters of the Agency as soon as practicable after the receipt by the Agency of the application for the licence.

Signed: _____

Tony McGrath (Agent, PM Group, LoughMahon Technology Park, Blackrock, Cork)

Date: 11th April 2014

Drawing 3: Site Notice Locations



0 20m 100m

THIS DRAWING WAS CREATED USING: AutoCAD

NOTES

1. THIS DRAWING IS TO BE READ IN CONJUNCTION WITH ALL RELEVANT ARCHITECTS AND ENGINEERS DRAWINGS AND SPECIDICATIONS
2. DO NOT SCALE DRAWING. USE FIGURED DIMENSIONS ONLY.
3. ALL DIMENSIONS ARE IN MILLIMETRES
4. ALL LEVELS INDICATED ARE IN METERS AND RELATIVE TO ORDNANCE DATUM : MALIN HEAD.

LEGEND

X SITE NOTICE

SITE BOUNDARY

FORMAL ISSUE
20140410.091434 – CHITL

ISSUE	DESCRIPTION	DRN	ORIG	AUTH CHK	APP	DATE
A	FOR IEL APPLICATION	LRC	BT	TMcG	TMcG	07/04/14

REGENERON

CLIENT: REGENERON IRELAND

PM GROUP

PROJECT: BIOPHARMACEUTICAL MANUFACTURING FACILITY

TITLE: INDUSTRIAL EMISSIONS LICENCE APPLICATION
DRAWING 3:
SITE NOTICE LOCATIONS

DRAWINGS PREPARED BY: PM GROUP
LOUGHMAHON TECHNOLOGY PARK
BLACKROCK
CORK

ON BEHALF OF: REGENERON IRELAND

IE0311171_22_DR_0003

CLIENT REF.

PROJECT No. IE0311171

CLIENT DRG No.

A3 SCALE 1:2000

PM DRG No. IE0311171-22-DR-0003

Attachment B.9-2: Newspaper Advertisement

BMW

13 D A **€86,950**

2013 BMW X5 3.0 XDRIVE 30D M Sport, Dub Reg, Dakota leather, Xenons, Bluetooth, Navigation-system Professional. Incl Service Pack. Many extras. Tax €580 P/A. J Donohoe
Co. Wexford
Tel: 053 9242526
carsireland.ie/1050700

13 D A **€85,950**

2013 BMW 6 Series 3.0 640D GRAN COUPE SE, Auto,Ivory White Dakota lthr,American Oak int. trim,Xenons, Cruise,Navigation system,Incl Service Pack & many extras. J Donohoe
Co. Wexford
Tel: 053 9242526
carsireland.ie/1050778

11 D A **€53,950**

2011 BMW 7 Series 3.0 730D M SPORT, Dublin Reg, Oyster/Black Dakota Leather, 20" Double-Spoke Alloys, Fine-wood Trim Ash, Front Seat heating, etc. J Donohoe
Co. Wexford
Tel: 053 9242526
carsireland.ie/1050785

MAGNIFICENT 520D SE '09, 6sp, stunning in liquid silver met., with unmarked warm charcoal looks leather int. Piano black trim. Huge spec, elec seats, full i Drive, sat nav, F+R park assist, alloys etc, NCT 06/16, only 75K mls with Full BMW SH, only €280 Tax, 12 month warranty, simply beyond comparison, viewing imperative. €16,950. Ph: **087 9206169**

BMW

11 D A **€30,500**

2011 BMW 5 Series 520D SE AUTO, Upgraded Spec incl. beige oyster Dakota leather seats, paddle shift gears, auto lights, Dual zone climate, bluetooth. Must see. Meridian Motors
Co. Carlow
Tel: 059 9130427
carsireland.ie/986772

07 P A **€6,995**

2007 BMW 318 i SE Z3SD, 2.0L, Petrol, Automatic, 4dr, all electric, silver, Full Service History, 2nd owner, NCT 03/15, Cruise Control, full leather interior. Needs to be seen
Co. Louth
Tel: 086 8317409
carsireland.ie/1048401

BMW MINI Specialists. Service and Diagnostics. Bloomfield Garage, SCR, Dublin 8. **Tel: 4531433 or www.bloomfieldgarage.ie**

COMMERCIALS FOR HIRE

FIAT

FIAT 500 lounge, 2010, Navy Blue, elec windows, bluetooth, sunroof, excellent condition 41k miles, €8,750 Ph: **087 2356068**

FIAT

04 P M **€2,450**

2004 Fiat Punto 1.2 Active. New type. Silver. 5 door. P/S. C/L. Radio & C/D player. E/W. Alarm. Air bags. 50,000 miles. Taxed to Christmas.
Co. Dublin
Tel: 087 9783991
carsireland.ie/1047441

FORD

06 D M **€5,900**

2006 Ford Focus 1.6L, Diesel, Manual, 95,250 miles, 2 owners, NCT 03/16, Tax 11/14, Hatchback, Air Conditioning, Central Locking, CD Player, Electric Windows, Airbag
Co. Kildare
Tel: 086 8372347
carsireland.ie/1051461

07 D M **€5,550**

2007 Ford Focus 1.6 turbo Diesel, 80K miles, NCT 2015, Tax 06/2014, FSH, 46mpg, 1 previous owner, 4 door saloon, Very economical, alloys, cruise, 2 keys, Private sale
Co. Dublin
Tel: 085 7279614
carsireland.ie/1048651

FUNERAL VEHICLES

Mercedes Hearse, E280 V6 2007, 5 door, Binz with CLS front, 48k miles, FMBSH, excellent condition. Private sale no trade in €50000. Ph: **087 6874775**

LANDROVER

14 D A **POA**

2014 Land Rover Range Rover 3.0 SDV6 HSE AUTO, 7 seater, 293bhp, 21" alloys, 14 way Powered Heated leather seats, Noble Paddle Shift. Must see ++. Meridian Motors
Co. Carlow
Tel: 059 9130427
carsireland.ie/1050809

MACHINERY FOR SALE

NEW & UNUSED, Concrete stairs 1.25m width. Flights & Landings indoor or outdoor use. Email:- **concreteformworkservices@gmail.com** Ph **083 3725527**

NEW & UNUSED, Kingspan micro-rib panels, Thickness 70mm Length 5-7m. Email:- **concreteformworkservices@gmail.com** Ph **083 3725527**

MERCEDES

MAGNIFICENT low mileage, automatic C200 CDI, '08, Special Elegance edition, finished in pacific blue met. with unmarked warm charcoal leather interior, wood trim, huge spec, elec seats, dual a/c, bluetooth, remote cd/radio, alloys etc. 1 owner, only 66K mls, FSH. NCT 03/16, 12 month warranty. Truly stunning example, €16,750. **087 9206169**

MERCEDES

05 P A **€6,400**

2005 Mercedes-Benz E 200 Kompressor classic, gold, full leather, new tyres, NCT 2015, 137K miles, Full service History, alloys etc. Needs to be seen.
Co. Cork
Tel: 086 8345810
carsireland.ie/1052941

MOTORS WANTED

JOHN KELLY NAVAN
KELLS ROAD, NAVAN, MEATH
CARS BOUGHT FOR CASH
All Makes and Models 2005 to 2012
Finance Clearance etc.
Trade Prices Paid Immediately
TEL: (046) 9021949

WANTED: Toyota Camry's petrol, 4 DR Merc's up to 04, Lexus RX 300's Ex Taxi plus H. milage and non runner's considered. Call **086 3149443**

MOTORS FOR HIRE

VAN RENTAL FROM HERTZ. Daily / Weekly Rentals. Insurance Included. **1890 826 826 / hertz.ie/vans**

MOTORS FOR SALE

Cars Wanted for Scrap
CARS TOWED AWAY FOR CASH / FREE CAN COLLECT ANYWHERE IN DUBLIN
END OF LIFE VEHICLE CERTS ISSUED
GANNONS DONABATE
Tel: 087 3629827 • 01 8907715

RENAULT

06 P M **€3,995**

2006 Renault Laguna 1.6 Dynamique Sky, Only 112K kms, New NCT 02/16, Keyless Entry, Sunroof, A/C, cd, Alloy wheels, stunning car throughout, trade in taken.
Co. Kildare
Tel: 086 8692711
carsireland.ie/1051684

TAXIS

A TAXI PLATE to rent. €29pw. Medium/long term. **087 7810985**

TOYOTA

08 D M **€12,500**

2008 Toyota Hilux Mountain top, 3.0L, Diesel, Manual, 256,000 km, 1 owner, Tax 10/14, Pickup, Air Conditioning, Central Locking, CD Player, Electric Windows, Airbag, Alloy
Co. Dublin
Tel: 086 8076840
carsireland.ie/1051534

TOYOTA

04 D M **€3,750**

2004 Toyota Avensis D4D Aura diesel. All electric. Alloy wheels. Spots. Immobiliser. Remote locking. 60 mpg. Radio c/d & tape player. New timing belt. Spotless cond. 90,000 mls.
Co. Dublin
Tel: 087 3816601
carsireland.ie/1051733

VOLKSWAGEN

13 D M **€26,500**

2013 Volkswagen Passat Rare R-Line Spec. 1.6TDI Bluemotion 6Spd Manual, Chrome Package,Mobile Device Interface (media-in), privacy glass, leather MFSW. Meridian Motors
Co. Carlow
Tel: 059 9130427
carsireland.ie/1040502

MAGNIFICENT low mileage, new model, Touareg, 2.5 TDI '07, 6sp, stunning in ultimate black met. with unmarked warm charcoal looks leather int. wood trim, huge spec. Full electrics pack, LED park assist, Dual a/c, remote cd/radio, Xenons, alloys etc. 1 owner. Only 44K mls (Yes 44K). FSH, NCT 06/15, 12 month warranty. This SUV could literally pass for brand new. €15,950. **087 9206169**

VOLVO

04 P A **€3,295**

2004 Volvo S40 AUTOMATIC, 1.8SE lux, Full lthr int, "NCT 02/15", A/C, C/C, cd, rcl,4ew,e/m, totally stunning cond throughout,literally drives like a new car,trade in taken.
Co. Kildare
Tel: 086 8692711
carsireland.ie/1045652

NURSING

WOODLANDS HOUSE Nursing Home located in Navan, Co Meath is currently in the process of expanding and is now seeking to recruit a nurse. The successful candidate will be registered with An Bord Altranais and have a minimum of 2 years experience. Interested candidates should reply with a cover letter and CV to Susan Walsh, Woodlands House Nursing Home, Trim Road, Navan, Co Meath or alternatively to **admin@woodlandshouse.ie**

PRIMARY TEACHERS

Ardfert Central National School, Ardfert, Co. Kerry invites suitable candidates to apply for the position of Preschool Teacher for the new unit which will be established next September 2014. Please apply in writing with CV to Chairperson, BOM, Ardfert Central National School, Ardfert, Tralee, Co. Kerry **before April 18th 2014.**

The Board of Management of St. Joseph's C.B.S. Primary School, Sunday's Gate, Drogheda, Co. Louth hereby gives notice that the Permanent Post of Principal is currently advertised on **Education Posts.ie** The commencement date for this position is September 1st 2014

SALES MARKETING

Sales Persons required nationwide to service new and established commercial customers. Full training given. Potential to earn €100K+ P/A. Send CV to turbovisionsales@gmail.com

SECONDARY TEACHERS

Music teachers with a minimum of BA Degree in Music needed for UAE, Qatar, Oman and Bahrain. Start August 2014. Send CV to **school@gulfteaching.net**

SECONDARY TEACHERS

ST. CIARÁN'S Community School, Kells, Co. Meath. The Board of Management invites applications from suitably qualified persons for the post of Deputy Principal. Application forms and further documentation may be obtained by emailing **stciaranskells@eircom.net** Closing date for application is 12 noon on Wed. 23rd April 2014.

SITUATIONS VACANT

A DRIVER CPC at **CPC.IE** €49 n/wide **087 636 3003** info@cpc.ie

BAR STAFF LONDON req'd full time (live in positions) for the London area, exp essential. Ph: **0044 780 883 6215.**

DO YOU WANT TO BE YOUR OWN BOSS? Index Books are currently recruiting in your area. Earn a realistic €35-€45k per annum. Selling highly discounted books and gifts direct to customers in their workplace. Full support and training to get you up and running. No start up fees. Start your business now call **053 9108048**

Experienced Bench Jeweller required for full time position in busy city centre Jewellers. Apply with CV to **conwaysjewellers@gmail.com**

FMB, Chartered Accountants & Registered Auditors
We are seeking a motivated hard working individual to join the FMB team as a trainee Internal Auditor in our Audit & Assurance department.
Requirements:
- Graduates with a minimum 2.1 Honours Degree
- Strong interpersonal and communication skills
- Computer literate
- Some internal audit experience would be advantageous
- Exam leave and course fees provided

Interested candidates should email your CV to **jobs@fmb.ie** or you can send to our offices: FMB Chartered Accountants, Longboat, 56 Sir John Rogersons Quay, Dublin 2.

FORKLIFT TRAINING AND CERTIFICATION
Call **01 8068000**

Quantity Surveyor Required for Telecoms Contracting company. Qualified to degree level with a min 2 year experience. Please email CV's to **info@glenline.ie** No agencies need apply.

SENIOR CHEF required for Beaumont House, part time or full time, carvery and a la carte experience essential. Forward CV to **beaumonthouse@eircom.net** or tel: **8371353** or **8371008.**

TELESALES Person Required D12 **ph Robert 014273010**

TECHNICAL ENGINEERING

Principal Engineer required for a new product introduction in a medical devices company in Clare. 10+ years of manufacturing process development experience within a cleanroom environment essential. Please send CVs to **bnicholson@careerwise.ie**

Technical Support Engineer, New Relic Dublin. New Relic needs you! **www.newrelic.com http://www.newrelic.com/about/jobs**

PUBLIC NOTICES

APPLICATION TO THE ENVIRONMENTAL PROTECTION AGENCY FOR A LICENCE

Regeneron Ireland, Ballycummin, Raheen Business Park, Raheen, Co. Limerick is applying to the Environmental Protection Agency (EPA) for an Industrial Emissions Licence for the operation of a Biopharmaceutical Manufacturing Facility under Class 5.16: The production of pharmaceutical products including intermediates, of the First Schedule of the Environmental Protection Agency Act 1992, as amended. The site is located at the former Dell Computer Manufacturing Facility, Ballycummin, Raheen Business Park, Raheen, Co. Limerick (National Grid Reference 155409E 152405N).

The application is accompanied by an Environmental Impact Statement (EIS) which will be submitted to the Agency and which has previously been submitted to Limerick County Council (Planning Reference 13/745) on 19th December 2013. The Environmental Impact Statement, and any further information relating to the effects on the environment of emissions from the activity which may be furnished to the Agency in the course of the Agency's consideration of the application, will be available for inspection at the headquarters of the Agency.

A copy of the application for the licence may be inspected on the Agency's website www.epa.ie or inspected at or obtained from the headquarters of the Agency as soon as practicable after the receipt by the Agency of the application for the licence.

Attachment B.9-3: Copy of Notice given to Limerick County Council

PM Group
LoughMahon Technology Park
Blackrock
Cork
Ireland

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The project delivery specialists

Our Reference: IE0311171-LET-0020

10 April 2014

Limerick County Council
Planning & Development Department
7/8 Patrick Street
Limerick

Re: Planning Reference No. 13/745
Notice to Limerick County Council of Proposed Industrial Emissions Licence (IEL) Application for Regeneron Ireland

Dear Sir / Madam

This notification is submitted to Limerick County Council to advise that Regeneron Ireland, Ballycummin, Raheen Business Park, Raheen, Co. Limerick is applying to the Environmental Protection Agency (EPA) for an Industrial Emissions Licence for the operation of a Biopharmaceutical Manufacturing Facility under *Class 5.16: The production of pharmaceutical products including intermediates,* of the First Schedule of the Environmental Protection Agency Act 1992, as amended. The site is located at the former Dell Computer Manufacturing Facility, Ballycummin, Raheen Business Park, Raheen, Co. Limerick (National Grid Reference 155409E 152405N).

The application is accompanied by an Environmental Impact Statement (EIS) which will be submitted to the Agency and which has previously been submitted to Limerick County Council (Planning Reference 13/745) on 19th December 2013. The Environmental Impact Statement, and any further information relating to the effects on the environment of emissions from the activity which may be furnished to the Agency in the course of the Agency's consideration of the application, will be available for inspection at the headquarters of the Agency.

A copy of the application for the licence may be inspected on the Agency's website www.epa.ie or inspected at or obtained from the headquarters of the Agency as soon as practicable after the receipt by the Agency of the application for the licence.

If you require any further information please do not hesitate to contact the undersigned.

Yours sincerely,

Tony McGrath
Director of Strategic Planning, PM Group
on behalf of Regeneron Ireland

Project Management Limited
t/a PM Group, is a private company limited by shares, registered in Ireland.
Company Registration No. 043789.
Registered Office: Killakee House, Belgard Square, Dublin 24, Ireland.

Directors D Flinter (Chairman), D Murphy (CEO), L Foley, B Gallagher, H Keelan, S Kelly, M Lynam, P McGrath, JC O'Connell, L O'Mahony, A Schouten (British), M Shelly, L Westman

Secretary J Sheehan

Attachment B.12: Supporting information on Regulations Controlling Fluorinated Greenhouse Gases and Ozone Depleting Substances

B.12 Regulations Controlling Fluorinated Greenhouse Gases and Ozone Depleting Substances

The facility will operate equipment containing fluorinated greenhouse gases contained in Annex I Part 1 of Regulation (EC) No. 842/2006.

The following systems containing Fluorinated Greenhouse Gases as Refrigerants will be used;

- Main Production Area Chillers
- Office/QA Lab Chillers
- Walk-In Cold Rooms and Freezer Rooms
- Miscellaneous Upright Refrigerators and Freezers
- Incubator Rooms
- Miscellaneous DX Air Conditioning Units.

Section C Attachment

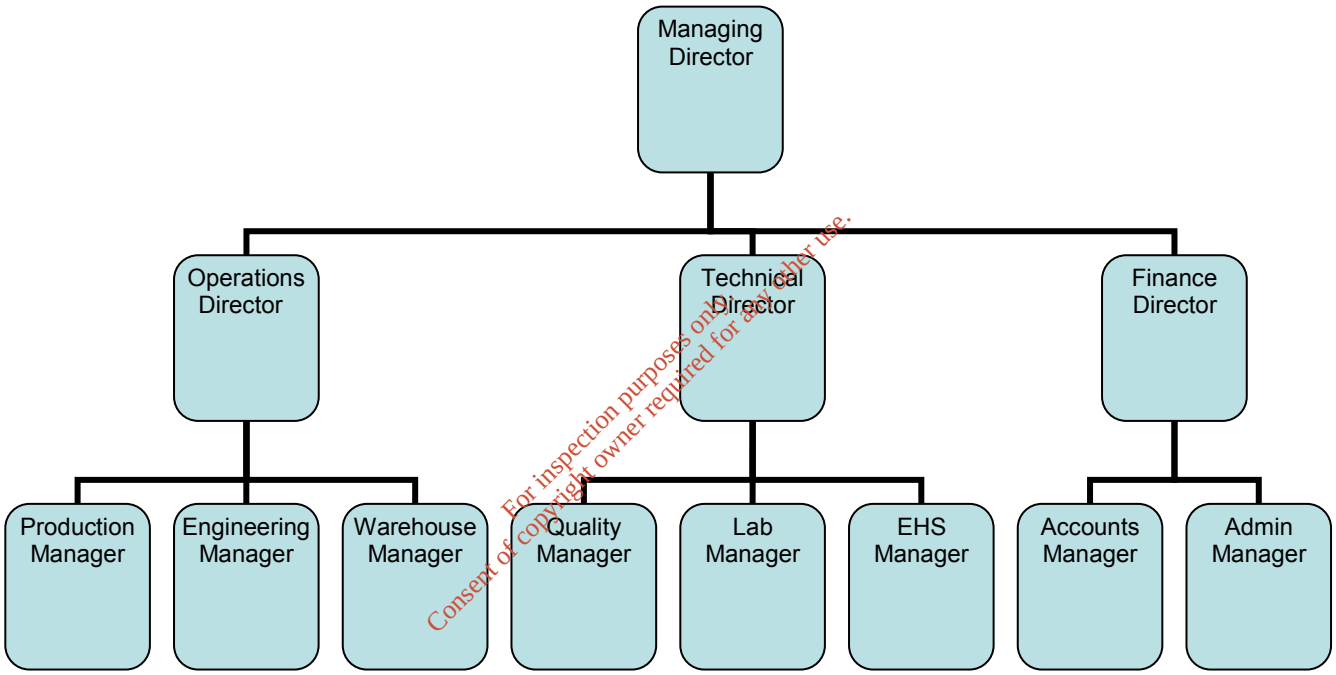
Attachment C. Site Management and Control

C.1 Site Management and Control

Regeneron is a leading science-based biopharmaceutical company based in Tarrytown, New York that discovers, invents, develops, manufactures, and commercialises medicines for the treatment of serious medical conditions.

Regeneron has identified a need for additional manufacturing capacity. To fulfil this need Regeneron is proposing to develop a new state-of the-art manufacturing centre in Europe. Following a rigorous site selection process the proposed location for this centre is the existing factory building referred to as the former Dell EMF3 computer assembly plant, which is located at Raheen Business Park in Limerick. In Raheen, Regeneron intends to invest $300m in the creation of new bulk manufacturing facilities for a range of biopharmaceutical derived medical products for patients worldwide, together with associated business support functions.

The organisation chart for the management of the proposed development when in operation is provided below.



While the full leadership team shall be accountable for environmental performance, specific functional responsibility for environment management will be the responsibility of the EHS Manager. Specific duties in that regard are listed below. The management team will be provided all the appropriate training and resources to effectively manage and control environmental compliance.

Specific Duties of the EHS Manager

The EHS Manager, reporting to the Technical Director, will have overall responsibility for maintenance and implementation of the Environmental Management System (EMS), including the compilation, distribution, amendment and maintenance of all EMS documentation at the installation. The EHS manager will develop the site EHS strategy for the start-up phase and extend into long term sustainable model. Specifically, the duties and responsibilities of the EHS Manager will include:

- Provide effective hands on, operational environmental health & safety support and advice to management and site personnel in all areas.
- Ensure compliance with existing and evolving regulatory and company Environmental, Health and Safety requirements & expectations.
- Ensure that new processes and associated equipment modifications are assessed from an environmental health and safety point of view through Risk Assessment.
- Provide a point of contact for communication and correspondence with the EPA

- Ensure compliance with IEL conditions
- Ensure provision of Annual Environmental Report to the EPA to include, amongst others, self-monitoring data, environmental management programme, schedule of environmental objectives and targets and licence specific reports
- Ensure compliance with REACH, HAS and DGSA requirements.
- Establish and document the environmental standards and criteria to be applied for each production and process
- Ensure that each department's responsibility for environmental performance is suitable documented.
- Ensure that adequate records are maintained for demonstration of conformance to environmental requirements.
- Conduct internal audits of the Environmental Management System to ensure continued adherence to documented requirements
- Monitor non-conformances within the environmental system
- Ensure that adequate resources are available to maintain the environmental system at its required level
- Ensure the health and safety regulations are catered for in the Environmental Management System
- Maintain a library of environmental literature and documentation
- Assist in internal dissemination of environmental information

Ongoing assessment of Environmental Performance

The facility will be subject to the following principles and conditions:

- Best Available Technique (BAT): BAT is a key principle in the Industrial Emissions Directive where emphasis is placed on pollution prevention techniques, including cleaner techniques and waste minimisation, rather than end-of-pipe treatment. Regeneron will subscribe fully to the principles of BAT in the design and operation of the Raheen facility.

- Waste Management:

Production and associated activities at the Raheen facility will unavoidably generate waste. Regeneron will operate and maintain a well-developed waste management, minimisation and auditing strategy at the Raheen site (further details in Section F – Materials Handling). The IEL will set out a series of requirements/conditions with respect to waste in terms of recording, reporting, and waste contractor requirements. Regeneron will comply fully with their obligations in terms of waste management as set out in the IEL.

- Environmental Management System (EMS) / Environmental Management Programme (EMP):

Improvements in environmental performance are encouraged in the EMP associated with the IEL by setting a series of objectives and targets commonly associated with reducing resource material use (e.g. water, energy, paper) and waste production generally. Regeneron will undertake the establishment of meaningful and aggressive targets for improvements in the areas of waste reduction throughout the lifetime of the operation of the facility.

Quality Control System

A Quality Management System (QMS) will be developed for the facility in accordance with the principles of ISO 9001:2008.

C.2 Environmental Management System

An Environmental Management System (EMS) will be developed for the facility. This will monitor environmental performance and set objectives and targets to reduce environmental impact. The EMS and Environmental Management Programme (EMP) will encourage improvements in environmental performance by setting a series of objectives and targets commonly associated with reducing material use (e.g. raw materials, water, energy, etc.) and waste production. Regeneron will undertake the

establishment of meaningful targets for improvements in the areas of waste reduction throughout the lifetime of the operation of the facility.

A copy of the environmental management programme for each year will be included in the Annual Environmental Report submitted to the EPA, along with the proposed programme or objectives and targets for each forthcoming year. The environmental management system will be audited on an ongoing basis, both internally and as part of third part verification.

C.3 Hours of Operation

(a) Proposed Hours of Operation

The proposed facility will operate 24 hours. Day staff will be on site from Monday to Friday, from 8 am to 5 pm each day. Site operatives will work over a 3 shifts:

- Shift 1 08:00 – 16:00
- Shift 2 16.00 – 00.00
- Shift 3 00.00 – 08.00

There will be a 24 hours security presence on site throughout the year.

(b) Proposed Hours of Construction and Development Works and Timeframes

Construction will occur for a period of 24 months. Normal construction working hours will be Monday to Friday 8:00am to 6:00pm however longer working hours and potentially shift working s envisage during peak construction periods.

(c) For waste activities, the proposed hours of waste acceptance

Not Applicable

(d) Any other relevant hours of operation expected

Not Applicable

C.4 Fit and Proper Person

- *Indicate whether the applicant or other relevant person has been convicted under the Environmental Protection Agency Act 1992, as amended, the Waste Management Act 1996, as amended, the Local Government (Water Pollution) Acts 1997 and 1990, the Air Pollution Act 1987 and the Air Pollution Act 1987 (Environmental Specifications for Petrol and Diesel Fuels)(Amendment) Regulations 2004.*

Neither Regeneron nor any Director of Regeneron has been convicted of any offence under the Environmental Protection Agency Act 1992 to 2011, the Waste Management Acts 1996 to 2011, the Local Government (Water Pollution) Acts 1997 and 1990, the Air Pollution Act 1987, and the Air Pollution Act 1987 (Environmental Specifications for Petrol and Diesel Fuels)(Amendment) Regulations 2004.

- *Provide details of the applicant's technical knowledge and/or qualifications, along with that of other relevant employees.*

The design and operation of the new facility is based on Regeneron's existing large-scale biopharmaceutical manufacturing facility in Rensselaer, New York. Regeneron intend to replicate the technologies and processes already being used at their existing facilities in the United States. The knowledge and skills that Regeneron has built up over the past twenty years in the design, operation and management of facilities around this technology will ensure that any potential environmental risks associated with the process will be minimised, in comparison with a situation where a new technology or manufacturing process is being introduced.

At present recruitment is ongoing however all personnel have to meet a minimum level of qualifications and standards before they can be considered for a position within Regeneron's team. In relation to the EHS Manager the minimum requirements are:

- 3rd Level Qualification (Science, (Environmental) Engineering)
- A minimum of 8-10 years EHS experience and a proven track record operating in a EH&S role in a bio-pharmaceutical manufacturing or equivalent environment is desirable.
- Experience working with the HSA and EPA
- A high level of initiative, energy and motivation are key role requirements, as well as organisational skills.
- Knowledge of pharmaceutical manufacturing
- IT Skills, Communication Skills, People Management Skills

The proposed EHS Manager will meet these requirements and he/she will be the main site contact for IEL related queries.

The management and staff of the facility will be supported by equipment vendor personnel for the purposes of commissioning and installation, training, maintenance and equipment replacement/repair. This will be formalised through the operation of service / maintenance contracts, as appropriate following completion of the construction phase.

- *Provide information to show that the person is likely to be in a position to meet any financial commitments or liabilities that may have been or will be entered into or incurred in carrying on the activity to which the application relates or in consequence of ceasing to carry out that activity.*

Regeneron is aware that as part of grant of the IEL that it may be requested to complete a Closure Plan and an Environmental Liabilities Risk Assessment (ELRA). These reports will identify the necessary costs required to cover these liabilities and at that point in time Regeneron will put in place the necessary financial provisions, following EPA approval.

See Attachment K: Environmental Liability Risk Assessment (PM Document No. IE0311171-22-RP-0006).

A detailed CRAMP will be developed and submitted to the EPA within six months of commencement of operations, or as otherwise agreed with the EPA, in accordance with the relevant Guidance on Environmental Liability, Risk Assessment, Residuals Management Plans and Financial Provision. The plan will be reviewed annually as part of the Annual Environmental Report (AER). Decommissioning of all aspects of the facility will be validated by the EPA prior to IEL surrender.

Section D Attachment

Attachment D. Infrastructure & Operation

Attachment D: Infrastructure & Operation

D.1.1 Operational History

The Raheen Business Park was originally developed in the 1970s and has grown through various expansions under the control of Shannon Development (formerly SFADCo) since then. Planning permission (98/1139) was first established on the 11.88 hectare site in 1998 when Limerick County Council granted permission to Dell Products (Europe) B.V. for a development described as 'Major-Construction of computer manufacturing plant to include single storey production area, two storey office area, utility building, loading bays, car parking spaces for 1606 vehicles', This application included an Environmental Impact Statement. It is understood the Dell facility was purpose build in 1999 on previously undeveloped land. Subsequent to this parent permission a number of applications were submitted and granted on the site for minor alterations to the site and building between 1999 and 2006.

The existing building, consisting of a two story administration facility and single story production hall, was used for the manufacture, assembly and distribution of PC computers with no chemical processes occurring on site. The facility was Dell's Main European Manufacturing plant. The facility closed in 2009, when manufacturing was transferred to central Europe.

An above ground bulk oil storage tank was originally located on the site close to the south west corner of the building. This tank was decommissioned after the facility closed and has since been removed. A new double skinned c5000L Polyethylene Oil Storage Tank has subsequently been located external to the northern elevation of the building as a fuel supply to the site boilers to maintain heating to the building. The previous operations were essentially dry process not involving the production of trade effluent. As set out in the EIS for the proposed redevelopment of the site by Regeneron, there was no record of any environmental incidents at the facility and this is supported by soil, groundwater and hydrogeological investigations carried out as part of the EIS and site acquisition process.

D.1. 2 Products

Regeneron intends to manufacture in Limerick a variety of therapeutic proteins that are either approved for marketing by various region or country regulatory bodies or are involved in late stage clinical studies. These proteins will be produced to the bulk or formulated state, and filled for shipping.

Regeneron's current product candidates have the potential to help patients living with conditions ranging from rheumatoid arthritis and asthma to cancer and hypercholesterolemia.

As such the Regeneron Facility is being designed with flexibility to reconfigure for manufacturing multiple products. The facility will have ultimately four production trains to meet current and future manufacturing needs.

D.1.3 Overview of the Production Process

The manufacturing processes to be employed by Regeneron at the Raheen facility will follow what are now considered as industry standard techniques for the production of "medicines for patients" using biotechnology derived processes. This approach is favored over traditional organic chemistry routes used in the past because it is capable of yielding more complex molecules for medicinal applications, is more efficient in terms of productivity, poses lower safety risks to the surrounding community, and has less environmental impact in terms of hazardous chemicals used or waste generated for disposal.

This facility is intended to ultimately accommodate four production trains within the Production Building to meet current and future manufacturing needs. The installation is being scheduled in two phases, each comprising two trains and associated support functions.

The primary process steps per production train are as follows;

Upstream: Cell Culture & Harvest
Downstream: Purification and Product Formulation

The overall process is represented in a Block Flow Diagram in Figure D.1.

All of these primary process steps will be located within cleanrooms to be constructed within the footprint of the existing building. These operations will be supported by the following process areas;

- Media Preparation (internal)
- Buffer Preparation (internal)
- Column Packing (internal)
- Wastewater Management (internal and external)
- Process Utility Supplies (internal)

D.1.4 Development of the plant

Regeneron intends to retrofit the existing site and facility to be utilized for the installation of clean room manufacturing and associated utility, warehouse, and locker space for the manufacture of bulk biologics. Regeneron also intends to upgrade the existing 2-storey administration headblock for office and cafeteria functions. The site will also include the design and construction of a new QA/QC/Process Science Lab Building.

The site will consist of a multi-train, bulk biopharmaceutical manufacturing facility including business support functions. All trains will have similar equipment set. The site will have supporting utilities and infrastructure, warehousing and associated functions, waste treatment, administrative offices, and QA/QC and Process Science lab support functions.

The design and operation of the new facility in Limerick is based on Regeneron's existing large-scale production facilities in Rensselaer, NY. The modifications to the existing facility to accommodate the new utility, warehouse, and process program scope requires internal alterations and new construction as well as the expansion of the existing facility to house a portion of the new warehouse.

A site layout is provided in Figure D.2. Identification of Core Production Area is shown in Figure D.3.

D.1.4.1 Plant Layout - Production Building

The process trains are organized to locate process equipment in a logical sequence of steps, or unit operations, flowing from east to west with the upstream and downstream suites separated into their own production blocks.

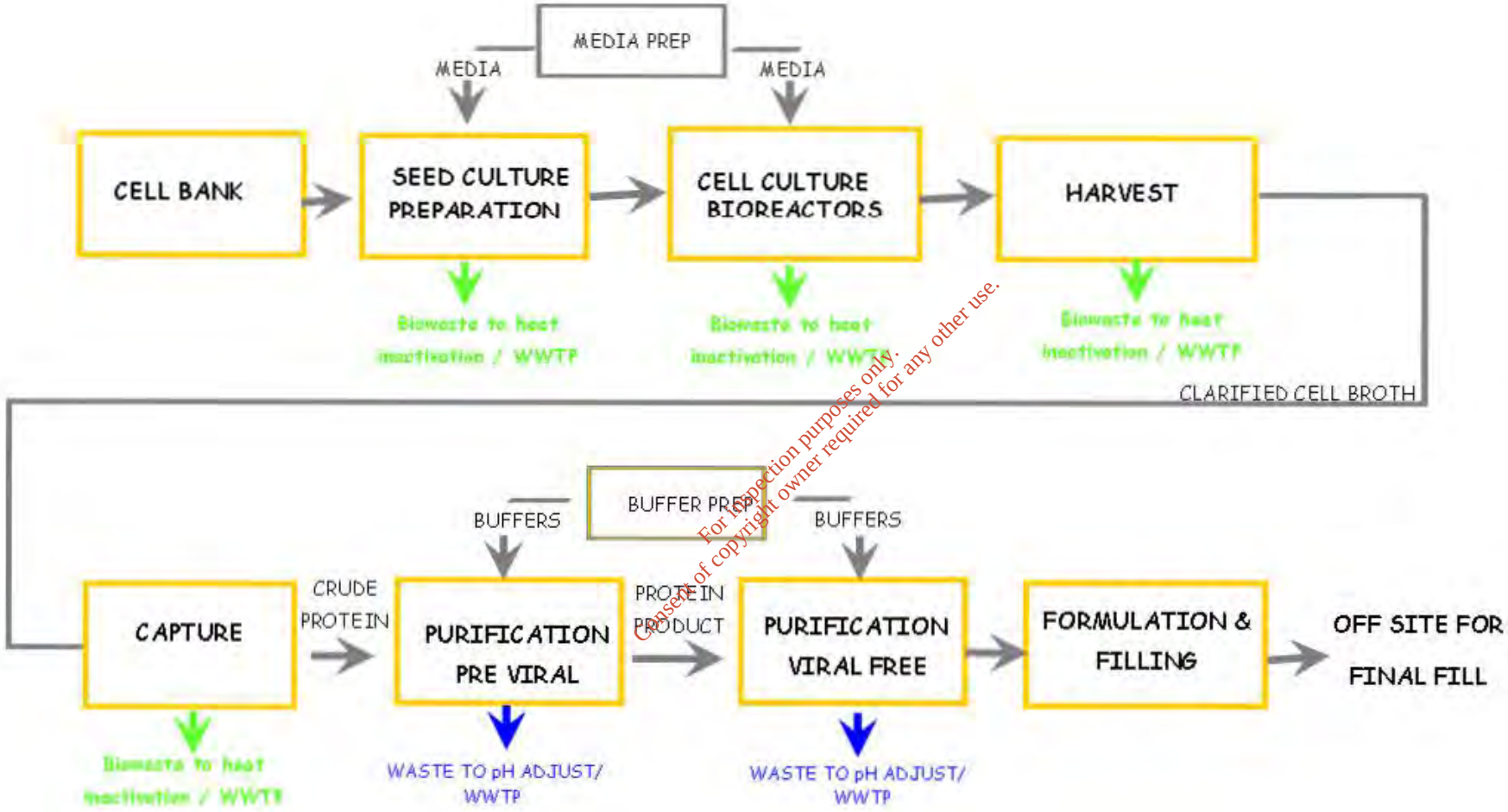


Figure D.1 Overall Process Flow Diagram

Figure D.2 Site Layout

The east to west flow of the process in each train is such that the upstream block has the seed labs located at the far east followed by the seed bioreactor rooms, then the production bioreactor rooms, then media prep, then the harvest suites, and finally the support functions of equipment wash and utility closets as you move to the west.

The downstream blocks are located west of the upstream blocks and also have an east to west flow. Here, the downstream block has the support equipment wash and utility closets at the east end of the block followed by buffer prep, then the individual initial purification unit operation rooms (capture, purification 1, and purification 2), then the final purification UFDF suites, and finally the formulation/bulk fill suite as you move to the west.

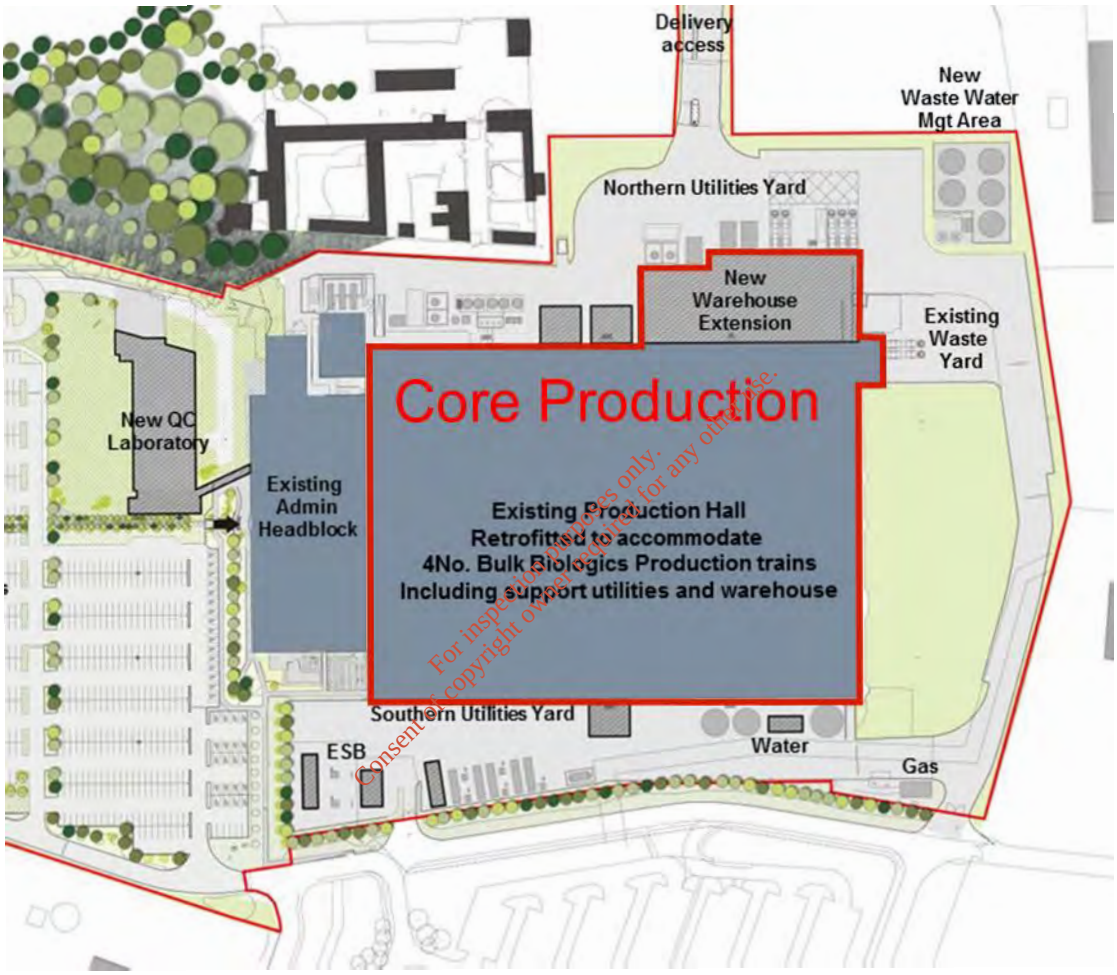


Figure D.3 Identification of Core Production Area on site plan

D.1.4.2 Plant Layout –QC Laboratory

Development of a new Quality Control (QC) Laboratory Building will consist of a 4,000m^2 approx. building over 3 floors complete with a 2-storey link corridor connecting to the existing Administration Headblock and a landscaped courtyard. Functions of the laboratory are discussed in Section D.1.6 'Key Support Functions'.

D.1.5 Detailed Description of the Production Process

D.1.5.1 Cell Culture (Seed room, Bioreactor Suite (Seed Bioreactors & Production Bioreactors))

The manufacturing process starts with the growth of genetically modified mammalian cells (GMM's) in a series of shaker flasks and wave bags to seed bioreactors of increasing size

and on to three large scale production bioreactors. These are the cells that are used to produce the therapeutic proteins used as medical products. See Figure D.4 for Process Flow Diagram.

Thawed vials are inoculated into flasks within the bio-safety cabinet (BSC) in the BSC room. Closed flasks are then passed out of the BSC room to the incubator room and grow in the incubator on a shake table. Shake flasks are brought back into the BSC room and are used to inoculate small bags in the bio-safety cabinet in the BSC room.

This small bag is passed out of the BSC room to the incubator room and grown in the incubator on a wave table. The small bag is brought back into the BSC room and is used to inoculate the larger bag in the bio-safety cabinet in the BSC room. This larger bag is brought back out to the incubator room on a cart and grows in the incubator on a wave table for the remaining growth time. Once the larger bag is ready, it is removed from the incubators and moved to the larger seed cell culture room on a cart.

The Seed Lab suite complete with two Biosafety Cabinet Rooms serves a pair of trains.

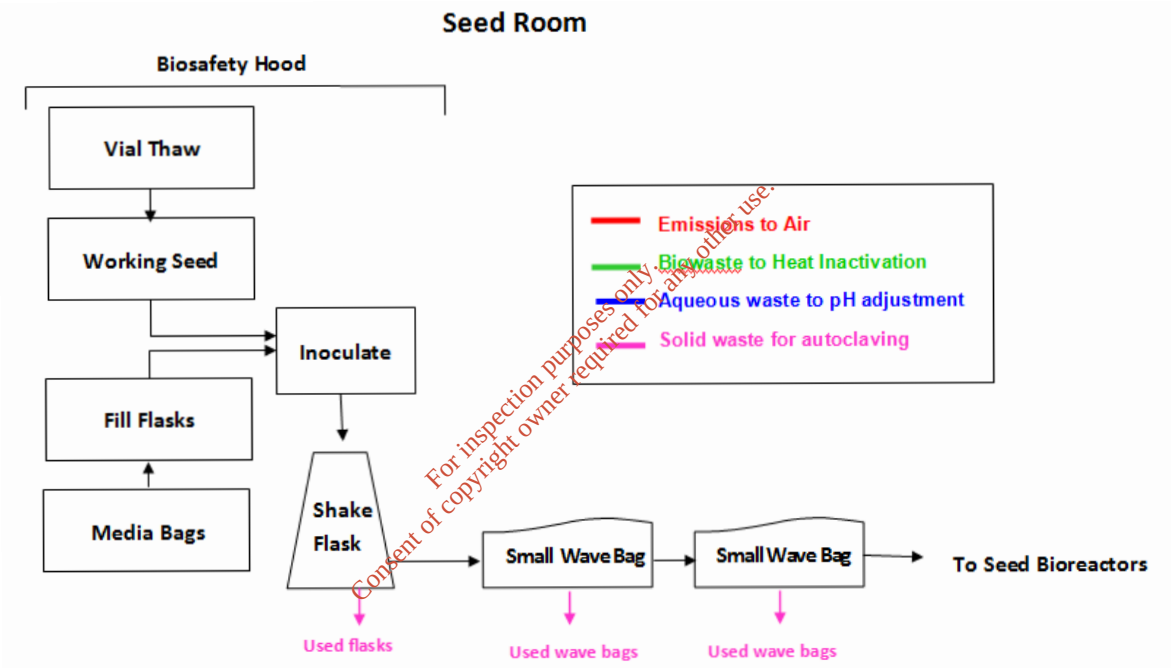


Figure D.4 Seed Room PFD Bioreactor Suite

Each process production train is composed of three Seed Cell Culture Bioreactor rooms and three Production Cell Culture Bioreactor rooms. See Figure D.5 for Process Flow Diagram in relation to Seed and Production Bioreactors.

Seed Bioreactors:
The seed bioreactors are operated on a four day batch cycle with approximately two days for growth and two days for equipment turnaround (cleaning, maintenance, setup for the next batch).

Production Bioreactors:
The cells are held in the bioreactors, provided with oxygen and growth media for cell culture growth and pH control and then transferred to the next bioreactor after a set number of days. Ultimately, the cells are maintained in the production bioreactors for a longer period so that they can produce the desired protein.

The growth media solutions are prepared by mixing pre-purchased mixture of solids with water on a batch basis in a separate area. These solutions are transferred to the bioreactors on a predetermined schedule to support the growth of the cells at different volume stages.

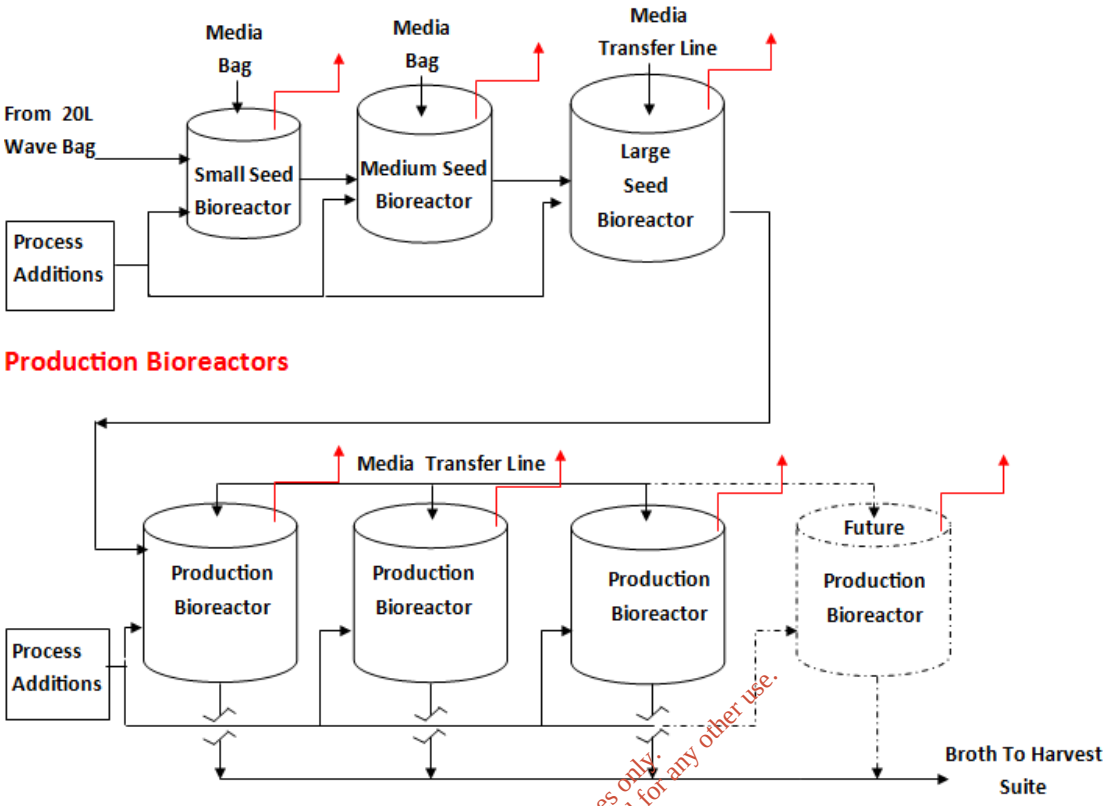


Figure D.5 Seed & Production Bioreactors PFD

Under normal operating conditions, there is no liquid waste from the bioreactors. Any in-process leaks or spills will be diverted to the floor drains, which in turn collect the liquid waste for heat treatment in the heat inactivation system.

All atmospheric vents from the process equipment will be equipped with sterile vent filters capable of retaining particles smaller than 0.2 micron in size. All contaminated solid waste will be processed through the decontamination autoclave.

D.1.5.2 Harvest

There will be one Harvest Suite per train. After a predetermined amount of time, the product is ready to be “harvested” from the production bioreactor. The bioreactor liquids (or broth) are centrifuged to remove suspended solids then further depth filtered to remove residual cell debris. The recovered product is then sent to the Capture and Purification suites for further processing.

The product process flow is through a centrifuge, then through depth filters in parallel, through polish filters in parallel, through final filters, onto a harvest tank where it will then pipe to capture suite.

All filters are intended to be single use throughout and thus are all disposable via a decontamination autoclave. See Figure D.6 for Harvest Process Flow Diagram.

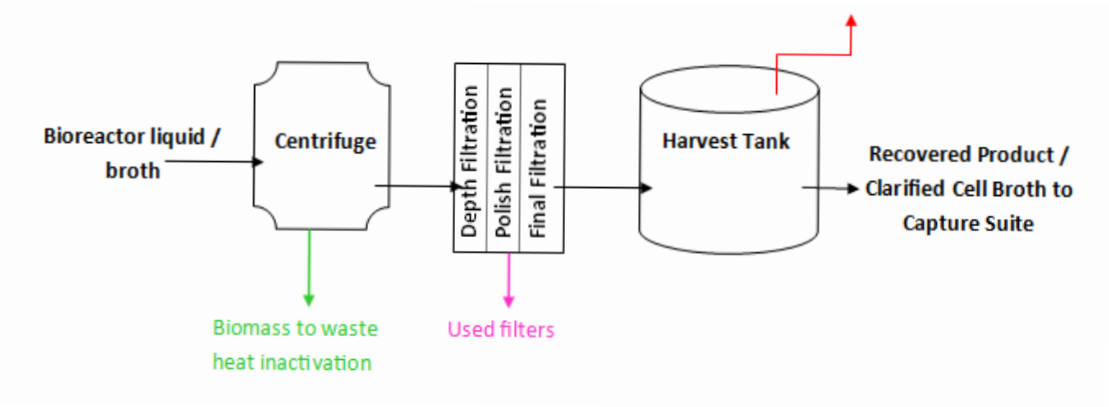


Figure D.6 Harvest PFD

D1.5.3 Capture (Downstream)

There will be one Capture/Protein A suite per train. See Figure D.7 for Capture Process Flow Diagram. Bioreactors are harvested every four days and processed through Capture. Clarified cell broth is passed through a chromatography column that retains the crude protein forwarded to Purification and allows biomass waste to be sent to drain. Up to seven product loads are required through Capture.

Product moves out of the bottom of load tank through a 3 round filter. From there it processes through the Protein A chromatography column. After the column it goes to the first pool tank for pH adjustment and then onto the second pool tank for further pH adjustment. Finally it goes through the depth filter in the suite and then to the next unit operation (Purification 1).

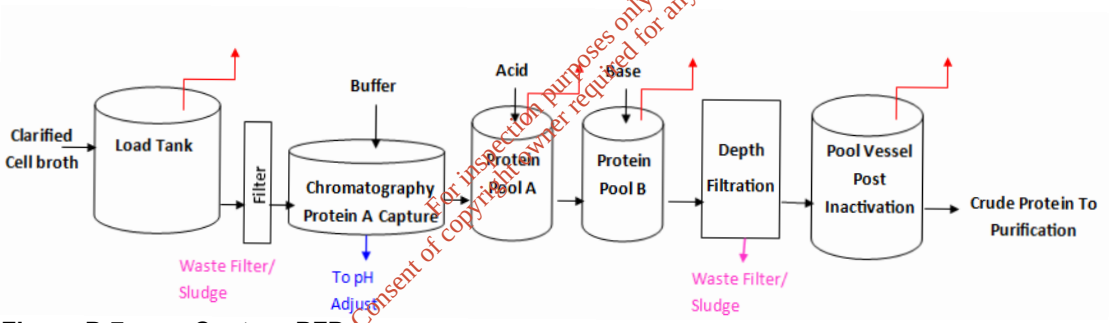


Figure D.7 Capture PFD

Liquid waste from the purification steps will be collected in the process waste drain system and then transferred to the pH adjustment area. Solid waste with cell debris will be passed through the decontamination autoclave.

D1.5.4 Purification

Pre-Viral Purification

After Capture, the batch is subdivided into two sub lots then processed through two chromatography steps and viral filtration. The purification steps remove remaining impurities and result in a pure protein containing solution that can be further processed for use as a medication. There will be one purification 1 and one purification 2 suite per train.

Chromatography is a process that separates components of a solution. This is done by passing it through a solid bed of resin and taking advantage of the fact that the components move at different speeds. Different resins can be used for the separation of specific impurities. Buffer solutions (salts) are used to return the resin to its original condition for processing of the next batch. See Figure D.8 for Pre-Viral Purification Process Flow Diagram.

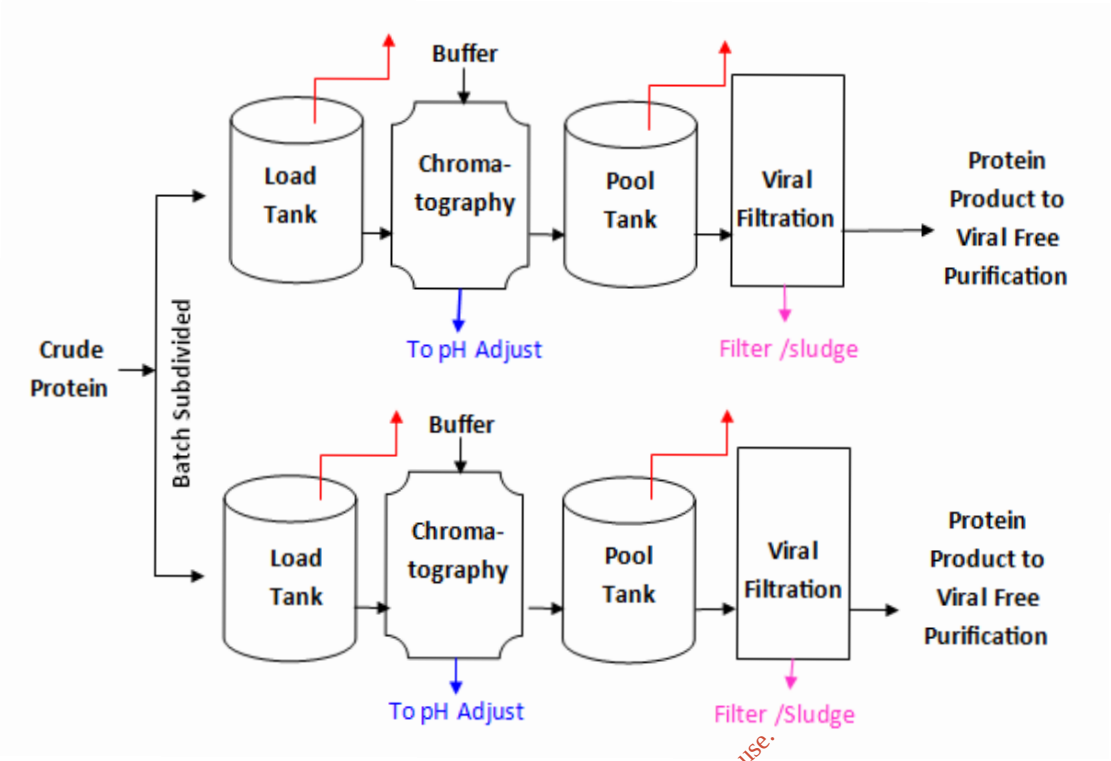


Figure D.8 Pre-Viral Purification PFD

Liquid waste from the purification steps will be collected in the process waste drain system and then transferred to the pH adjustment area. Solid waste with cell debris will be passed through the decontamination autoclave.

Viral-Free Purification

There will be one Ultrafiltration and Diafiltration (UF/DF) suite per train. The UF/DF process is used to concentrate the product near the end of its manufacture. The solution that it resides in may be conditioned and/or replaced with a different buffer solution. See Figure D.9 for Viral-Free Purification, Formulation and Fill Process Flow Diagram.

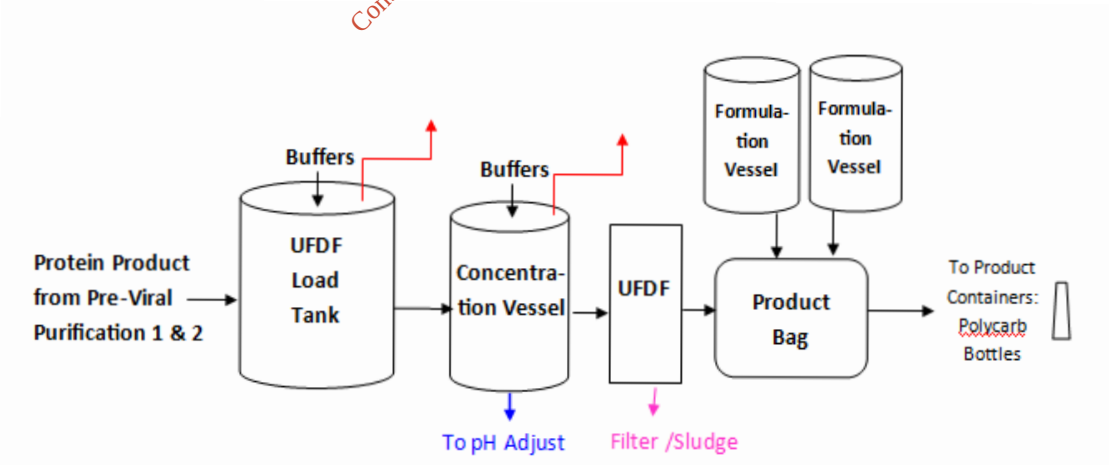


Figure D.9 Viral-Free Purification, Formulation & Fill PFD

D1.5.5 Product Formulation and Bulk Fill

There will be one singular Formulation/Bulk Fill suite to serve a pair of trains. Following final purification (UFDF) the product is mixed with formulation buffer and sterile filled into bulk containers. These filled bottles are initially cooled in a -30°C freezer room and then separately to -80°C in a cascade freezer within the product storage area of the warehouse.

Once final product is ready to ship, multiple containers are bundled and packaged with dry ice in an enviro-container and placed on pallets for shipping.

The process unit operations described above are operated in conjunction with the following key support functions.

D.1.6 Key Support Functions

D.1.6.1 Media Preparation

There will be separate media prep suite for each train, the media prep suites are located upstream just before the harvest suites. See Figure D.9 for Media Preparation Process Flow Diagram. The growth media solutions are prepared by mixing pre-purchased mixture of solids with water on a batch basis in mix tanks within the media preparation area. Raw materials will be charged manually into the top of the prep vessels. All other additions for bioreactors are hydrated in the media prep suite per train.

Media is made up and dispensed into (1) 500L tote, (1) 100L bag and (1) 50L bag. Once dispensed, these containers are held in the cold room staging area. These solutions are transferred to the bioreactors in single use bags, portable containers or via permanent piping on a predetermined schedule to support the growth of the cells at different volume stages

Section G of the IE Licence Application provides a comprehensive list of all materials used on site.

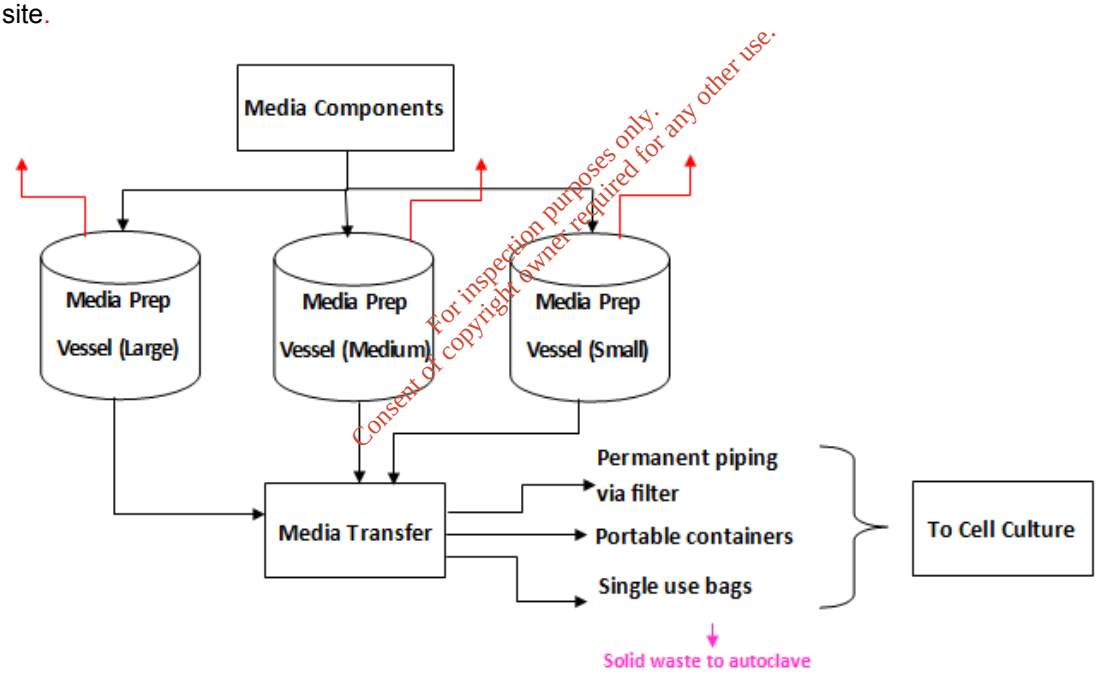


Figure D.10 Media Preparation PFD

D.1.6.2 Buffer Preparation

There will be a combined buffer prep suite serving a pair of trains. See Figure D.11 for Buffer Preparation Process Flow Diagram. The Buffer Preparation Area is located downstream, before the Capture suite. Buffer prep & supply solutions of inorganic salts and other solids are mixed with water in the buffer preparation area.

Mix tanks are used to prepare aqueous buffer solutions used in Purification for chromatography and UF/DF process steps. These solutions are used for cleaning and conditioning of the chromatography resins as well as for containing the product in a stable solution. The buffer solutions are transferred to the points of use by permanent piping or portable bag containers. Raw materials will be charged manually into the top of the prep vessels.

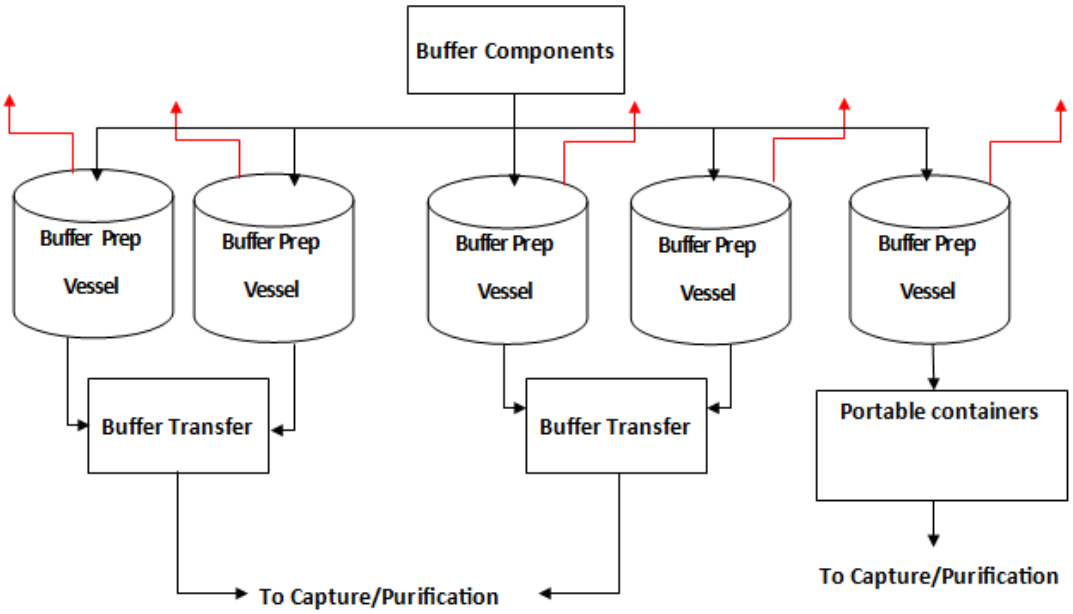


Figure D.11 Buffer Preparation PFD

D.1.6.3 Ethanol Preparation

The process uses ethanol in the column packing operations. Larger quantities of ethanol will be stored in a tank(s) outside of the building in proximity to the Column Prep area and pumped to smaller containers inside the building. The ethanol tank(s) will be provided with a conservation vent and nitrogen blanket. The ethanol will be diluted to 20% with water in the solvent store area of the Warehouse.

D.1.6.4 Column Packing

There will be consolidated central column prep and staging area located in the North West area of the warehouse to accommodate management of chromatography columns for all four trains. This Column Prep/staging area will use a 20% ethanol solution (currently anticipated up to 4,000L at any given time) as well as a smaller volume of 70% ethanol.

Within Column packing, containers of resin are opened and the 20% ethanol is decanted off into a waste barrel that will be routed out of the building for off-site waste disposal. The resin "sand" will be re-hydrated with water for injection "WFI". The rehydrated resin is then added to the 1,000L resin slurry tank. Slurry from the slurry tank is pumped through the packing skid and into the column. Any resin remaining in the slurry tank is pumped into carboys on a floor scale. The WFI in the remaining resin slurry is decanted off and 20% ethanol re-added to the resin for storage. These carboys are then routed back out to the warehouse for storage.

D.1.6.5 Material Sampling

All raw materials, including flammables, may be sampled in this suite prior to use in the process. The Material Sampling suite is located within the Warehouse east of the Weigh and Dispense Suite. This space will consist of a fume hood with dust collection and dispensing hood.

D.1.6.6 Weigh & Dispense

A consolidated central Weigh & Dispense suite to accommodate prepping, dispensing, and staging of raw or dispensed materials for all four trains will be located within the Warehouse area. Raw materials will be brought in and dispensed into smaller dedicated containers sized for manual addition to the process.

D.1.6.7 Equipment Cleaning / CIP

In order to maximize productivity, all of the major processing equipment is cleaned via an automated Clean In Place (CIP) system. The equipment is rinsed with WFI and residual soil is removed by use of recirculating cleaning solutions. All aqueous wastewater is recovered from the cleaning systems and directed to the Wastewater Management Area.

The CIP approach for this facility will include a series of CIP skids per production train. Cleaning of upstream equipment is accomplished by four CIP skids (media prep, seed bioreactors, production bioreactors, harvest). Cleaning of downstream equipment is accomplished by five CIP skids. Within the Cell Culture area, initial rinses from the CIP skids in cell culture will be diverted to the biowaste collection and heat inactivation system.

The bulk CIP chemicals used to make up the CIP caustic wash solution (0.2N caustic) and acid rinse solution (0.5% phosphoric acid) will be 10N caustic and 33% phosphoric acid, respectively.

D.1.6.8 Equipment Wash

There will be one Equipment Wash Suite to serve each pair of upstream process trains and, separately, one Equipment Wash Suite to serve each pair of downstream process trains. Each of these Equipment wash suites will have two pass through style parts washers.

The wash carts are loaded on the used equipment side with used parts and then placed in the washer for cleaning. Next, the wash cart is unloaded from the parts washer on the clean equipment side where the clean parts are pulled and offloaded onto racks. Finally, the wash carts are passed from the clean equipment side back to the used equipment side using the parts washers as a pass through.

D.1.6.9 Waste Management Area

All process waste from cell containing areas is routed through and managed in this area within the east side of the Warehouse and includes:

- An area for bio-waste management to accommodate bio-waste heat inactivation skids, tanks, and containment. This is described in further detail in Section D.1.9.1.
- An area for one pass through style decontamination autoclave along with areas for staging of pre and post autoclaved material.
- A Waste Handling Area and Waste Compactor Area, this is described in more detail in Section H of the Application Form.

D.1.6.10 QC Laboratory

A new QC Laboratory will be constructed on the site to accommodate quality control test procedures related to the proposed manufacturing process. Testing requirements will include;

- Product release testing
- Raw material testing
- In-process control testing and
- Environmental monitoring and microbial testing

The QC Laboratory will consist of three separate laboratories under the following disciplines: Biochemistry, Chemistry and Microbiology.

All aqueous biological waste will be inactivated in the laboratory prior to discharge using either bleach or autoclaving at 121^{o}C. All solid biological wastes will be autoclaved in the lab to render it non-hazardous. The autoclave in the manufacturing area may also be used as back up, son long as the material from the lab area is brought to the autoclave external to the production floor.

D.1.6.11 Warehouse

The primary functions within the warehouse include Receiving, Shipping, GMP Ambient/Cold Warehouse Storage, 2-8°C GMP Warehouse Staging, Final Product Storage, General Staging, Cell Bank Room and Manufacturing Retain Sample Storage.

There is a number of 2-8°C cold storage rooms located in the Warehouse area. There are also a number of -30°C freezer rooms within the Warehouse.

D.1.7 Site Utilities

Special high purity utility systems will be provided at the Regeneron manufacturing facility which will be used in all locations that could potentially come in contact with product. The following service supplies will be generated;

D.1.7.1 Water for Injection (WFI)

WFI will be used for cleaning (CIP) process equipment and to prepare media / buffer solutions used in the upstream and downstream process steps. This high purity water is prepared by the vapor recompression distillation and subsequent condensing of the WFI. The WFI is stored and distributed to all locations requiring water, including the CIP systems as well as the buffer and media solution prep areas.

The WFI stills will discharge into two pairs of WFI storage tanks. The WFI storage tanks will be maintained at temperatures above 85^{o}C. Each pair of tanks will be provided with WFI supply skids equipped with circulation pumps for hot and ambient WFI supply. Hot WFI will be supplied to the CIP skids and ambient WFI will be supplied to the media prep, harvest, buffer prep and wash areas.

D.1.7.2 Clean Steam

Clean steam is prepared by the heating and vaporisation of WFI. The steam is distributed to the processing equipment and is used primarily for the sanitization of the processing equipment prior to its use. Clean steam will be used to steam sterilize the seed bioreactors, production bioreactors, harvest equipment and purification equipment associated with each train. The media tanks / transfer lines and buffer tanks / transfer lines will not normally be SIPed.

Three clean steam generators will be provided for the facility. Two of them will each provide steam to two process trains. The third one will act as a standby spare.

D.1.7.3 Process Gases

Process air is prepared by the compression and subsequent filtration of air. It is distributed throughout the facility for use with the processing equipment. Process gases (oxygen, carbon dioxide, nitrogen) will be used primarily for the bioreactor operations (overlay / sparge gas).

D.1.7.4 Compressed Air

Process compressed air will be used for material transfers, bioreactor operations (overlay / sparge gas), SIP operations (pressure test, SIP cool down), CIP operations (air blows), glass washers, material lifting devices, instrumentation, and general area drops.

D.1.7.5 Plant Steam

5 No. new 7.9 MW natural gas-fired boilers used for steam generation. During normal operation the boilers will operate on a 5 Duty / 2 Standby basis. Plant steam for Phase 1 will include three fire tube, natural gas operated low NOx (<80 mg/Nm^3) emission output boilers, each of capacity to produce 26,000 lbs/hr steam 8.6 barg will be provided.

Process plant steam will be used for water heat-up for the carbon filter sanitisation, WFI still operation, clean steam generator operation, AWFI heat-up, maintaining hot WFI temperature, parts washer operation, biowaste inactivation system operation, CIP skid operation, HTST operation, harvest tank / purification load tank heat-up, and maintaining the bioreactor operation temperature.

D.1.7.6 Potable Water (PW) and Water for Operations (WFO)

A new public water supply (from existing network serving the Raheen Business Park) will be required and routed to two local storage tanks each of capacity of approx. 950m^3 located near the plan southeast corner of the site. A meter and back flow preventer will be installed in the supply line prior to connection to the storage tank.

A pump room will be part of the new pump house that will also house the fire pumps also located near the plan southwest corner of the site. Pumps controlled by pressure sensor in line will distribute water from the tank to the building users.

D.1.7.7 Low Temperature Hot Water (LTHW)

2 No. existing 1.8 MW natural gas-fired boilers will be used for LTHW (low temperature hot water) generation. LTHW will be generated in the building for the HVAC system. This will be a packaged skid which will include two steam to water heat exchangers (each sized for 75% of connected load), 8.6 barg high pressure steam will be used to generate the hot water for distribution to heating coils.

D.1.8 Utility Yards

The existing site is characterised by large paved areas on the northern and southern sides of the Production Building which were used as truck staging areas for goods shipping and receiving. The development now proposed by Regeneron aims to utilise the available yard space to accommodate the key external utility items required to support the manufacturing processes within the Production Building.

In broad terms, utilities have been split between the northern yard area and the southern yard area on the following basis:

Southern yard area – incoming utilities

- 38kV substation and emergency generators, including diesel storage up to 80m^3 approx.
- Process water storage tanks (24 hr supply) and pump house
- Fire water storage tank and pumps
- Natural gas pressure reducing station

D.1.8.1 Water Supply

Water supply to the site is currently via a 200mm diameter main entering from the south (Cloghkeating Avenue). A new supply from the same main will be routed to the new on-site process water storage tanks (2No.) to be located in the southern utility yard. This main will also serve the new firewater storage tank adjacent to the process water tanks. There is an existing direct domestic supply to the headblock building which will also be maintained, and extended to serve the new laboratory building.

D.1.8.2 Natural Gas

Existing natural gas supply to the site enters from the north. In line with the utility strategy for the new development, and in consultation with Bord Gais, it is proposed that a new gas supply will enter the site from an existing gas main to the south on Cloghkeating Avenue. This gas feed (4bar) will enter a new pressure reducing station to be located inside the southern boundary of the site, from where low pressure gas will be distributed around the site.

D.1.8.3 Firewater Main

Firefighting water supply will be from a new firewater storage reservoir located near the plan southeast corner of the site. The reservoir will have a nominal capacity of 1136 m^3 will be split into two equal compartments to allow for cleaning one section while the other is maintained in service.

Fire pumps will be in a dedicated pump room within a pump house located near the plan southwest corner of the site. Two diesel fire pumps will be provided.

D.1.8.4 Electrical Distribution

The site will be serviced by a new twin underground 38 kV supply from the utility provider ESB Networks to a location in the south west of the site close to the southern elevation of the existing Production Building. No new overhead lines will be required. Both lines will feed a gas-insulated 38 kV substation with dedicated transformers for distribution around the site at 10/20 kV. Total site power requirement is anticipated to be up to 12 MVA for the fully developed site. The substation will be constructed as an enclosed building which will be

owned and maintained by ESB Networks and which will be accessed via an existing site access gate on Cloghkeating Avenue.

Emergency power generation will be provided by up to five 2500 kVA diesel fueled generators giving a total back-up of up to 12.5 MVA. These will be situated in a separate compound east of the proposed 38 kV substation on the southern elevation of the building and fed from the site diesel fuel storage tank to be located adjacent to the generators.

Northern yard area – site utilities
The utilities located in the northern yard consist of:

- Cooling towers and chillers
- Waste water management area
- Gas storage area (O_2, CO_2 & N_2 Tanks)
- Bulk Chemical storage (phosphoric acid, caustic and ethanol)

D.1.8.5 Cooling Towers and Chillers

A total of seven cooling tower cells will be installed. A chemical addition system to treat the tower water will be provided for corrosion protection, microbiological control, and to increase solubility of mineral salt. Process tower water will be used for cooling the AWFI loop, cooling the biowaste following the heat inactivation operation, and cooling the aqueous waste.

Chilled Water
A total of five chillers will be installed. 4°C chilled water for HVAC and Process will be generated in the building. Process chilled water will be used for cooling the AWFI loop, cooling the media after the HTST operation, material cool down in tanks, tank cool down following SIP, WFI still cooling (compressor and blowdown), clean steam generator cooling (sampling), UF/DF skid cooling (pump heat load removal, etc.), centrifuge cooling, and bioreactor cooling (to maintain set-point bioreactor operating temperature).

D.1.8.6 Gas Storage Area

Three process gases will be required in the process, nitrogen (N_2) to support cell bank room and final product storage and carbon dioxide (CO_2) and oxygen (O_2) to support the cell culture area. Bulk liquid gas storage systems located on the northern side of the facility will be the source for all the gases.

D.1.8.7 Bulk Chemical and Diesel Storage Area

Bulk bunded chemical storage tanks (acid 25 m^3, caustic 25 m^3 and ethanol 25 m^3) will be located on the north side of the facility.

The bulk CIP chemicals used to make up the CIP caustic wash solution (0.2N caustic) and acid rinse solution (0.5% phosphoric acid) will be 10N caustic and 33% phosphoric acid, respectively.

D.1.8.8 Underground Drainage Systems

Wastewater arising from the site operations will be segregated, collected and managed according to the philosophy described in Figure D.13.

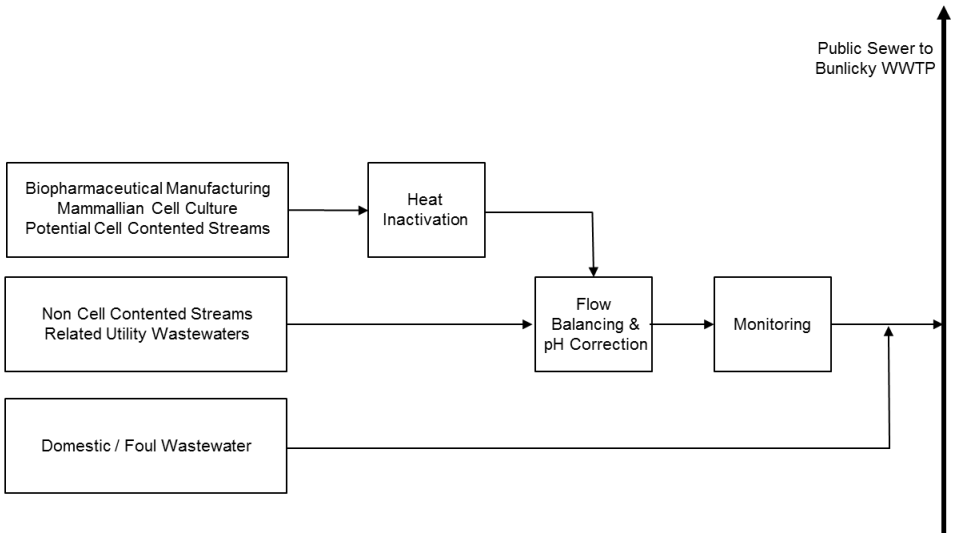


Figure D.13 Site Wastewater Management Process Drainage

The existing site does not have a separate process drainage network. As such, new process drainage to connect the Production Area with the new external Waste Water Management Area (comprising Flow Balancing and pH Correction) will be required to be installed. All new underground process drainage pipework will be double contained and include leak detection. A new gravity drainage line to connect from the Waste Water Management Area to the exiting discharge manhole connecting to the Shannon Development sewer will also be laid on the eastern side of the site.

All streams from the manufacturing facility and laboratory which have the potential to contain GMM contented effluent (i.e. biowaste) will be de-activated prior to discharge to the site process drainage system and site flow balancing and pH correction facility.

Depending on design preferences, some of the process drainage pipework may comprise collection sumps with aboveground pumped lines.

Foul Drainage

Domestic waste water from the facility (toilets, lockers, showers, canteen, etc.) will utilise the existing site foul sewer network. Domestic effluent be collected in the existing sewer network and transferred directly to the local municipal sewer without further on site treatment.

There is an existing underground foul drainage network serving the site, which links the existing Administration Headblock to the west with the 450mm diameter Shannon Development foul sewer on the eastern side of the site. It is intended this sewer will be maintained, with some branch extensions to pick up new elements of the site, in particular the new QC Laboratory.

Storm Water Drainage

An extensive storm water drainage network currently serves the entire site and collects rainwater run-off from three distinct catchment areas;

- Shipping and receiving yards and site circulation roads
- Car park area
- Building roofs

The network combines in the north west of the site close to the existing personnel access from Ballycummin roundabout. A 900mm diameter outfall pipe passes through a petrol interceptor system prior to connecting to the public storm water sewer outside the north western boundary of the site.

It is intended that the existing storm water drainage network will be preserved as far as possible except where local diversions are required to accommodate proposed building

extensions. A key feature of the proposed redevelopment of the site is the fact that the overall impermeable area of the site will reduce as a result of the project. The reduction will be over 5% (4,700m^2) which will be achieved mostly by the replacement of excess parking area with permeable surfaces and landscaping. This reduction will have a positive impact on off-site downstream drainage capacity.

The proposed development will include the upgrade or replacement of the existing site petrol interceptor and the installation of an actuated valve on the outlet of the storm water drainage system to facilitate greater control on the release of storm water from the site. Storm water drainage, including on-site management and off-site drainage routes is discussed in more detail in Section E.

D.1.9 Abatement, Recovery and Treatment Systems to be Used On-site

The following is a brief overview of treatment, abatement and recovery systems on site. A more detailed description is provided as required in Section F of the Application Form.

D.1.9.1 Treatment Systems

Heat Inactivation - Process Waste, Laboratory and Cleaning Solution Wash

GMM Classification
The classification associated with the GMM material to be used in the inoculation process is a Class 1 GMM material. Contained Use (CU) approach of GMMs is classified in relation to the nature of risks present for human health & environment. Classification is based on risk assessment and containment and other protective measures specified according to the classification of CU:

Classification of GMM:
Class 1 – Activities of no or negligible risk: Containment Level 1 (CL1)
Class 2 – Activities of low risk: Containment Level 2 (CL2)
Class 3 – Activities of moderate risk: Containment Level 3 (CL3)
Class 4 – Activities of High risk: Containment Level 4 (CL4)

All GMM contaminated waste including effluent must be rendered safe in accordance with the legislation as enforced in Ireland by the EPA.

Process effluent from each production line will comprise two distinct streams; GMM contented effluent and Non-GMM contented effluent. Any material or effluent potentially containing GMM cells will require treatment in the form of inactivation before discharge to the Non-GMM contented effluent system.

Heat Inactivation – Overview:
Biowaste, defined as liquid process waste that could contain live cells, will be collected from the Cell Culture and Harvest areas of each train in under slab drain piping and flow by gravity through a 12000 L sump and pumped to the Biowaste Treatment Area. Biowaste will be held in the Biowaste Hold Tanks, and then will be fed to the inactivation system. The Hold Tank is intended to provide enough retention capacity to temporarily store an off-spec bioreactor batch and allow production to continue on a temporary basis.

The biowaste will be processed through the inactivation system, designed to heat treat the waste at 120^{o}C which will kill any live cells that may be present. Direct steam injection will be used to heat the biowaste in the steam jet. Downstream of the steam jet, the retention tube will insure that the biowaste is kept at elevated temperature for a long enough period to kill any organisms i.e. two minutes contact time. The system will operate continuously to heat up and cool down the waste as opposed to using a batch type system.

Two biowaste surge tanks and two heat inactivation systems are planned. Post-treatment cooling will be provided to minimize steam consumption and cool the treated waste to a safe level for recombining with other process waste at the Flow Balancing / pH Correction system.

Flow Balancing / pH Correction System

Non-cell containing process waste, primarily from the Buffer Prep, Media Prep and Purification areas, will be collected in under slab drain piping and flow by gravity to a lift station and transferred to the Flow Balancing / pH Correction system. The process waste will be combined with treated biowaste in a series of Waste Balancing Tanks.

The Flow Balancing and pH Correction system will provide preliminary treatment to the combined process effluent and will consist of the following component treatment steps:

- Waste Water Balancing
- Cooling
- Neutralisation
- Odour Control
- Monitoring

The main purpose of the balance tank system is to provide buffering capacity to smooth out variations in the flow and pollution loads. This will allow a uniform discharge to the public sewer, and provide natural buffering to pH fluctuations allowing the effluent feed to the downstream neutralisation stage to remain steady. An additional buffer tank will also be provided to cater for periods of peak load or abnormal concentration requiring retention. Peak loads can be diverted to the buffer tank away from the balance tank and bled back into the system over time allowing for a more uniform treatment and discharge profile. Overall, up to 5No. tanks are envisaged, each of approximately 375m^3 capacity, to cater for the Phase I and Phase II projected load profile for the facility.

The pH control will be achieved utilising inline dosing, with a PLC controlled chemical dosing system (acid and caustic). There will be upstream and downstream pH sensors installed allowing for effective pH adjustment. The recirculation loop will be provided downstream monitoring point to reverse wastewater back to the balancing tanks if the quality of discharge wastewater does not comply with the requirements.

Decontamination Autoclave

The decontamination autoclave will be located adjacent to the waste staging area in the warehouse. The decontamination autoclave will treat cell-containing solid waste exiting the manufacturing building.

D.1.9.2 Abatement Systems

In addition to the treatment systems described for site waste water management above, the following abatement measures will be employed in relation to atmospheric emissions;

Bioreactor Vents to Atmosphere

HEPA Filters (0.2 µm) will remove particles and GMM greater than 0.2 um from gases exiting the bioreactor vents.

Low NO_x Burners – Air Emissions

The natural gas-fired steam boilers will be fitted with low NOx burners. Emissions from gas combustion in the burners will be less than 80 mg/m^3 NOx.

Due to the innocuous nature of the proposed manufacturing process, no other abatement facilities are required.

Section E Attachments/Drawings

Attachment E.1: Emissions to Atmosphere

Drawing 4: Air Emission Points (1 of 4)

Drawing 5: Air Emission Points (2 of 4)

Drawing 6: Air Emission Points (3 of 4)

Drawing 7: Air Emission Points (4 of 4)

Attachment E.3: Emissions to Sewer

Drawing 8: Sewer Emission Points

Drawing 9: Wastewater Process Flow Diagram

Attachment E.5: Noise Emissions

Drawing 10: Noise Emission Sources

Drawing 11: Noise Sensitive Locations

Attachment E.6: Tabular Data on Emission Points

Attachment E.1: Emissions to Atmosphere

E.1 Emissions to Atmosphere

The emissions to atmosphere from the proposed facility are classified according to:

- Boiler Emissions
- Main Emissions
- Minor Emissions
- Fugitive and Potential Emissions

The following Air Emission tables in the IEL Application form have been completed:

- Table E.1 (i) for boiler emissions.
- Table E.1 (iv) has been completed for all minor emissions from the facility
- Table E.1 (v) has been completed for all potential/fugitive emissions

All emission points are shown on Drawings No. 4-7.

Boiler Emissions

The proposed facility will consist of 5 No. 7.9 MW natural gas-fired steam boilers. These boilers will produce steam to service production operations and air handling units (AHUs) within the Production Building (steam humidification units and low pressure hot water plate heat exchangers). For Phase 1 of the project (i.e. two production lines in operation plus associated services) 2 boilers will be in operation plus one on standby. With the facility in full operation i.e. four production lines plus associated facilities (Phase 2) four boilers will be operational plus, with the fifth on standby.

The proposed development will also consist of 2 No. 1.8 MW natural gas-fired boilers used for LPHW (low pressure hot water) generation servicing the QC Lab and Administration Buildings which will be operated on a duty/assist basis for Phase 2.

Of the substances listed in the schedule of S.I. 394 of 2004, emissions from these gas-fired boilers will include the products of combustion, NO_2, CO. As these boilers are natural gas-fired, the emission of particulates (PM_{10}, $_{2.5}$) and of SO_2 is negligible.

A summary list of these emission points to atmosphere is provided in Table E1.1.

Table E1.1 – Boiler Emission Points

Emission Ref	Description	Type of Emission	Location
A1-1	Steam Boiler No. 1 (Natural Gas fired)	Boiler (NO_X, CO)	Boiler Room
A1-2	Steam Boiler No. 2 (Natural Gas fired)	Boiler (NO_X, CO)	Boiler Room
A1-3	Steam Boiler No. 3 (Natural Gas fired)	Boiler (NO_X, CO)	Boiler Room
A1-4	Steam Boiler No. 4 (Natural Gas fired)	Boiler (NO_X, CO)	Boiler Room
A1-5	Steam Boiler No. 5 (Natural Gas fired)	Boiler (NO_X, CO)	Boiler Room
A1-6	LTHW Boiler No. 1 (Natural Gas fired)	Boiler (NO_X, CO)	Utility Building
A1-7	LTHW Boiler No. 2 (Natural Gas fired)	Boiler (NO_X, CO)	Utility Building

Main Emissions

There are no main emissions to atmosphere from the proposed facility.

Minor Emissions

Minor emission points are those which on the basis of their concentration and mass are not considered sufficiently environmentally significant to be classified a main emission or boiler emission. General clean air HVAC vents are not listed.

The main minor emission points associated with the facility are detailed in the sub-sections below.

It should be noted that as detailed design of the facility progresses, consolidation of emission points may be possible as well as the addition of further points.

Cell Culture Process Equipment

The extract vent lines from the Bio-safety cabinets (BSCs) used to inoculate the genetically modified mammalian cells (GMMs) will all contain HEPA (high efficiency particulate air) filters which will remove any GMMs greater than 0.2 µm in the extract air.

Similarly, all the vents from cell culture process equipment will be equipped with 0.2 µm sterile vent filters.

Other Process Equipment & Process Support Equipment

Vents from the harvest vessels will also be fitted with 0.2 µm sterile vent filters.

The rooms containing the Parts Washers will be fitted with extract canopies which extract any water vapour produced during the opening of the washers' doors.

Ethanol Storage/Column Prep Area

20% Ethanol solution (along with smaller volumes of 70% ethanol) will be used in the preparation of resins for the Chromatography Columns in the Column Packing room. A 25,000 litre ethanol storage vessel in the Utility yard will provide the ethanol for these operations. This storage tank will have a nitrogen blanket and conservation vent to minimise ethanol vapour emissions to the atmosphere. Ethanol will be diluted in the solvent store area of the warehouse.

The ethanol vapour emissions associated with these activities will be minor.

Material Sampling/Dispensing

The manipulation of solids in the dispensing area will be done on a small scale manual basis and contained within dispensing booths equipped with HEPA filters.

Any dust generated during the sampling of powders will be contained through the use of a fume hood equipped with a dust filter.

QC Laboratory Fumehoods

It is expected that small quantities of solvent will be used in some of the process support operations and in the QC Laboratory. Volatile Organic Compound (VOC) emissions arising from these operations are expected to be minor. Small quantities of powder will be used in one the Gel Lab fumehoods which will be fitted with a HEPA filter.

QC Laboratory Building Utility Equipment

The QC Lab building will use a 1.8MW Steam Boiler (1570 kg/hr steam output) and a 120kW Water Heater Boiler. Both boilers will be natural gas fired and will emit NOx and carbon monoxide. The emissions from both boilers are minor as they are below the 5MW threshold.

A clean steam generator will also be located in the QC Lab Building with a vent line (water vapour/steam) to atmosphere.

Process Waste/Biowaste Drainage & associated Sump Vessels

Process waste and biowaste drain lines will have a vent line at the end of each sub-header to assist the free drainage of waste liquid into their associated sump vessels.

Clean Utility /Black Utility Equipment

The WFI Still Generators and Clean Steam Generators will have vent lines containing water vapour/steam. The vent lines from the WFI Still generators assist in the degassing of the heated feed water. During the start-up of the Clean Steam Generators, the steam output is directed to a vent line fitted with a discharge silencer.

Each of the burners associated with the LTHW and Steam Boilers will contain a control gas vent line (small diameter) which emits natural gas.

Cooling towers

Seven cooling towers will be provided for the new facility. The air exiting the cooling tower will be saturated with water, which under certain conditions may form a visible plume. There are no main polluting substances associated with the cooling towers.

Waste Water Balancing System

The proposed development will have a waste water balancing system in order to adjust flow and pH to the downstream municipal WWTP if required. Process wastewater from the production areas will flow directly into these tanks where it will be dosed with acid and/or base in order to neutralize its pH.

A summary list of the minor emission points to atmosphere is provided in Table E1.2.

Table E1.2 – Minor Emission Points

Emission Ref	Description	Type of Emission	Location
A3-1	Incubators Train 1 Vent	Water vapour	Production Building
A3-2	Incubators Train 2 Vent	Water vapour	Production Building
A3-3	Incubators Train 3 Vent	Water vapour	Production Building
A3-4	Incubators Train 4 Vent	Water vapour	Production Building
A3-5	Wave Reactors Vent Train 1	Water vapour	Production Building
A3-6	Wave Reactors Vent Train 2	Water vapour	Production Building
A3-7	Wave Reactors Vent Train 3	Water vapour	Production Building
A3-8	Wave Reactors Vent Train 4	Water vapour	Production Building
A3-9	Seed Bioreactors Vent Train 1	Water vapour	Production Building
A3-10	Seed Bioreactors Vent Train 2	Water vapour	Production Building
A3-11	Seed Bioreactors Vent Train 3	Water vapour	Production Building
A3-12	Seed Bioreactors Vent Train 4	Water vapour	Production Building
A3-13	Production Bioreactor 1 - Train 1	Water vapour	Production Building

Emission Ref	Description	Type of Emission	Location
A3-14	Production Bioreactor 2 - Train 1	Water vapour	Production Building
A3-15	Production Bioreactor 3 - Train 1	Water vapour	Production Building
A3-16	Production Bioreactor 1 - Train 2	Water vapour	Production Building
A3-17	Production Bioreactor 2 - Train 2	Water vapour	Production Building
A3-18	Production Bioreactor 3 - Train 2	Water vapour	Production Building
A3-19	Production Bioreactor 1 - Train 3	Water vapour	Production Building
A3-20	Production Bioreactor 1 - Train 3	Water vapour	Production Building
A3-21	Production Bioreactor 1 - Train 3	Water vapour	Production Building
A3-22	Production Bioreactor 1 - Train 4	Water vapour	Production Building
A3-23	Production Bioreactor 2 - Train 4	Water vapour	Production Building
A3-24	Production Bioreactor 3 - Train 4	Water vapour	Production Building
A3-25	Biologics Safety Cabinet Seed #1 Extract Fan - Train 1	Water vapour, particulates	Production Building
A3-26	Biologics Safety Cabinet Seed #1 Extract Fan - Train 2	Water vapour, particulates	Production Building
A3-27	Biologics Safety Cabinet Seed #1 Extract Fan - Train 3	Water vapour, particulates	Production Building
A3-28	Biologics Safety Cabinet Seed #1 Extract Fan - Train 4	Water vapour, particulates	Production Building
A3-29	Harvest Tank Vent -Train 1	Water vapour	Production Building
A3-30	Harvest Tank Vent -Train 2	Water vapour	Production Building
A3-31	Harvest Tank Vent -Train 3	Water vapour	Production Building
A3-32	Harvest Tank Vent -Train	Water vapour	Production Building
A3-33	Parts Washer Extract Canopy - Trains 1 & 2	Water vapour	Production Building
A3-34	Parts Washer Extract Canopy - Train 1& 2	Water vapour	Production Building
A3-35	Parts Washer Extract Canopy - Train 3 & 4	Water vapour	Production Building
A3-36	Parts Washer Extract Canopy - Train 3& 4	Water vapour	Production Building

Emission Ref	Description	Type of Emission	Location
A3-37	Column Prep Room Extract Fan	Solvent vapour	Warehouse
A3-38	Solvent Store Extract Fan	Solvent vapour	Warehouse
A3-39	Waste Room Extract Fan	Solvent vapour	Warehouse
A3-40	Material Sampling Fume Hood Extract Fan	Particulates, Solvent vapour	Warehouse
A3-41	Dispensing Booth Suite 1 Extract Fan	Particulates	Warehouse
A3-42	Dispensing Booth Suite 2 Extract Fan	Particulates	Warehouse
A3-43	Dispensing Booth Suite 3 Extract Fan	Particulates	Warehouse
A3-44	Dispensing Booth Suite 4 Extract Fan	Particulates	Warehouse
A3-45	Dispensing Booth Suite 5 Extract Fan	Particulates	Warehouse
A3-46	Dispensing Booth Suite 6 Extract Fan	Particulates	Warehouse
A3-47	Biowaste Equalisation Tank Vent	Water Vapour	Biowaste
A3-48	Biowaste Sump Vessel Trains 1 & 2	Water Vapour	Production Building
A3-49	Biowaste Sump Vessel Train 3 & 4	Water Vapour	Production Building
A3-50	Process Waste Equalisation Tank #1 Vent	Water Vapour	WWTP Area
A3-51	Process Waste Sump Vessel Vent - Trains 1 & 2	Water Vapour	Production Building
A3-52	Process Waste Sump Vessel Vent - Train 3 & 4	Water Vapour	Production Building
A3-53	Process Waste Equalisation Tank #2 Vent	Water Vapour	WWTP Area
A3-54	WWTP Biological odour treatment vent (future)	Water vapour	WWTP Area
A3-55	Biowaste drain vent 1 - Train 1	Water vapour	Production Building
A3-56	Biowaste drain vent 2 - Train 1	Water vapour	Production Building
A3-57	Biowaste drain vent 1 - Train 2	Water vapour	Production Building
A3-58	Biowaste drain vent 2 - Train 2	Water vapour	Production Building
A3-59	Biowaste drain vent 1 - Train 3	Water vapour	Production Building

Emission Ref	Description	Type of Emission	Location
A3-60	Biowaste drain vent 1 - Train 3	Water vapour	Production Building
A3-61	Biowaste drain vent 1 - Train 4	Water vapour	Production Building
A3-62	Biowaste drain vent 2 - Train 4	Water vapour	Production Building
A3-63	Process drain vent 1 - Train 1	Water vapour	Production Building
A3-64	Process drain vent 2 - Train 1	Water vapour	Production Building
A3-65	Process drain vent 1 - Train 2	Water vapour	Production Building
A3-66	Process drain vent 2 - Train 2	Water vapour	Production Building
A3-67	Process drain vent 1 - Train 3	Water vapour	Production Building
A3-68	Process drain vent 2 - Train 3	Water vapour	Production Building
A3-69	Process drain vent 1 - Train 4	Water vapour	Production Building
A3-70	Process drain vent 1 - Train 4	Water vapour	Production Building
A3-71	Process drain vent	Water vapour	Utility Room
A3-72	Process drain vent	Water vapour	Utility Room
A3-73	Process drain vent	Water vapour	Utility Room
A3-74	Process drain vent	Water vapour	Utility Room
A3-75	Process drain vent	Water vapour	Warehouse
A3-76	Process drain vent	Water vapour	Warehouse
A3-77	Ethanol dilution vessel	Ethanol vapour	Warehouse
A3-79	Process drain vent #1	Water vapour	QC Lab Building
A3-80	Process drain vent #2	Water vapour	QC Lab Building
A3-81	QC Lab Steam Boiler (natural gas fired) Vent	NO_X, CO	QC Lab Building
A3-82	QC Lab Water Heater (natural gas fired) Vent	NO_X, CO	QC Lab Building
A3-83	QC Lab Clean Steam Generator vent	Steam	QC Lab Building

Emission Ref	Description	Type of Emission	Location
A3-84	Cooling Tower 1	Water vapour	Utility Yard
A3-85	Cooling Tower 2	Water vapour	Utility Yard
A3-86	Cooling Tower 3	Water vapour	Utility Yard
A3-87	Cooling Tower 4	Water vapour	Utility Yard
A3-88	Cooling Tower 5	Water vapour	Utility Yard
A3-89	Cooling Tower 6	Water vapour	Utility Yard
A3-90	Cooling Tower 7	Water vapour	Utility Yard
A3-93	Ethanol Storage Tank Vent	Ethanol vapour	Utility Yard
A3-94	Bulk Caustic Storage Tank Vent	Caustic vapour	Utility Yard
A3-95	Bulk CIP Acid Storage Tank Vent	Phosphoric acid/water vapour	Utility Yard
A3-96	WFI Still Generator 1 Vent	Water vapour	Utility Room
A3-97	WFI Still Generator 2 Vent	Water vapour	Utility Room
A3-98	WFI Still Generator 3 Vent	Water vapour	Utility Room
A3-99	WFI Still Generator 4 Vent	Water vapour	Utility Room
A3-100	WFI Still Generator 5 Vent	Water vapour	Utility Room
A3-101	Clean Steam Generator 1 Vent (commissioning startup)	Steam	Utility Room
A3-102	Clean Steam Generator 2 Vent (commissioning startup)	Steam	Utility Room
A3-103	Clean Steam Generator 3 Vent (commissioning startup)	Steam	Utility Room
A3-104	Boiler Deaerator 1 Vent	Water vapour	Utility Room
A3-105	Boiler Deaerator 2 Vent	Water vapour	Utility Room
A3-106	Diesel Storage Tank Vent	Diesel vapour	S-West of Production Building
A3-108	LTHW Skid Vent	Water vapour	Utility Room
A3-109	Steam Boiler #1 Burner control vent	Natural gas	Utility Room

Emission Ref	Description	Type of Emission	Location
A3-110	Steam Boiler #2 Burner control vent	Natural gas	Utility Room
A3-111	Steam Boiler #3 Burner control vent	Natural gas	Utility Room
A3-112	Steam Boiler #4 Burner control vent	Natural gas	Utility Room
A3-113	Steam Boiler #5 Burner control vent	Natural gas	Utility Room
A3-114	Process Waste Equalisation Tank #3 Vent	Water vapour	WWTP Area
A3-115	Process Waste Equalisation Tank #4 Vent	Water vapour	WWTP Area
A3-116	Process Waste Equalisation Tank #5 Vent	Water vapour	WWTP Area
A3-117	Raw Material Lab Fumehood #2 Extract	Solvent vapour	QC Lab Building
A3-118	Raw Material Lab Fumehood #3 Extract	Solvent vapour	QC Lab Building
A3-119	Raw Material Lab Fumehood #4 Extract	Solvent vapour	QC Lab Building
A3-120	Process Science Lab Fumehood Extract	Solvent vapour	QC Lab Building
A3-122	Kitchen Canopy Extract	Water vapour	Admin Building
A3-123	HPLC Lab Fumehood #1 Extract	Solvent vapour	QC Lab Building
A3-124	HPLC Lab Fumehood #2 Extract	Solvent vapour	QC Lab Building
A3-125	HPLC Lab Fumehood #3 Extract	Solvent vapour	QC Lab Building
A3-126	PCR Extraction Lab Hood#1 Extract	Solvent vapour	QC Lab Building
A3-127	PCR Extraction Lab Hood#2 Extract	Solvent vapour	QC Lab Building
A3-128	Gels Lab Fumehood #1 Extract	Solvent vapour, particulates	QC Lab Building
A3-129	Gels Lab Fumehood #2 Extract	Solvent vapour	QC Lab Building
A3-130	Raw Material Lab Fumehood #1 Extract	Solvent vapour	QC Lab Building

Fugitive and Potential Emissions

Fugitive emissions:

There are a number of bulk material storage tanks located in the utility yard. These tanks will be filled by connection to a road tanker. Some minor emissions could arise during their filling

operation. These potential fugitive emissions primarily relate to the ethanol and diesel bulk storage vessels as opposed to the less volatile bulk material storage tanks of caustic and phosphoric acid solutions. These emissions are considered to be 'fugitive' and will not give rise to negative air quality impacts off-site.

Other potential sources of fugitive emissions arising from the process, in addition to ethanol, include IPA (isopropyl alcohol) and glacial acetic acid. Small quantities of IPA will be used for filter integrity testing and the cleaning of various surfaces. Glacial acetic acid will be used for buffer solution make-up in the Buffer Prep rooms.

The plant will be designed to minimise the number of potential sources of fugitive emissions by minimising the numbers of components from which minor leakages could occur. The use of low-leak equipment (valves, pumps etc.) in the plant will significantly reduce the potential for fugitive emissions.

Potential Emissions

Potential emission points are points from which there is no emission during normal operations but emissions to atmosphere may result from equipment malfunctions or accidents. To reduce the possibility of such emissions, current GMP and international standards are used for the specification, design and construction or manufacture of plant equipment.
The potential emission points for the proposed facility consist of the following:

- *Emergency Generators* - In the event of a loss of electrical power 5 No. 2,500 kVa Emergency Generators will provide back-up power. The emissions from these diesel fired generators, when operational, will include the products of combustion, NO_2, CO , $PM_{10\,/\,2.5}$ and SO_2. These generators will only be used for emergency cover. Under normal circumstances, they will be run for short periods estimated at a maximum of 30 minutes per week, for test and maintenance purposes.
- *Fire Water Pumps* – In the event of a fire onsite these diesel supplied fire water pumps will be used. Their emissions include NOx, CO, $PM_{10/2.5}$ and $S0_2$.
- *Pressure Relief Vents from Utility Equipment and Storage Vessels - The* over-pressurisation of Utility Equipment (such as Boilers, Chillers, Clean Steam Generators and Autoclave) as well as storage vessels (Ethanol, O_2, CO2, and N2), results in the activation of their associated pressure relief device/s and a discharge of material to atmosphere. The equipment will be designed to reduce the frequency of occurrence of such over-pressurisation events to a minimum.
- *Chiller Room Extract Fan* – In the event of a leakage of refrigerant in the Chiller Room a leak detection system will activate an extract fan to dilute the workplace concentration of the refrigerant.

A summary list of these emission points to atmosphere is provided in Table E1.3.

Table E1.3 – Potential Emission Points

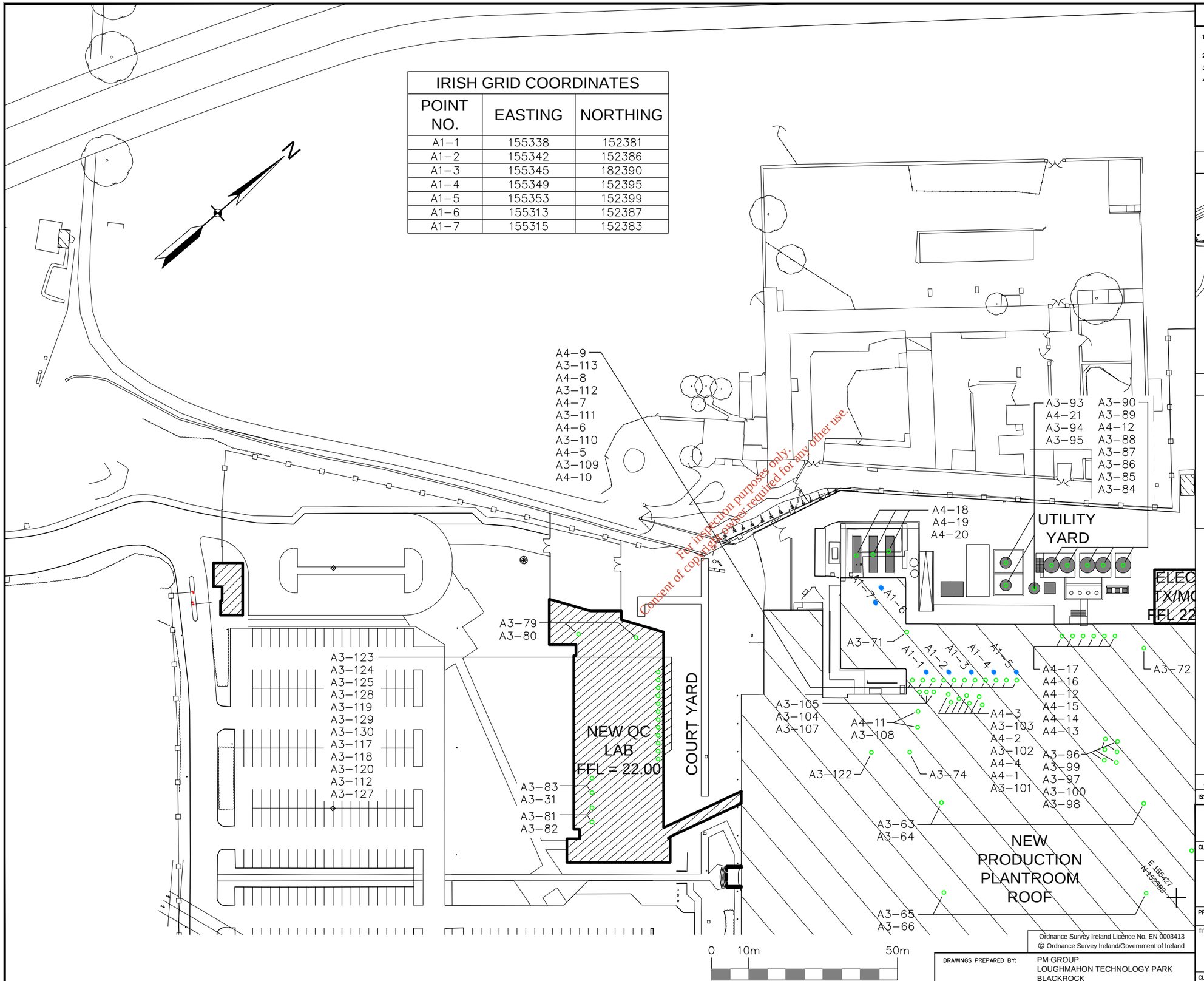
Emission Ref	Description	Type of Emission	Location
A4-1	Clean Steam Generator 1 Relief Vent	Steam/Water	Utility Room
A4-2	Clean Steam Generator 2 Relief Vent	Steam/Water	Utility Room
A4-3	Clean Steam Generator 3 Relief Vent	Steam/Water	Utility Room
A4-4	Clean Steam Distribution Relief Vents	Steam	Utility Room
A4-5	Steam Boiler No. 1 Relief Vent	Steam/Water	Utility Room
A4-6	Steam Boiler No. 2 Relief Vent	Steam/Water	Utility Room

Emission Ref	Description	Type of Emission	Location
A4-7	Steam Boiler No. 3 Relief Vent	Steam/Water	Utility Room
A4-8	Steam Boiler No. 4 Relief Vent	Steam/Water	Utility Room
A4-9	Steam Boiler No. 5 Relief Vent	Steam/Water	Utility Room
A4-10	Steam Distribution Relief Vent	Steam	Utility Room
A4-11	LTHW Skid Relief Vent	Steam/Water	Utility Room
A4-12	Chiller Room extract Vent	Refrigerant	Utility Room
A4-13	Chiller 1 Relief Vent	Refrigerant	Chiller Room
A4-14	Chiller 2 Relief Vent	Refrigerant	Chiller Room
A4-15	Chiller 3 Relief Vent	Refrigerant	Chiller Room
A4-16	Chiller 4 Relief Vent	Refrigerant	Chiller Room
A4-17	Chiller 5 Relief Vent	Refrigerant	Chiller Room
A4-18	Bulk Carbon Dioxide Storage Tank Relief Vent	CO_2	Utility Yard
A4-19	Bulk Nitrogen Storage Tank Relief Vent	N_2	Utility Yard
A4-20	Bulk Oxygen Storage Tank Relief Vent	O_2	Utility Yard
A4-21	Ethanol Storage Vessel Relief Vent	Ethanol	Utility Yard
A4-22	Decon. Autoclave Relief	Steam	Warehouse
A4-23	Emergency Generator No. 1 (Diesel)	NO_X, CO, SO_2, $PM_{10/2.5}$	South-east of Production Building
A4-24	Emergency Generator No. 2 (Diesel)	NO_X, CO, SO_2, $PM_{10/2.5}$	South-east of Production Building
A4-25	Emergency Generator No. 3 (Diesel)	NO_X, CO, SO_2, $PM_{10/2.5}$	South-east of Production Building
A4-26	Emergency Generator No. 4 (Diesel)	NO_X, CO, SO_2, $PM_{10/2.5}$	South-east of Production Building
A4-27	Emergency Generator No. 5 (Diesel)	NO_X, CO, SO_2, $PM_{10/2.5}$	South-east of Production Building
A4-29	Fire Water Pump No. 1 (Diesel)	NO_X, CO, SO_2, $PM_{10/2.5}$	South-east of Production Building

Emission Ref	Description	Type of Emission	Location
A4-30	Fire Water Pump No. 2 (Diesel)	NO_X, CO, SO_2, $PM_{10/2.5}$	South-east of Production Building
A4-31	QC Lab Clean Steam Generator Relief Vent	Steam	QC Lab Building

Drawing 4: Air Emission Points (1 of 4)

IRISH GRID COORDINATES		
POINT NO.	EASTING	NORTHING
A1–1	155338	152381
A1–2	155342	152386
A1–3	155345	182390
A1–4	155349	152395
A1–5	155353	152399
A1–6	155313	152387
A1–7	155315	152383



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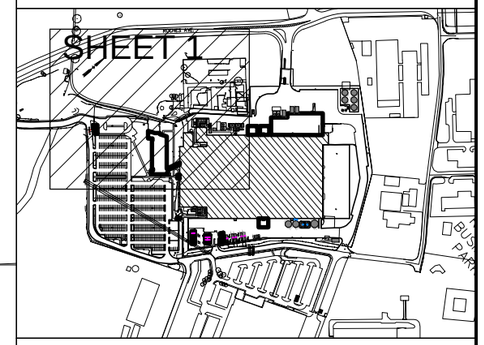
KEYPLAN



LEGEND

- MINOR EMISSION – APPROXIMATE LOCATION (REFER TO TABLE E.1(iv) OF IEAL APPLICATION FOR DESCRIPTION)
- POTENTIAL EMISSION – APPROXIMATE LOCATION (REFER TO TABLE E.1(v) OF IEAL APPLICATION FOR DESCRIPTION)
- BOILER EMISSION – IRISH GRID LOCATION (REFER TO TABLE E.1(i) OF IEAL APPLICATION FOR DESCRIPTION)

FORMAL ISSUE
20140410.091524 – CHITL

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A	FOR IEL APPLICATION	LRC	FB	TMcG	TMcG	07/04/14

REGENERON

CLIENT: REGENERON IRELAND

PM GROUP

PROJECT: BIOPHARMACEUTICAL MANUFACTURING FACILITY

TITLE: INDUSTRIAL EMISSIONS LICENCE APPLICATION
DRAWING 4: ATMOSPHERIC EMISSION POINTS
SHEET 1 OF 4

DRAWINGS PREPARED BY: PM GROUP
LOUGHMAHON TECHNOLOGY PARK
BLACKROCK
CORK

ON BEHALF OF: REGENERON IRELAND

IE0311171_22_DR_0004

CLIENT REF.		CLIENT DRG No.	
PROJECT No.	IE0311171		
A3 SCALE	1:1000	PM DRG No.	IE0311171-22-DR-0004

Drawing 5: Air Emission Points (2 of 4)

EXISTING TRUCK ENTRANCE

N

A3–50
A3–54
A3–53
A3–114
A3–115
A3–116

WASTE WATER MANAGEMENT AREA

GAS TANK YARD

A3–75
A3–77

A3–39
A3–38
A3–37

COLD & AMBIENT STORAGE

WAREHOUSE EXTENSION FFL 22.00

A3–76

ELECT. /MCC 22.00 FFL

ELECT. TX/MCC

A3–68

EXISTING WASTE MANAGEMENT YARD

72

A3–73

A3–41
A3–44
A3–42
A3–45
A3–43
A3–46

A4–22

NEW PRODUCTION PLANTROOM ROOF

A3–33
A3–34
A3–35
A3–36

A3–9
A3–55
A3–13
A3–14
A3–15
A3–29
A3–56

A3–47

A3–1
A3–5
A3–25

A3–57
A3–10
A3–16
A3–17
A3–18
A3–58
A3–30

A3–2
A3–6
A3–26

0 10m 50m

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NOTES

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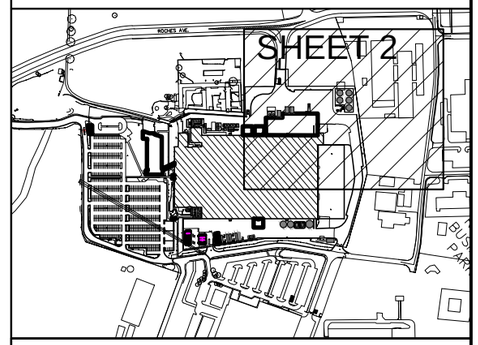
KEYPLAN



LEGEND

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- POTENTIAL EMISSION – APPROXIMATE LOCATION (REFER TO TABLE E.1(v) OF IEAL APPLICATION FOR DESCRIPTION)
- BOILER EMISSION – IRISH GRID LOCATION (REFER TO TABLE E.1(i) OF IEAL APPLICATION FOR DESCRIPTION)

FORMAL ISSUE
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REGENERON

CLIENT: REGENERON IRELAND

PM GROUP

PROJECT: BIOPHARMACEUTICAL MANUFACTURING FACILITY

TITLE: INDUSTRIAL EMISSIONS LICENCE APPLICATION
DRAWING 5: ATMOSPHERIC EMISSION POINTS
SHEET 2 OF 4

DRAWINGS PREPARED BY: PM GROUP
LOUGHMAHON TECHNOLOGY PARK
BLACKROCK
CORK

ON BEHALF OF: REGENERON IRELAND

IE0311171_22_DR_0005

CLIENT REF.

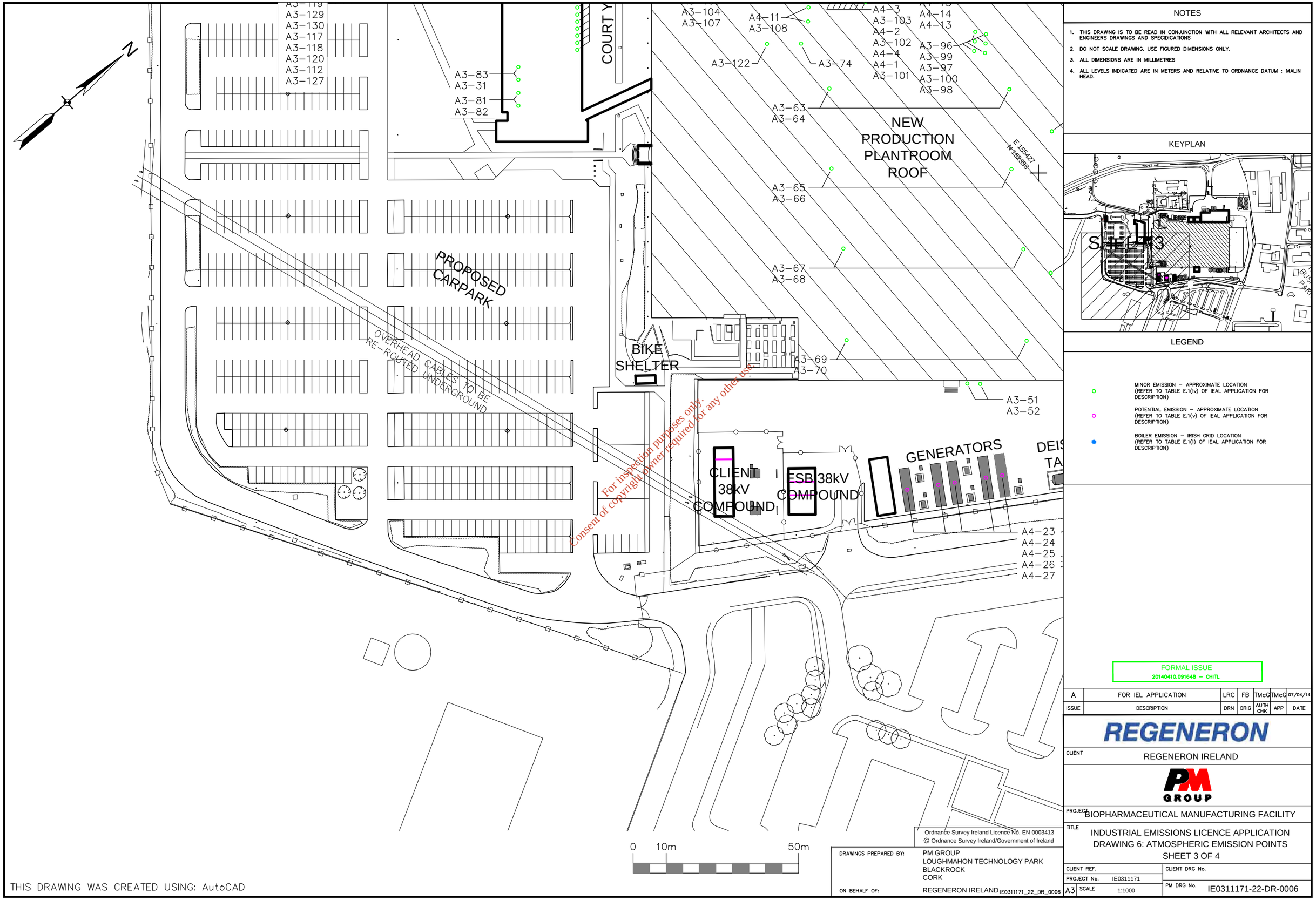
PROJECT No. IE0311171

A3 SCALE 1:1000

CLIENT DRG No.

PM DRG No. IE0311171-22-DR-0005

Drawing 6: Air Emission Points (3 of 4)



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KEYPLAN

LEGEND

- MINOR EMISSION – APPROXIMATE LOCATION (REFER TO TABLE E.1(iv) OF IEAL APPLICATION FOR DESCRIPTION)
- POTENTIAL EMISSION – APPROXIMATE LOCATION (REFER TO TABLE E.1(v) OF IEAL APPLICATION FOR DESCRIPTION)
- BOILER EMISSION – IRISH GRID LOCATION (REFER TO TABLE E.1(i) OF IEAL APPLICATION FOR DESCRIPTION)

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REGENERON

CLIENT: REGENERON IRELAND

PM GROUP

PROJECT: BIOPHARMACEUTICAL MANUFACTURING FACILITY

TITLE: INDUSTRIAL EMISSIONS LICENCE APPLICATION
DRAWING 6: ATMOSPHERIC EMISSION POINTS
SHEET 3 OF 4

DRAWINGS PREPARED BY: PM GROUP
LOUGHMAHON TECHNOLOGY PARK
BLACKROCK
CORK

ON BEHALF OF: REGENERON IRELAND

IE0311171_22_DR_0006

CLIENT REF.

CLIENT DRG No.

PROJECT No. IE0311171

A3 SCALE 1:1000

PM DRG No. IE0311171-22-DR-0006

Drawing 7: Air Emission Points (4 of 4)

A3–33
A3–34
A3–35
A3–36

A3–9
A3–55
A3–13
A3–14
A3–15
A3–29
A3–56

A3–47

A3–1
A3–5
A3–25

A3–57
A3–10
A3–16
A3–17
A3–18
A3–58
A3–30

A3–2
A3–6
A3–26

A3–59
A3–11
A3–19
A3–20
A3–21
A3–31
A3–60

A3–3
A3–7
A3–27

A3–61
A3–12
A3–22
A3–23
A3–24
A3–62
A3–32

A3–4
A3–8
A3–28

A3–48
A3–49

A4–29
A4–30

PROCESS WATER TANKS

PUMP HOUSE

FIRE WATER TANK

DEISAL TANK

A3–106

23
24
25
26
27

N

0 10m 50m

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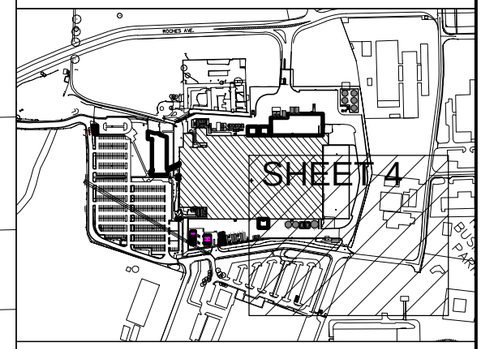
KEYPLAN



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- POTENTIAL EMISSION – APPROXIMATE LOCATION (REFER TO TABLE E.1(v) OF IEAL APPLICATION FOR DESCRIPTION)
- BOILER EMISSION – IRISH GRID LOCATION (REFER TO TABLE E.1(I) OF IEAL APPLICATION FOR DESCRIPTION)

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REGENERON

CLIENT: REGENERON IRELAND

PM GROUP

PROJECT: BIOPHARMACEUTICAL MANUFACTURING FACILITY

TITLE: INDUSTRIAL EMISSIONS LICENCE APPLICATION
DRAWING 7: ATMOSPHERIC EMISSION POINTS
SHEET 4 OF 4

DRAWINGS PREPARED BY: PM GROUP
LOUGHMAHON TECHNOLOGY PARK
BLACKROCK
CORK

ON BEHALF OF: REGENERON IRELAND

IE0311171_22_DR_0007

CLIENT REF.		CLIENT DRG No.	
PROJECT No.	IE0311171		
A3 SCALE	1:1000	PM DRG No.	IE0311171-22-DR-0007

Attachment E.3: Emissions to Sewer

E.3 Emissions to Sewer

It is proposed that trade effluent from the facility will receive preliminary treatment on-site, prior to discharging to the Shannon Development foul sewer within Raheen Business Park, which ultimately connects to Irish Water's public foul sewer serving Limerick City and Environs.

This emission point is referred to as SE1

It is proposed that uncontaminated storm water run-off from the facility will discharge to the Shannon Development storm water sewer serving the Raheen Business Park, which ultimately drains via the Barnakyle stream to the River Shannon.

This emission point is referred to as SE2.

There will be no List I or List II substances, as listed in the Annex to EU Directive 2006/11/EC (as amended) contained in any emission to sewer from the site.

Drawing 8: Sewer Emission Points includes details of the locations of emission points SE1 and SE2, and all associated underground drainage networks within the site.

Table E.3 (i) and E.3 (ii) have been completed in full.

Sources of Effluent at the Site (to SE1)

Waste water generated from the proposed development will arise from a number of sources, namely process/manufacturing, labs, utilities and sanitary. As shown in Figure E.3.1 below it is proposed that process waste waters (non-sanitary) arising from the proposed development will undergo preliminary treatment on-site which will render the waste water amenable for discharge to the local municipal sewer and subsequent downstream treatment at the Limerick City & Environs Waste Water Treatment Plant (WWTP) in Bunlicky which discharges into the River Shannon estuary. Figure E.3.2 shows (schematically) the route of waste water from the site.

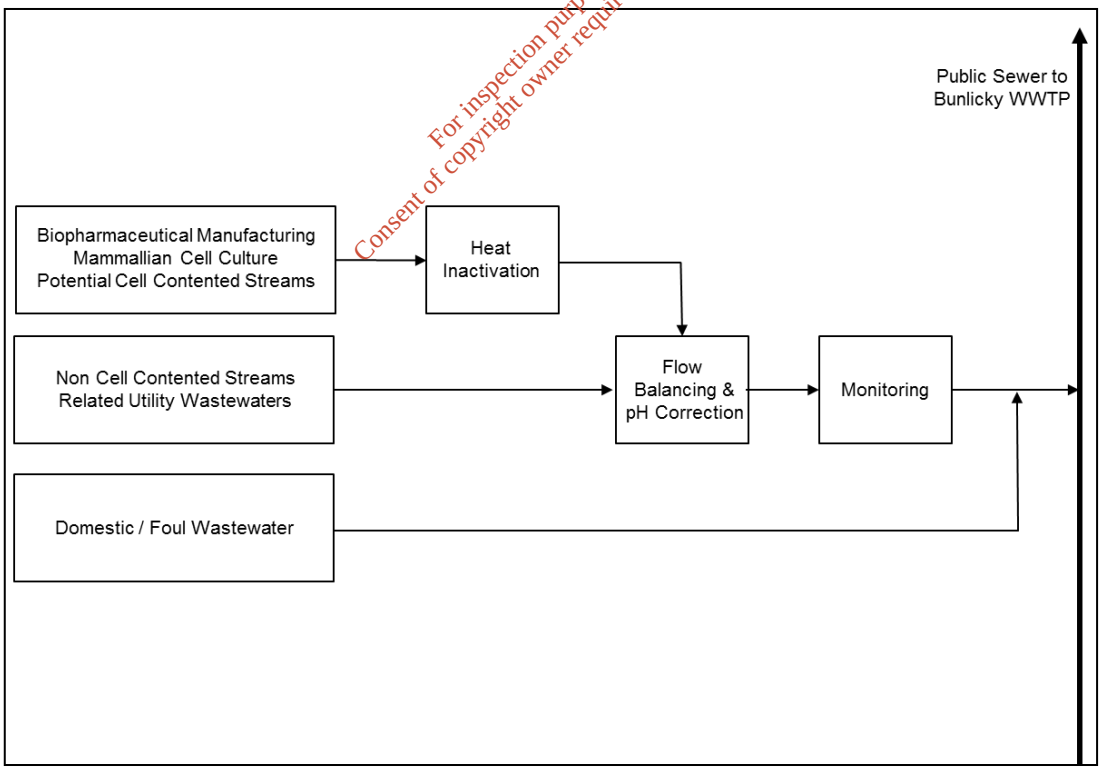


Figure E.3.1 *Sources of Waste Water*

Figure E.3.2 *Sources of Waste Water*

Storm Water Run-Off (to SE2)

It is proposed to continue to use current arrangements for discharge storm water run-off from the proposed development. Storm water from the site arises from run-off from buildings, car-parks, road-ways, service yards and other developed areas of the site which discharge via a petrol interceptor to the main Raheen Business Park storm water system. The storm water discharge from the Raheen Business Park exits the estate and follows the route of a culvert and pipe to Loughmore Common canal, which enters the Barnakyle River, which in turn flows into the Maigue River, which ultimately discharges to the River Shannon Estuary.

Bunlicky Waste Water Treatment Plant

The Limerick City and Environs Waste Water Treatment Plant at Bunlicky and the main lift pumping station at Corcanree together with some 45 kilometres of large diameter interceptor sewers were constructed to meet the requirements of the EU Directive on Urban Waste Water Treatment and to ensure compliance with the Shannon Estuary Water Quality Management Plan. The Waste Water Treatment Plant has a design capacity of 130,000 population equivalents (PE).

The first stage in the treatment process is preliminary treatment which involves the screening and removal of inorganic material, debris, large solids and grit. These materials are then washed and compacted before disposal to licensed landfill.

Preliminary treatment is followed by primary treatment, a settlement process to separate the solid material from the waste water. The solids are removed for further treatment within the adjacent sludge treatment installation.

The “settled” waste water is transferred for secondary or aerobic biological treatment in the aeration tanks. In the oxygen-rich environment of the aeration tanks micro-organisms absorb and breakdown the organic material in the incoming settled sewage. An anoxic and an aerobic zone together with an internal recirculation flow system, to facilitate the operation of a de-nitrification regime (for the removal of nitrogen), are provided in each aeration tank.

After a number of hours the resultant mixture, which is rich in living organisms, is transferred on to a secondary settlement process where the biomass (the living organisms) is separated

from the treated waste water and returned to the biological phase to sustain the process. The treated waste water, which now meets the standards required by the EU Urban Waste Water Treatment Directive, and is in compliance with the Shannon Estuary Water Quality Management Plan, is discharged to the Shannon Estuary through a 1.1 kilometre outfall.

The sludge produced in the primary treatment and biological phases of the process are forwarded to the adjacent sludge treatment installation for thermal drying.

The plant is licensed by the EPA (Reg. No. D0013-01) and is operated by a private contractor on behalf of Irish Water.

Characteristics of the Site Waste Water

Table E.3 (ii) in the application outlines the expected characteristics of the emissions to sewer from the facility as SE1, following on-site collection, management, and preliminary treatment.

Waste water will be generated as part of the proposed Biopharmaceutical Manufacturing Facility development at the former Dell EMF3 plant in Raheen, Limerick. Effluent will arise from a number of sources, namely the new process/manufacturing operations, labs, utilities and sanitary. The project is expected to develop in 2 phases:

Phase 1: 2 No. production lines and associated utilities

Phase 2: 2 No. additional production lines and associated utilities

It is planned that effluent arising from the development will undergo preliminary treatment on site, designed and sized to initially accommodate Phase I effluent only, before discharge to the municipal sewer. The on-site waste water management facility will be designed to allow for modular expansion for Phase II effluent and will include the following operations;

- Heat inactivation of streams potentially containing cells from the process (biowaste)
- Balancing and neutralisation of all process waste waters
- Cooling, odour management and monitoring

The biotechnology processes to be used at the Regeneron facility will generate a range of aqueous waste streams containing biodegradable organic components and nutrients. The utility equipment that will be provided at the facility to support the production process will also generate aqueous streams containing low levels of biodegradable organics. Sanitary waste water (sewage) will also arise due to approximately 300 full-time staff which ultimately could be employed at the facility.

The majority of waste water arising from the facility will be generated in the production areas, and in particular from the waters associated with vessel cleaning.

Description of the Proposed On-Site Waste Water Management System

A Process Flow Diagram describing the operation of the proposed on-site Waste Water Management System is provided in Drawing 9: Wastewater Process Flow Diagram.

The proposed on-site waste water management system will provide preliminary treatment to the process/trade effluent only and will consist of the following component treatment steps:

- Heat Inactivation (biowaste or cell-contented waste only)
- Waste Water Balancing
- Cooling
- Neutralisation
- Odour Control
- Monitoring

Note: Sanitary effluent from the facility (from lockers, toilets and canteen) will combine with the process effluent downstream of the Waste Water Management System prior to entering the Shannon Development foul sewer in Raheen Business Park.

Heat Inactivation

Biowaste, defined as liquid process waste that could contain live cells, will be collected from the Cell Culture and Harvest areas of each of the four production trains in under slab drain piping and flow by gravity through a sump and pumped to the Biowaste Treatment Area. Biowaste will be held in the Biowaste Hold Tank, and then will be fed to the inactivation system. The Hold Tank is intended to provide enough retention capacity to temporarily store an off-spec bioreactor batch and allow production to continue on a temporary basis.

The biowaste will be processed through the inactivation system, designed to heat treat the waste at 120^{o}C which will kill any live cells that may be present. Direct steam injection will be used to heat the biowaste in the steam jet. Downstream of the steam jet, the retention tube will insure that the biowaste is kept at elevated temperature for a long enough period to kill any organisms i.e. two minutes contact time. The system will operate continuously to heat up and cool down the waste as opposed to using a batch type system.

A stand-by inactivation treatment system will be provided to allow the primary system to be taken offline without stopping production. Phase 2 expansion will include installation of a second Hold Tank and a third biowaste inactivation system.

Post-treatment cooling will be provided to minimise steam consumption and cool the treated waste to a safe level for recombining with other process waste at the downstream Waste Water Balancing and Neutralisation System.

Waste Water Balancing

The main purpose of the balance tank system is to provide buffering capacity to smooth out variations in the flow and pollution loads. This will allow a uniform discharge to the public sewer, and provide natural buffering to pH fluctuations allowing the effluent feed to the downstream neutralisation stage to remain steady.

An additional buffer tank will also be provided to cater for periods of peak load or abnormal concentration requiring retention. Peak loads can be diverted to the buffer tank away from the balance tank and bled back into the system over time allowing for a more uniform treatment and discharge profile.

Overall, up to 5 No. tanks are envisaged, each of approximately 375m^{3} capacity, to cater for the Phase 1 and Phase 2 projected load profile for the facility.

Cooling

Process effluent from the production facility will be at elevated temperatures due to the thermal deactivation of production wastes and the potential use of high temperature utilities such as Water for Injection (WFI). Discharge permit conditions are likely to restrict effluent temperature to a maximum of 40^{o}C; therefore it may be necessary to reduce effluent temperature.

Cooling will naturally occur during effluent transfer and equalisation. Air cooled heat exchangers are also envisaged.

Neutralisation

The pH control will be achieved utilising inline dosing, with a PLC controlled chemical dosing system (acid and caustic). There will be upstream and downstream pH sensors installed allowing for effective pH adjustment. The recirculation loop will be provided downstream monitoring point to reverse wastewater back to the balancing tanks if the quality of discharge wastewater does not comply with the requirements.

Odour Control

Under normal circumstances it is not expected that odours will arise from the waste water management system. However, given the organic nature of the process effluent, the formation of odours cannot be excluded at this stage. Following initial monitoring of the plant, in the event of odour arising, an odour treatment package, comprising a carbon filter bed will be installed as part of the plant.

Monitoring

The following parameters will require continuous monitoring at SE1:

- Flow
- Temperature
- pH

A 24 hour proportional flow composite sampler, with refrigeration, will also be installed.

Drawing 8: Sewer Emission Points

N

ROCHES AVE.

EXISTING CONNECTIONS TO SHANNON DEVELOPMENT FOUL SEWER

SE-01

SHANNON DEVELOPMENT SURFACE WATER DRAIN

SHANNON DEVELOPMENT FOUL DRAIN

E 155409
N 152405

PROPOSED CARPARK

EXISTING CONNECTION TO SHANNON DEVELOPMENT SURFACE WATER SEWER

EXISTING PETROL INTERCEPTOR

FOUL PUMPING STATION

SE-02

0 20m 100m

THIS DRAWING WAS CREATED USING: AutoCAD

NOTES

1. THIS DRAWING IS TO BE READ IN CONJUNCTION WITH ALL RELEVANT ARCHITECTS AND ENGINEERS DRAWINGS AND SPECIDICATIONS
2. DO NOT SCALE DRAWING. USE FIGURED DIMENSIONS ONLY.
3. ALL DIMENSIONS ARE IN MILLIMETRES
4. ALL LEVELS INDICATED ARE IN METERS AND RELATIVE TO ORDNANCE DATUM : MALIN HEAD.

LEGEND

- PROPOSED PROCESS (TRADE EFFLUENT) DRAIN
- EXISTING SURFACE WATER DRAIN
- PROPOSED SURFACE WATER DRAIN
- EXISTING FOUL WATER DRAIN
- PROPOSED FOUL WATER DRAIN
- SEWER EMISSION POINT
- PROPOSED BUILDING
- PROPOSED EQUIPMENT

FORMAL ISSUE
20140410.092027 – CHITL

ISSUE	DESCRIPTION	DRN	ORIG	AUTH CHK	APP	DATE
A	FOR IEL APPLICATION	LRC	BT	TMcG	TMcG	07/04/14

REGENERON

CLIENT: REGENERON IRELAND

PM GROUP

PROJECT: BIOPHARMACEUTICAL MANUFACTURING FACILITY

TITLE: INDUSTRIAL EMISSIONS LICENCE APPLICATION
DRAWING 8:
SEWER EMISSION POINTS

DRAWINGS PREPARED BY: PM GROUP
LOUGHMAHON TECHNOLOGY PARK
BLACKROCK
CORK

ON BEHALF OF: REGENERON IRELAND

IE0311171_22_DR_0008

CLIENT REF.

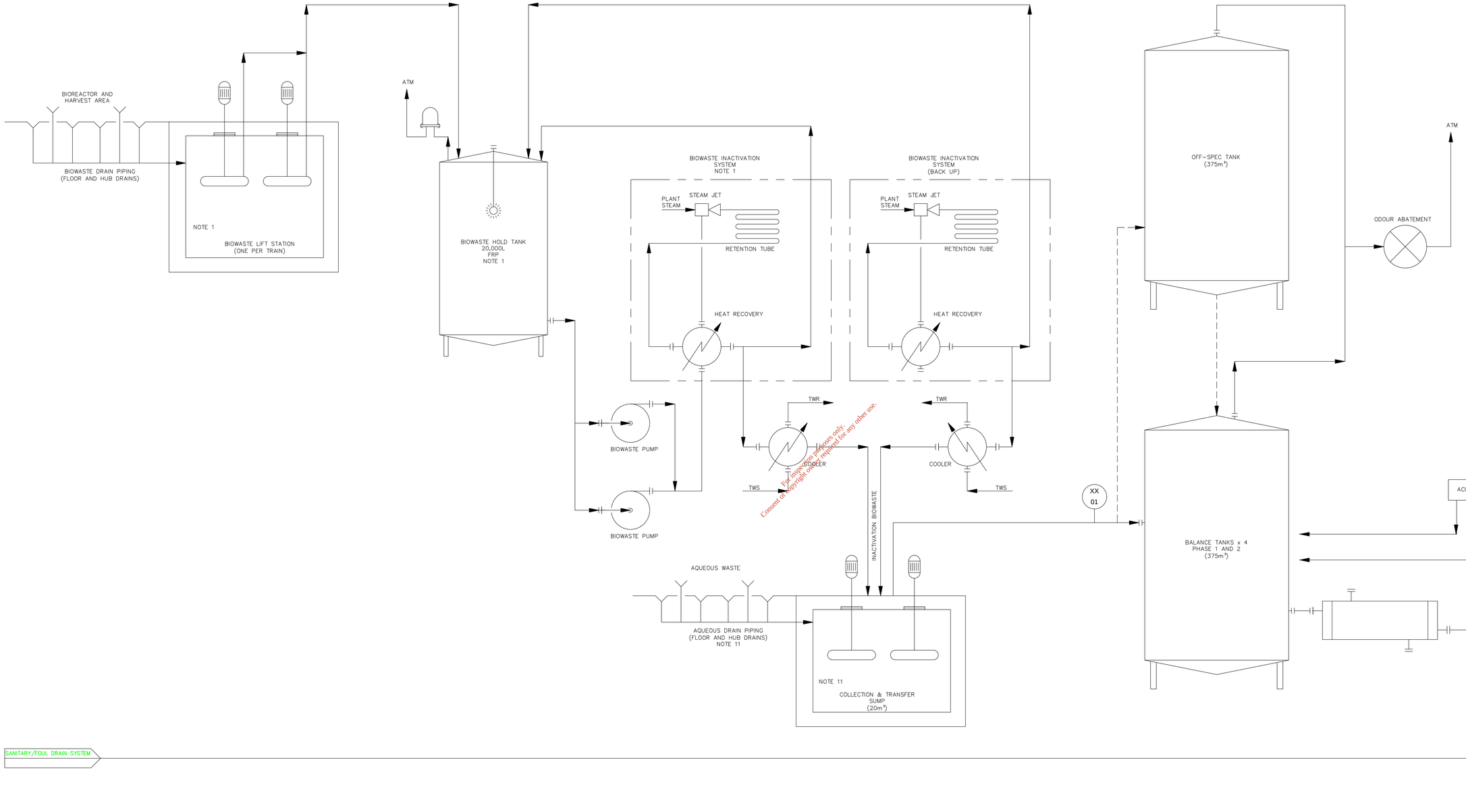
PROJECT No. IE0311171

A3 SCALE 1:2000

CLIENT DRG No.

PM DRG No. IE0311171-22-DR-0008

Drawing 9: Wastewater Process Flow Diagram



NOTES

1. THIS BIOWASTE INACTIVIATION SYSTEM IS INTENDED TO PROCESS THE BIOWASTE FROM TRAINS 1 & 2 (ONE 20,000L SURGE TANK, ONE ACTIVATION SYSTEM, ONE BACK UP INACTIVATION SYSTEM). IN THE FUTURE A SECOND 20,000L SURGE TANK AND A THIRD INACTIVATION SYSTEM WILL BE ADDED TO PROCESS THE BIOWASTE FROM FUTURE TRAINS 3 & 4.
2. PH WILL BE MONITORED PRIOR TO DISCHARGE TO EXISTING LOCAL SEWER SYSTEM.
3. WASTE WATER WILL BE COOLED TO TEMPERATURE BELOW DISCHARGE LIMITS.
4. EFFLUENT TRANSFER FROM PRODUCTION LINE SUMPS (x4) TO WWTP COLLECTION SUMP.
5. EFFLUENT TRANSFER FROM HEAT INACTIVATION SYSTEM TO WWTP COLLECTION SUMP. ONE LINE PER PHASE (TBC).
6. FOUR NUMBER BALANCE TANKS PROPSED (2 PER PHASE) YIELDING A HRT OF 24hrs BASED ON TYPICAL DAILY FLOWS.
7. DIVERT TO 375m³ CALAMITY TANK FOR OFF-SPEC FLOWS ALLOWING BLEED BACK OVER TIME.
8. pH CORRECTION SYSTEM TO BE CONFIRMED AT DETAILED DESIGN. TWO STAGE ALLOWED FOR GIVING FINE ADJUSTMENT POST BALANCING IF REQUIRED.
9. HEAT EXCHANGE ONLY IF REQUIRED (TBC).
10. TANKAGE TO BE COVERED WITH ALLOWANCE FOR VENTING TO ODOUR ABATEMENT SYSTEM IF REQUIRED.
11. 3 NUMBER AQUEOUS DRAIN SUMPS AROUND BUILDING.
12. CONTINUOUS MONITORING OF FLOW, pH AND TEMPERATURE. FLOW PROPORTIONATE COMPOSITE SAMPLER FOR 24 HOUR COMPOSITE SAMPLING.

FORMAL ISSUE
20140410.092059 – CHITL

PM PROJECT No.	PM DRG No.
IE0311171	IE0311171-22-DR-0011

PM GROUP

Rev #	Date:	Description	Drawn By:	Orig	Auth	App
A	07/04/14	FOR IEL APPLICATION	CMcC	BMcD	TMcG	TMcG
-						
-						
-						
-						
-						
-						

REGENERON
Regeneron Pharmaceuticals, Inc.
81 Columbia Turnpike
Rensselaer, NY 12144

INDUSTRIAL EMISSIONS LICENCE APPLICATION
DRAWING 9:
WASTEWATER PROCESS FLOW DIAGRAM

Drawing No. **IE0311171-22-DR-0009**
Old Drawing No.

Scale: NTS | Bldg.: | File No.: **IE0311171-22-DR-0009** | Date: 13.03.14 | Revision: **A** | Sheet: 1 of 1

Attachment E.5: Noise Emissions

E.5 Noise Emissions

The main sources of noise have been identified in Table E.5 (i) of this application and are shown in Drawing 10: Noise Emission Sources. In line with the attached EIS and Attachment I.7 of this application, noise attributable solely to onsite activities shall not exceed the below criteria:

- Daytime (07:00 to 19:00hrs): 55dB LAr,T;
- Evening time (19:00 to 23:00hrs): 50dB LAr,T;
- Night time (23:00 to 07:00hrs): 45dB LAeq,T.

The nearest noise sensitive locations to the Regeneron facility are shown in Drawing 11: Noise Sensitive Locations. NSL1 (Noise Sensitive Location 1) is an individual residential dwelling on the northern side of the R526 road to the north-west of the site, located 610 metres from the site. NSL2 is a residential area on the Ballycummin Road, located ca. 400 metres to the north/north-east of the site.

Operational Noise Emissions

There will be a number of noise generating equipment and activities associated with the operation of the proposed development. Any noise from production and utilities equipment located inside/within the site buildings will be mitigated by both equipment design and/or the building structure to prevent any external noise impact.

There will be a number of externally located utilities equipment which could potentially impact on ambient noise levels which includes the following:

Major Noise Sources

- 5 No. Cooling Towers located in utility yard on western side of site
- 5 No. Cooling Tower Pumps located in utility yard on western side of site
- 3 No. HVAC Chillers located in utility yard on western side of site
- 10 No. Condensors for low temperature storage on Warehouse Extension Roof
- 10 No. Condensors for low temperature storage/incubators on QC Lab Roof

Minor Noise Sources

- 2 No. Electric Process Water Pumps located in Pump-house on north-eastern side of site (no significant noise from electric pumps anticipated external to pump house)
- 2 No. Diesel Fired Firewater Pumps located in Pump-house on north-eastern side of site (Emergency Use Only)
- 5 No. Diesel Fired Emergency Generators located on eastern side of site (Emergency Use Only)

No significant noise is anticipated from the process water pump-house and with respect to the emergency equipment listed above (i.e. firewater pumps and emergency generators), this equipment was not included in the noise model, because other than for testing purposes (ca. 15-20 minutes testing per week during daytime hours only), this equipment will only be run during emergency situations. The firewater pumps will be located in a pump-house which will attenuate noise from the pumps, and the emergency generators will incorporate acoustic enclosures/sound insulation material to attenuate noise. Therefore noise from this emergency equipment is not considered normal operational noise for the purposes of this assessment.

For the purposes of the impact assessment, vendor noise source data was available for the majority of the equipment listed above. Where vendor data was not yet available, sound power levels were estimated for the equipment based on design data for similar equipment.

Where required construction materials and cladding for the buildings housing noise generating plant and equipment will have an appropriate Sound Reduction Index (SRI).

Based on the existing noise levels and noise impact assessment (as detailed in Attachment I of this application) it is predicated that the additional noise contribution from the facility will not cause a significant negative impact at the nearest noise sensitive locations.

The minimisation of noise will form an integral part of the detailed design. The various noise control and attenuation measures to be employed at the plant can be summarised as follows:

- As part of the detailed design and tendering process, stringent noise level criteria will be specified for all plant and equipment;
- Acoustic insulation / enclosures and attenuation will be provided on plant and equipment as necessary;
- Plant and equipment will be maintained and serviced on a maintenance schedule;
- Site access roads will be of smooth hard standing surface to reduce vehicular noise.

Other Noise Emissions

Most significant sources of plant noise during the operational phase will be located within the main building, i.e. air handling units. There will be a roof mounted chiller installed at the facility. The other sources of noise emissions associated with the proposed development are construction phase noise and site traffic, as described below.

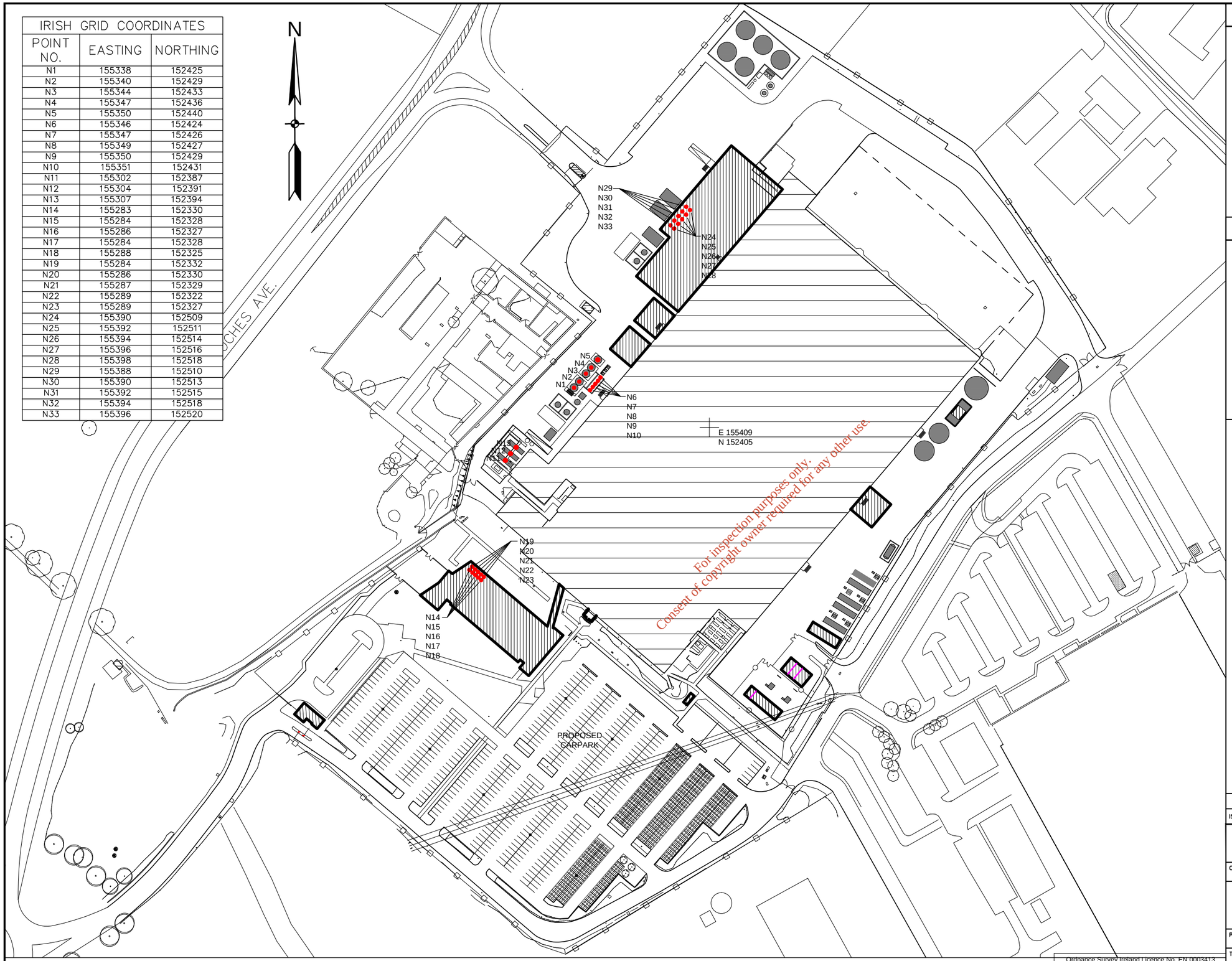
Construction Phase Noise

An assessment of noise generated during construction of the facility was completed as part of the EIS (Section 8.5.1 of EIS – Attachment B.6 of this application). In summary, construction noise will be generated for a limited period during the construction phase.

The level of construction noise during the daytime will be minimised as much as practicable to limit the impact on ambient noise levels and noise sensitive receptors (e.g. residential dwellings) in the vicinity.

Drawing 10: Noise Emission Sources

IRISH GRID COORDINATES		
POINT NO.	EASTING	NORTHING
N1	155338	152425
N2	155340	152429
N3	155344	152433
N4	155347	152436
N5	155350	152440
N6	155346	152424
N7	155347	152426
N8	155349	152427
N9	155350	152429
N10	155351	152431
N11	155302	152387
N12	155304	152391
N13	155307	152394
N14	155283	152330
N15	155284	152328
N16	155286	152327
N17	155284	152328
N18	155288	152325
N19	155284	152332
N20	155286	152330
N21	155287	152329
N22	155289	152322
N23	155289	152327
N24	155390	152509
N25	155392	152511
N26	155394	152514
N27	155396	152516
N28	155398	152518
N29	155388	152510
N30	155390	152513
N31	155392	152515
N32	155394	152518
N33	155396	152520



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NOTES

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LEGEND

PROPOSED BUILDING

PROPOSED EQUIPMENT

N1. NOISE SOURCE

NOISE SOURCES

N1-N5:	COOLING TOWERS
N6-N10:	COOLING TOWER PUMPS
N11-N13:	CHILLERS
N14-N23:	CONDENSERS (LAB ROOF).
N24-N33:	CONDENSERS (WAREHOUSE EXTENTION).

FORMAL ISSUE
20140410.092136 – CHITL

ISSUE	DESCRIPTION	DRN	ORIG	AUTH CHK	APP	DATE
A	FOR IEL APPLICATION	LRC	BT	TMcG	TMcG	07/04/14

DRAWINGS PREPARED BY: PM GROUP
LOUGHMAHON TECHNOLOGY PARK
BLACKROCK
CORK

ON BEHALF OF: REGENERON IRELAND IE0311171_22_DR_0010

REGENERON

CLIENT: REGENERON IRELAND

PM GROUP

PROJECT: BIOPHARMACEUTICAL MANUFACTURING FACILITY

TITLE: INDUSTRIAL EMISSIONS LICENCE APPLICATION
DRAWING 10:
NOISE EMISSION SOURCES

CLIENT REF.	CLIENT DRG No.
PROJECT No. IE0311171	PM DRG No. IE0311171-22-DR-0010
A3 SCALE 1:2000	

Drawing 11: Noise Sensitive Locations

REGENERON	Drawing 11 – *Noise Sensitive Locations*		PM GROUP
	Environmental Impact Statement, Raheen Business Park, Limerick – Regeneron Ireland		
	Project No.: IE0311171	Doc No.: IE0311171-22-RP-0006	April 2014

Attachment E.6: Tabular Data on Emission Points

Attachment E6: Tabular Data on Emission Points

Point Code	Point Type	Easting	Northing	Verified	Emission
A1-1	A	155338	152381	N	NOx, CO
A1-2	A	155342	152386	N	NOx, CO
A1-3	A	155345	152390	N	NOx, CO
A1-4	A	155349	152395	N	NOx, CO
A1-5	A	155353	152399	N	NOx, CO
A1-6	A	155313	152387	N	NOx, CO
A1-7	A	155315	152383	N	NOx, CO
SE1	SE	155555	152519	N	Wastewater
SE2	SE	155058	152181	N	Storm Water
N1	N	155338	152425	N	Noise
N2	N	155340	152429	N	Noise
N3	N	155344	152433	N	Noise
N4	N	155347	152436	N	Noise
N5	N	155350	152440	N	Noise
N6	N	155346	152424	N	Noise
N7	N	155347	152426	N	Noise
N8	N	155349	152427	N	Noise
N9	N	155350	152429	N	Noise
N10	N	155351	152431	N	Noise
N11	N	155302	152387	N	Noise
N12	N	155304	152391	N	Noise
N13	N	155307	152394	N	Noise
N14	N	155283	152330	N	Noise
N15	N	155284	152328	N	Noise
N16	N	155286	152327	N	Noise
N17	N	155284	152328	N	Noise
N18	N	155288	152325	N	Noise
N19	N	155284	152332	N	Noise
N20	N	155286	152330	N	Noise
N21	N	155287	152329	N	Noise
N22	N	155289	152322	N	Noise
N23	N	155289	152327	N	Noise
N24	N	155390	152509	N	Noise
N25	N	155392	152511	N	Noise
N26	N	155394	152514	N	Noise
N27	N	155396	152516	N	Noise
N28	N	155398	152518	N	Noise
N29	N	155388	152510	N	Noise
N30	N	155390	152513	N	Noise
N31	N	155392	152515	N	Noise
N32	N	155394	152518	N	Noise
N33	N	155396	152520	N	Noise

Section F Attachments/Drawing

Attachment F.1: Treatment, Abatement and Control Systems

Attachment F.2: Emissions Monitoring and Sampling Points

Drawing 12: On-site Monitoring/Sampling Locations

Attachment F.3: Tabular Data on Monitoring and Sampling Points

Attachment F.1: Treatment, Abatement and Control Systems

F.1 Treatment, Abatement and Control Systems

There are a range of abatement and control techniques proposed for treating emissions to atmosphere, emissions to sewer, stormwater and noise. Each is summarised below and additional details, together with technical specifications, are also provided in this attachment.

Emissions to Air

The abatement and control systems to be implemented for the operational phase of the proposed facility can be summarised as follows:

Boiler Emissions

The proposed facility will consist of 5 No. 7.9 MW boilers located in the Boiler Room and 2 No. 1.8 MW boilers located in the Utility yard, all of which will be naturally gas-fired. The emissions from these boilers will include the products of combustion, oxides of nitrogen (NO_x) and carbon monoxide (CO). Given that they are fired by natural gas, particulate ($PM_{10/2.5}$) and sulphur dioxide (SO_2) emissions will be negligible.

Each boiler will be designed for low NOx emissions (NOx emission concentration less than 80 mg/Nm^3 dry basis, 3% 02). The low NOx emission design will be achieved through fuel-air ratio control.

Emergency Generator System

In the event of a loss of electrical power 5 No. 2,500 kVa Emergency Generators will provide back-up power. The emissions from these diesel fired generators, when operational will include the products of combustion, NO_2, CO, $PM_{10\,/\,2.5}$ and SO_2. These generators will only be used for emergency cover. Under normal circumstances it will be run for short periods estimated at a maximum of 30 minutes per week, for test and maintenance purposes.

Process Emissions

- Cell Culture Equipment:

  Each of the 4 No. Biologics Safety Cabinets (one for each train) will be fitted with a HEPA (high efficiency particulate air) filter.

  All the cell culture vessels (wave reactors, seed bioreactors and production bioreactors) will be fitted with a sterile filter (0.2µm) preventing particles and GMM greater than 0.2 um from exiting the vent lines.

- Harvest & Biowaste Vessels:

  Each of the 4 No. Harvest vessels (one for each train) will be fitted with a 0.2µm vent filter. Similarly the vents from the 2 No. Biowaste sumps and the Biowaste Equalisation vessel will be fitted with 0.2µm filter.

- Material Sampling/Dispensing:

  Operations involving solids will be carried out on a small scale manual basis in dispensing booths. Each dispensing booth (6 No.) will be equipped with HEPA filters.

  Any dust generated during the sampling of powders will be contained through the use of a fume hood equipped with a dust filter.

- Ethanol storage vessel:

  The 25,000 litre ethanol storage vessel in the Utility yard will have a conservation vent and blanketed with nitrogen to minimise the release of ethanol to the atmosphere.

QC Lab Emissions

Minor fugitive VOC emissions may also arise from some of the QC laboratory activities. The levels of VOC fugitive emissions will be very minor. As such, no particular abatement technology will be required.

Small scale manual powder handing activities will take place in one of the Gel Lab fumehoods which will be fitted with a HEPA to prevent the release of particulates.

Emissions to Sewer

The proposed on-site waste water management system will provide preliminary treatment to the process/trade effluent only and will consist of the following component treatment steps:

- Heat Inactivation (biowaste or cell-contented waste only)
- Waste Water Balancing
- Cooling
- Neutralisation

Note: Sanitary effluent from the facility (from lockers, toilets and canteen) will combine with the process effluent downstream of the Waste Water Management System prior to entering the Shannon Development foul sewer in Raheen Business Park.

A Process Flow Diagram describing the operation of the proposed on-site Waste Water Management System is provided in Drawing 9: Wastewater Process Flow Diagram.

Heat Inactivation

Biowaste, defined as liquid process waste that could contain live cells, will be collected from the Cell Culture and Harvest areas of each of the four production trains in under slab drain piping and flow by gravity through a sump and pumped to the Biowaste Treatment Area. Biowaste will be held in the Biowaste Hold Tank, and then will be fed to the inactivation system. The Hold Tank is intended to provide enough retention capacity to temporarily store an off-spec bioreactor batch and allow production to continue on a temporary basis.

The biowaste will be processed through the inactivation system, designed to heat treat the waste at 120°C which will kill any live cells that may be present. Direct steam injection will be used to heat the biowaste in the steam jet. Downstream of the steam jet, the retention tube will insure that the biowaste is kept at elevated temperature for a long enough period to kill any organisms i.e. two minutes contact time. The system will operate continuously to heat up and cool down the waste as opposed to using a batch type system.

A stand-by inactivation treatment system will be provided to allow the primary system to be taken offline without stopping production. Phase 2 expansion will include installation of a second Hold Tank and a third biowaste inactivation system.

Post-treatment cooling will be provided to minimise steam consumption and cool the treated waste to a safe level for recombining with other process waste at the downstream Waste Water Balancing and Neutralisation System.

Waste Water Balancing

The main purpose of the balance tank system is to provide buffering capacity to smooth out variations in the flow and pollution loads. This will allow a uniform discharge to the public sewer, and provide natural buffering to pH fluctuations allowing the effluent feed to the downstream neutralisation stage to remain steady.

An additional buffer tank will also be provided to cater for periods of peak load or abnormal concentration requiring retention. Peak loads can be diverted to the buffer tank away from the balance tank and bled back into the system over time allowing for a more uniform treatment and discharge profile.

Overall, up to 5 No. tanks are envisaged, each of approximately 375m^3 capacity, to cater for the Phase 1 and Phase 2 projected load profile for the facility.

Cooling

Process effluent from the production facility will be at elevated temperatures due to the thermal deactivation of production wastes and the potential use of high temperature utilities such as Water for Injection (WFI). Discharge permit conditions are likely to restrict effluent temperature to a maximum of 40°C; therefore it may be necessary to reduce effluent temperature.

Cooling will naturally occur during effluent transfer and equalisation. Air cooled heat exchangers are also envisaged.

Neutralisation

The pH control will be achieved utilising inline dosing, with a PLC controlled chemical dosing system (acid and caustic). There will be upstream and downstream pH sensors installed allowing for effective pH adjustment. The recirculation loop will be provided downstream monitoring point to reverse wastewater back to the balancing tanks if the quality of discharge wastewater does not comply with the requirements.

Fire Water Run Off

A preliminary risk assessment has been carried out for the Regeneron site to establish the technical requirement or otherwise for on-site emergency firewater retention i.e., for the prevention of potentially contaminated firewater run-off (or storm water run-off) from reaching the environment. The risk assessment methodology is based on the inventory of potentially polluting materials within the site and the risk of that material being released to the environment in an emergency event such as a fire. Because the manufacturing process at Regeneron is an aqueous based activity, the inventory of chemical material potentially stored on site is relatively small and does not exceed any of the typical guideline thresholds for firewater retention. Furthermore, storage of all potentially polluting materials on the site will be within local secondary bunding. Consequently, the risk assessment concludes that on-site emergency retention is not required.

Notwithstanding this conclusion, it is proposed that the following modifications will be implemented at the site, all of which will further minimise any risk of contaminated fire water run-off being released to the local surface water environment:

- Installation of an actuated valve arrangement at the end of the site storm water drainage system to allow automatic shut-off of the storm water sewer, upstream of its point of connection to the external public storm water sewer. The storage capacity of the site storm water drainage network is estimated to be at least 400m^3.
- Installation of Total Organic Carbon (TOC) monitoring on the end of the storm water drainage system such that any contamination, including that arising from run-off in the event of a fire, will be detected, allowing shut off of the actuated valve and storage of run-off in the collection system.

Noise Emissions

As can be seen from the noise modelling carried out for the proposed development, the predicted noise contribution from the facility at noise sensitive locations is well below the EPA noise criterion. See Attachment I.7-2: Baseline Noise Survey & Modelling Report (PM Document IE03011171-22-RP-0008).

The facility has been designed so that there will be no clearly audible tonal or impulsive component in the noise from the proposed facility at any noise sensitive locations. These noise criteria have been set by the EPA to avoid disturbance at noise sensitive locations. Therefore by designing the facility to comply with these stringent criteria the noise contribution from the proposed plant during normal operation should not have any significant impact on noise sensitive locations.

In accordance with the EPA Guidance Note NG4, noise attributable solely to onsite activities shall not exceed the values given below:

- Daytime (07:00 to 19:00hrs) – 55dB LAr,T
- Evening time (19:00 to 23:00hrs) – 50dB LAr,T
- Night time (23:00 to 07:00hrs) – 45dB LAeq,T

The noise control and mitigation measures to be implemented for the operational phase of the development can be summarised as follows:

- Location of noisy equipment within buildings, cladded structures and acoustic enclosures so far as practicable to minimise any external noise impact

- Design, procurement and installation of equipment to relevant industry standards (IS, EN etc.)
- Specification of maximum noise limit criteria for equipment in procurement contracts, including the absence of tonal/impulsive components in external equipment
- Inspection and Maintenance of equipment as part of preventive maintenance programme to ensure continued normal operation and minimise any noise issues occurring
- Restricting any specific noisy activities which could impact on ambient noise levels (e.g. testing of emergency equipment, construction work) to daytime hours only
- Restricting deliveries/shipments to daytime hours only

Attachment F.2: Emissions Monitoring and Sampling Points

F.2 Emissions Monitoring and Sampling Points

Emissions to Air

Boiler Emissions

The boiler emission points (A1-1 to A1-7) will be monitored as follows:

Table F2.1 – Boiler Emission Monitoring

Parameter	Frequency of monitoring	Monitoring method
NO_x	Annually	Grab Sample (Chemiluminescence)
CO	Annually	Grab Sample (Non-dispersive infrared spectrometry)

Minor Emissions

No sampling or monitoring is planned for minor emission points.

Emissions to Surface Water

There will be no planned emissions to surface water from the facility.

Emissions to Sewer:

Monitoring will be carried out on the process effluent at emission point SEMP1 in line with BAT, as follows:

Parameter	Frequency of monitoring	Monitoring method
Flow Rate	Continuous	Flow meter/recorder
pH	Continuous	pH meter
Temperature	Continuous	Temperature Probe
BOD	Monthly	Standard method testing of composite sample
COD	Monthly	Standard method testing of composite sample
Suspended Solids	Monthly	Standard method testing of composite sample
Total Nitrogen	Monthly	Standard method testing of composite sample
Total Phosphorus	Monthly	Standard method testing of composite sample
Oils, Fats and Greases	Monthly	Standard method testing of composite sample
Sulphates	Monthly	Standard method testing of composite sample

Total Organic Carbon (TOC) will be monitored at SEMP2 using a continuous TOC Analyser.

Emissions to Ground

There will be no planned emissions to ground from the facility. Any contamination of groundwater arising due to site activities will be as a result of an unplanned event, which will be minimised by the design of the facility, the containment of potentially polluting materials during storage and transport, and the site's SOPs and Environmental Management System.

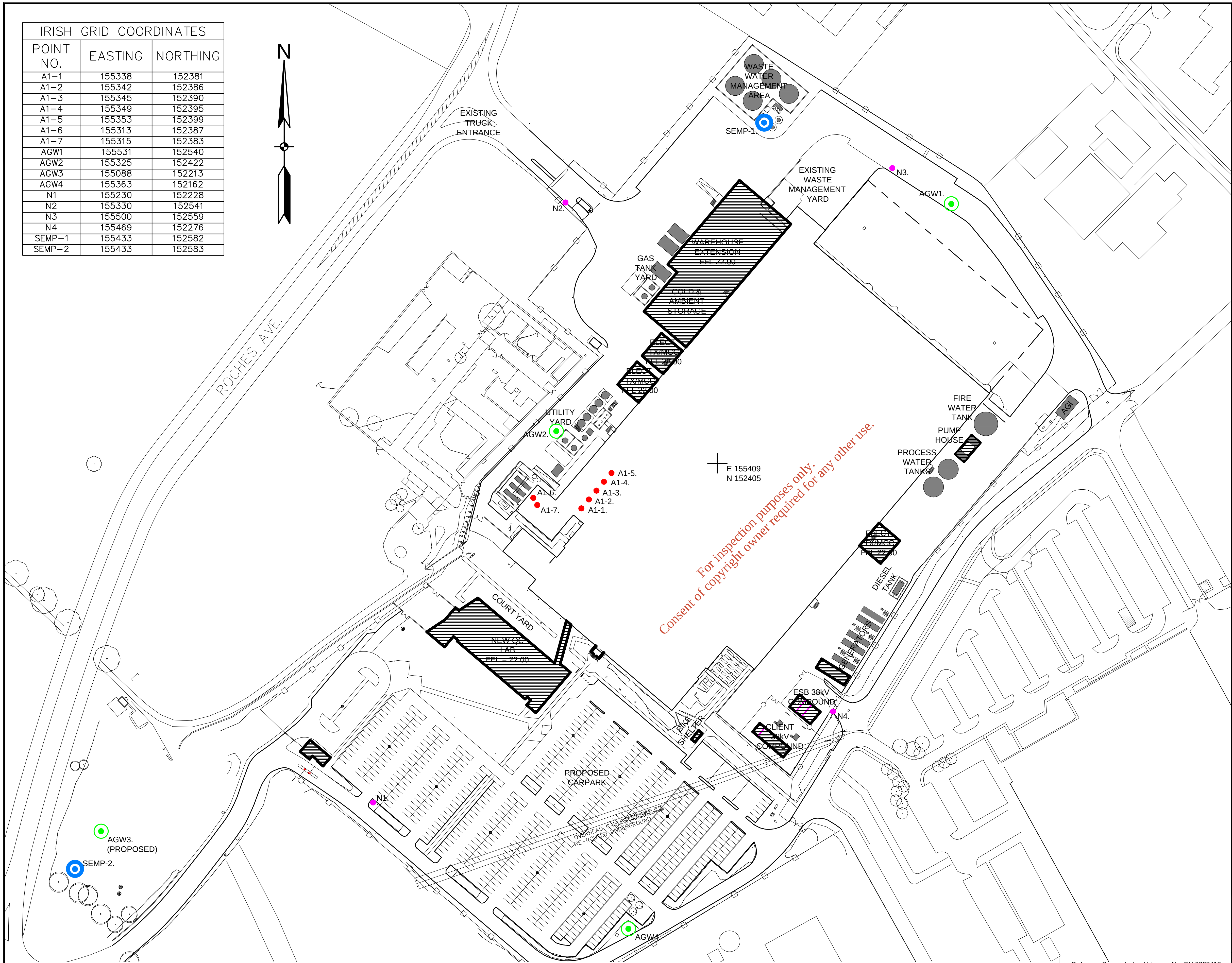
It is propose that groundwater is monitored annually from 4 boreholes on site (AGW1-AGW4). See Drawing 12: On Site Monitoring/Sampling Locations for the locations. AGW3 is proposed, the remaining boreholes are existing.

Noise Emissions

An ambient noise survey will be carried out annually at 4 no. boundary locations and 2 no. Noise Sensitive Locations; see Drawings 11 and 12 for locations. The results will be reported annually to the EPA and included as part of the Annual Environmental Report (AER). Ambient monitoring will be carried out in accordance with the EPA NG4 Guidance Note. Refer to Table F.2 (ii) of this application

Drawing 12: On-site Monitoring/Sampling Locations

IRISH GRID COORDINATES		
POINT NO.	EASTING	NORTHING
A1-1	155338	152381
A1-2	155342	152386
A1-3	155345	152390
A1-4	155349	152395
A1-5	155353	152399
A1-6	155313	152387
A1-7	155315	152383
AGW1	155531	152540
AGW2	155325	152422
AGW3	155088	152213
AGW4	155363	152162
N1	155230	152228
N2	155330	152541
N3	155500	152559
N4	155469	152276
SEMP-1	155433	152582
SEMP-2	155433	152583



0 20m 100m

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LEGEND

- PROPOSED BUILDING
- PROPOSED EQUIPMENT
- AIR (A1-1 - A1-7)
- SEWER (SEMP-1, SEMP-2)
- NOISE (N1, N4) NOTE: NSL1 & NSL2 OFF SITE.
- GROUNDWATER (AGW1, AGW4)

FORMAL ISSUE
20140410.092235 – CHITL

ISSUE	DESCRIPTION	DRN	ORIG	AUTH CHK	APP	DATE
A	FOR IEL APPLICATION	LRC	BT	TMcG	TMcG	07/04/14

REGENERON

CLIENT: REGENERON IRELAND

PM GROUP

PROJECT: BIOPHARMACEUTICAL MANUFACTURING FACILITY

TITLE: INDUSTRIAL EMISSIONS LICENCE APPLICATION
DRAWING 12:
ON SITE MONITORING/SAMPLING LOCATIONS

DRAWINGS PREPARED BY: PM GROUP
LOUGHMAHON TECHNOLOGY PARK
BLACKROCK
CORK

ON BEHALF OF: REGENERON IRELAND IE0311171_22_DR-0012

CLIENT REF.:
CLIENT DRG No.:
PROJECT No.: IE0311171
A3 SCALE: 1:2000
PM DRG No.: IE0311171-22-DR-0012

Attachment F.3: Tabular Data on Monitoring and Sampling Points

Attachment F.3: Tabular Data on Monitoring and Sampling Points

Point Code	Point Type	Easting	Northing	Verified	Pollutant
A1-1	S	155338	152381	N	NOx, CO
A1-2	S	155342	152386	N	NOx, CO
A1-3	S	155345	152390	N	NOx, CO
A1-4	S	155349	152395	N	NOx, CO
A1-5	S	155353	152399	N	NOx, CO
A1-6	S	155313	152387	N	NOx, CO
A1-7	S	155315	152383	N	NOx, CO
SEMP1	S	155433	152582	N	Flow, pH, temperature, BOD, COD, Suspended Solids, Total Nitrogen, Total, Phosphorus, Oils, Fats and Grease, Sulphates
SEMP2	M	155058	152181	N	TOC
AGW1	M	155531	152540	N	pH, COD, Conductivity, parameters specified in accordance with Environmental Objectives (Groundwater) Regulations 2010 (S.I. No. 9 of 2010)
AGW2	M	155325	152422	N	
AGW3	M	155088	152213	N	
AGW4	M	155363	152162	N	
N1	M	155230	152228	N	Noise
N2	M	155330	152541	N	
N3	M	155500	152559	N	
N4	M	155469	152276	N	
NSL1	M	154790	152759	N	
NSL2	M	155979	152547	N	

Section G Attachment

Attachment G.2: Energy Efficiency Programme

G.2 Energy Efficiency

As part of the proposed development, the measures described below are being carried out in order to reduce site energy demand:

Energy Consumption:

- Use of Vapour Compression WFI (Pure Water For Injection) generation as opposed to multi-effect distillation reduces steam usage.
- Minimise clean room area and volume through reduction of footprint and ceiling heights where possible to reduce the HVAC heating, cooling and electricity demands.
- Introduce some level of recirculation with the air handling units on select ISO 8 areas in lieu of once through air to reduce volume and energy usage.
- Use of De-humidification in QA building coldrooms to reduce frost induced inefficiencies in the refrigeration systems.
- Engineering out the need for liquid nitrogen back-up on QA building -70ºC resulting in saving on Liquid Nitrogen venting. Liquid Nitrogen production is energy intensive.
- Laying out QA/QC labs to minimise the solar heat gain into the building, thus reducing the cooling demand.

Energy Generation

- The site proposes to use best available technology for steam generation with direct digital combustion control, oxygen trim and heat recovery through economisers and flash steam recovery. A high level of condensation recovery will also be implemented.
- The Heating demand for the QA building and Admin block will be carried out using low pressure hot water boilers as opposed to inherently less efficient steam/LPHW heat exchanger system.
- VSD technology will be deployed where appropriate to ensure that electrical drives operate efficiency over their demand range.
- Use of electronic expansion valves in QA/QC building coldrooms and refrigeration systems.
- Use of VSD's on Air Compressors to reduce electricity demand.

Section H Attachments/Drawings

Attachment H.1: Materials, Intermediates and Product Handling

Drawing 13: Material Storage Area Locations

Drawing 14: Waste Storage Area Locations

Attachment H.2: Waste Prevention

Attachment H.3: Recovery and Disposal of Wastes

Attachment H.4: Waste Hierarchy

Attachment H.5: Waste recycling and recovery

Attachment H.1: Materials, Intermediates and Product Handling

H.1 Raw Materials, Intermediates and Product Handling

Raw materials and products are listed in Tables G.1 (i) and G.1 (ii) of this application.

Raw materials, intermediates and products will be stored, used, tested, and treated in the following areas:

1. Warehouse
2. Production Area
3. Utilities Yard (2 no.)
4. Laboratory
5. Wastewater Management Area

In general, most raw materials will be stored in the Warehouse and transferred to the Production Area and laboratory as required. Compressed gases for production and laboratory use will be stored in the utility yards and piped to the point of use. Laboratory chemicals will be stored in the Lab Building. Wastewater treatment area chemicals will be stored in bunded bulk containers in the wastewater treatment area. These locations are shown in the site layout included in Drawing 13: Material Storage Area Locations.

Details of the locations, storage conditions, segregation systems, transport of materials and any required analyses, where relevant, are given as follows:

- **Warehouse**

Material Flow in the Warehouse

Shipping/Receiving

Incoming Raw Materials will be offloaded in the shipping/receiving area and shall be transferred from wooden pallets to plastic pallets before being allowed into the main warehouse area.

The shipping/receiving area shall be provided with a driver check-in point which shall be accessed from outside and which shall not have access to the warehouse activities unless allowed by warehouse operators.

Quarantine Area

Upon arrival of a shipment of raw material, warehouse personnel will verify the identity and quantity of the received material and record it on the computer system, which automatically assigns a lot number. The lot will automatically be assigned a quarantine status. After appropriate labelling and sampling, warehouse personnel will place the goods in the Quarantine area of the warehouse and note the location in the computer system.

Ethanol Storage & Make-Up

The Ethanol Preparation Area will be located in the warehouse. Approximately three to four 1000 L containers will be stored in the Solvent Room. The exact number and size of the concentrated ethanol storage containers and storage enclosure requirements are to be determined.

CIP Chemicals

Bulk CIP chemicals (phosphoric acid, sodium hydroxide solutions) will be stored outside the warehouse in bulk containers and will be pumped to day tanks on the skids and washers in the production area. The plastic storage tanks will be bunded and contained. Caustic and acid storage will be segregated.

Transport of Materials in the Warehouse

Bulk materials on pallets, in drums or in 1000L IBCs will be transported by forklift within the warehouse. Smaller quantities will be moved by trolleys/carts. CIP chemicals will be pumped directly to the production area.

- **Laboratory**

Material movement will originate from the warehouse area. Chemicals, consumables, glassware and other laboratory supplies will be stored there until required and will be transported by pallet truck. Materials will be transported from here by lab cart to their designated storage areas. Adequate storage space has been allocated within the laboratory for daily/weekly usage requirements.

Liquid nitrogen will be delivered to the QC cell bank area in the lab via hand pallet truck.

- **Wastewater Management Area**

The wastewater treatment area is a collection of preliminary treatment processes required to render the site wastewater amenable for direct discharge to the public sewer. The chemicals used will include Phosphoric Acid and Sodium Hydroxide (caustic) for neutralisaton.

- **Shipping**

Once final product is ready to ship, multiple containers are bundled and packaged with dry ice in an enviro-container and placed on pallets for shipping.

The shipping includes space for lay down and truck loading.

A Shipping Prep area accommodates staging for product carts holding the final product 5L bottles and an area for transfer and packing of final product 5L bottles into enviro-tainers with dry ice for shipping.

Drawing 13: Material Storage Area Locations

N

ROCHES AVE.

EXISTING TRUCK ENTRANCE

WASTEWATER BALANCING TANKS

WASTE WATER MANAGEMENT AREA

ACID (SULPHURIC) CAUSTIC (SODIUM HYDROXIDE)

CARBON DIOXIDE (C02).

NITROGEN (N_2).

OXYGEN (02).

EXISTING WASTE MANAGEMENT YARD

WAREHOUSE EXTENSION FFL 22.00

GAS TANK YARD

ETHANOL

COLD & AMBIENT STORAGE

ELEC. TX/MCC FFL 22.00

ELEC. TX/MCC FFL 22.00

NEW PRODUCTION PLANTROOM ROOF

UTILITY YARD

COOLING TOWER CHEMICALS.

ACID (PHOSPHORIC) CAUSIC (SODIUM HYDROIXIDE)

E 155409
N 152405

FIRE WATER TANK

PUMP HOUSE

PROCESS WATER TANKS

GAS

AGI

DIESEL

SALT.

ELEC. TX/MCC FFL 22.00

DIESEL TANK

GENERATORS

COURT YARD

NEW QC LAB FFL = 22.00

LAB CHEMICALS

PROPOSED SITE SECURITY HUT AT MAIN ENTRANCE

ESB 38kV COMPOUND

CLIENT 38kV COMPOUND

PROPOSED CARPARK

OVERHEAD CABLES DIVERTED & RE-ROUTED UNDERGROUND

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LEGEND

PROPOSED BUILDING

MATERIAL STORAGE LOCATIONS

FORMAL ISSUE
20140410.092315 – CHITL

ISSUE	DESCRIPTION	DRN	ORIG	AUTH CHK	APP	DATE
A	FOR IEL APPLICATION	LRC	BT	TMcG	TMcG	07/04/14

DRAWINGS PREPARED BY: PM GROUP
LOUGHMAHON TECHNOLOGY PARK
BLACKROCK
CORK

ON BEHALF OF: REGENERON IRELAND IE0311171_22_DR-0013

REGENERON

CLIENT: REGENERON IRELAND

PM GROUP

PROJECT: BIOPHARMACEUTICAL MANUFACTURING FACILITY

TITLE: INDUSTRIAL EMISSIONS LICENCE APPLICATION
DRAWING 13:
MATERIAL STORAGE LOCATIONS

CLIENT REF.

PROJECT No. IE0311171

CLIENT DRG No.

A3 SCALE 1:2000

PM DRG No. IE0311171-22-DR-0013

Drawing 14: Waste Storage Area Locations

N

EXISTING TRUCK ENTRANCE

ROCHES AVE.

WASTE WATER MANAGEMENT AREA

EXISTING WASTE MANAGEMENT YARD

1.

WAREHOUSE EXTENSION FFL 22.00

GAS TANK YARD

COLD & AMBIENT STORAGE

2.

ELEC. SUBSTATION FFL 22.00

ELEC. SUBSTATION FFL 22.00

UTILITY YARD

NEW PRODUCTION PLANTROOM ROOF

E 155409
N 152405

FIRE WATER TANK

PUMP HOUSE

PROCESS WATER TANKS

AGI

ELEC. SUBSTATION FFL 22.00

DIESEL TANK

3.

4.

COURT YARD

NEW QC LAB FFL 22.00

PROPOSED SITE SECURITY HUT AT MAIN ENTRANCE

ESB 38kV COMPOUND

CLIENT 38kV COMPOUND

PROPOSED CARPARK

OVERHEAD CABLES DIVERTED & RE-ROUTED UNDERGROUND

0 20m 100m

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LEGEND

PROPOSED BUILDING

PROPOSED EQUIPMENT

PRODUCTION WASTE STORAGE AREAS (SEE BELOW).

1. BIOWASTE, DECON AUTOCLAVE, WASTE HANDLING & WASTE COMPACTOR.
2. WAREHOUSE WASTE STORAGE AREA.
3. CANTEEN WASTE STORAGE AREA.
4. LABRATORY WASTE STORAGE AREA.

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ISSUE	DESCRIPTION	DRN	ORIG	AUTH CHK	APP	DATE
A	FOR IEL APPLICATION	LRC	BT	TMcG	TMcG	07/04/14

REGENERON

CLIENT: REGENERON IRELAND

PM GROUP

PROJECT: BIOPHARMACEUTICAL MANUFACTURING FACILITY

TITLE: INDUSTRIAL EMISSIONS LICENCE APPLICATION
DRAWING: 14
WASTE STORAGE AREA LOCATIONS

DRAWINGS PREPARED BY: PM GROUP
LOUGHMAHON TECHNOLOGY PARK
BLACKROCK
CORK

ON BEHALF OF: REGENERON IRELAND IE0311171_22_DR-0014

CLIENT REF.

CLIENT DRG No.

PROJECT No. IE0311171

A3 SCALE 1:2000

PM DRG No. IE0311171-22-DR-0014

Attachment H.2: Waste Prevention

Attachment H.3: Recovery and Disposal of Wastes

Attachment H.4: Waste Hierarchy

Attachment H.5: Waste recycling and recovery

H.2 Waste Prevention

The proposed facility is designed and operated to prevent the acceptance of unnecessary wastes to the site and maximise the recovery of recyclables from the incoming wastes.

This functional area is sited at the east side of the northeast corner of the existing facility. The intent is to reuse the existing waste dock area with the existing compactors and truck docks.

To further consolidate waste management activity, all process waste from cell containing areas is routed through and managed in this area. This functional area is required to include:

- Circulation for routing of solid waste.
- An area for bio-waste management to accommodate bio-waste heat inactivation skids, tanks, and containment.
- An area for (1) pass through style decon autoclave along with areas for staging of pre and post autoclaved material.
- A Waste Handling Area.
- Reuse of the existing Waste Compactor Area with associated existing dock doors and compactor/dock equipment. Upgrade of finishes & equipment in this area needs to be validated in the next phase.

H.3 Arrangements for the recovery or disposal of solid and liquid wastes generated at the installation.

Details are outlined in Table H.3 (i) of this application.

H.4 Waste Hierarchy

Non-Hazardous Waste Management

All recyclable wastes will be segregated on site and collected for recycling by permitted waste contractors. General non-hazardous wastes will be compacted on site and collected for disposal by a licensed waste disposal contractor. All documentation will be retained on site in accordance with legislative requirements and the Environmental Management System for the site.

A range of non-hazardous wastes are expected to be generated on site as follows:

- Packaging waste
- Office waste
- General non-hazardous waste
- Kitchen waste
- Empty containers
- Filters

This waste will be managed in accordance with the waste hierarchy and in accordance with all relevant Irish and EU waste management legislation. It is anticipated that 60% of non-hazardous wastes will be recycled. These materials will be stored for collection and transported off-site by a licensed waste contractor for off-site recovery or disposal as non-hazardous waste.

Hazardous Waste Management

All hazardous waste will be labelled appropriately, covered where necessary and stored in contained areas on site before being collected by a permitted hazardous waste contractor and brought to a licensed facility for disposal, recovery or recycling. This will include laboratory wastes, empty hazardous containers and waste oils. All documentation will be retained on site in accordance with legislative requirements and the Environmental Management System for the site. Standard operating procedures will be developed to cover waste management activities at the site.

Laboratory waste chemicals will be segregated where possible and stored in a designated chemical store in suitable, labelled containers prior to collection by a licensed waste contractor for recovery or disposal as licensed hazardous waste management facilities in Europe.

Hazardous wastes from the production of drugs will include raw material packaging, spent filters, and reject product and reject packaged product.

As with any industrial facility, standard hazardous wastes such as fluorescent tubes, batteries, oils, etc. will arise from time to time. These wastes will be stored and managed as hazardous waste. Under licensed waste management contract, these wastes will be sent for recovery and recycling.

Expected waste arisings are outlined in Table H.3 (i) of this application.

H.5 Waste Recycling and Recovery

Environmental Management System (EMS) / Environmental Management Programme (EMP):

Improvements in environmental performance will encouraged in the EMP associated with the IEL by setting a series of objectives and targets commonly associated with reducing resource material use (e.g. water, energy, paper) and waste production generally. Regeneron will undertake the establishment of meaningful targets for improvements in the areas of waste reduction throughout the lifetime of the operation of the facility.

Food waste will be managed in accordance with the Waste Management (Food Waste) Regulations 2009. It is noted that there is no canteen with catering facilities proposed for this facility. A kitchen area for staff will be provided.