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Marc O'Donoghue



Finance Director AbbVie Ireland
James Egan




Quality Director
Daniela Toia




Technical Operations Manager
Vacant


Human Resources Manager
Emmet Wrafter




Manufacturing Director
Darragh Pattwell




Supply Chain & Program Manager
Dermot Fennelly




Site Services & EHS&E Manager
Michael Gallagher



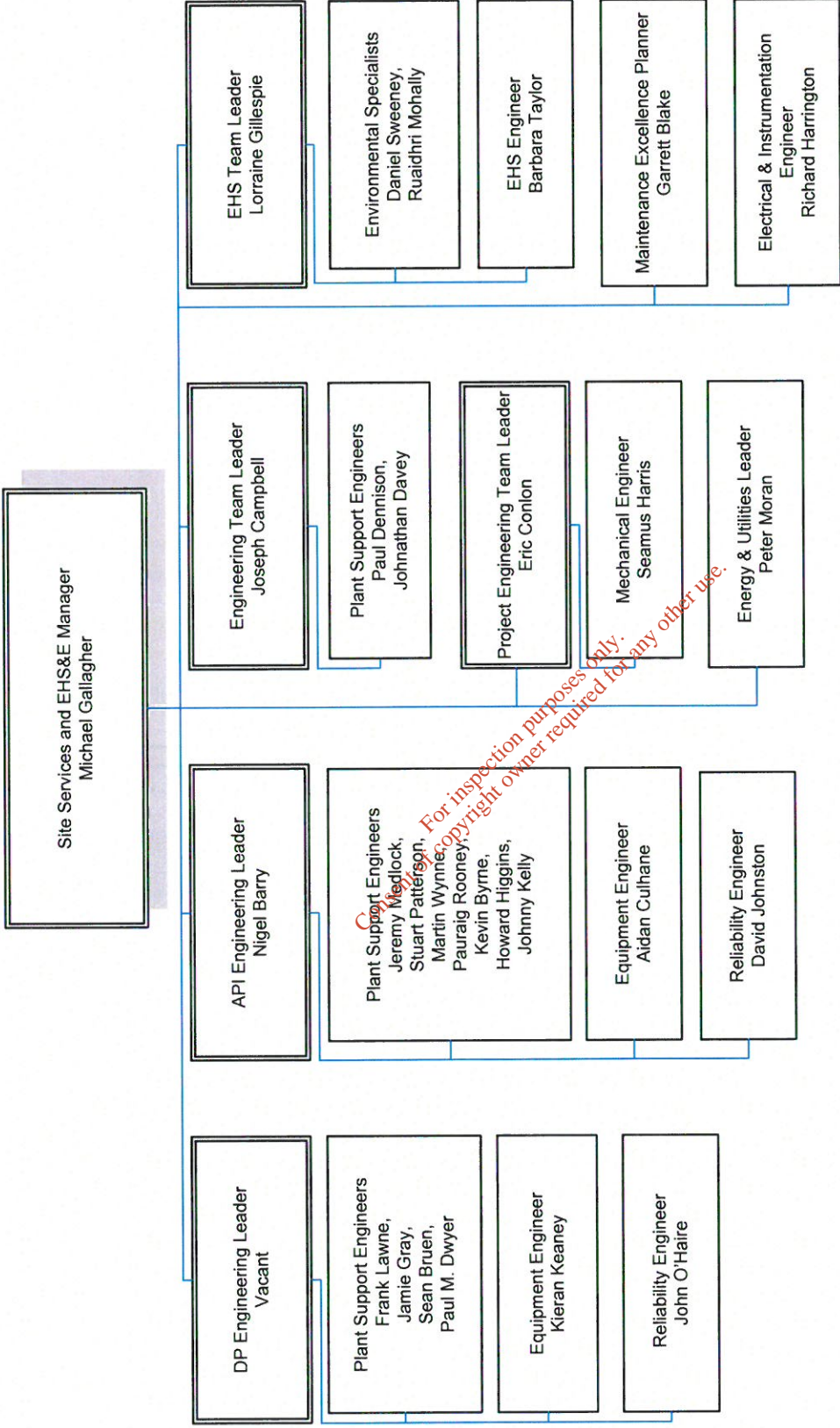
Business Operations Manager
Liam Thompson



Personal Assistant
Martina Moloney



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Environmental, Health & Safety Policy

AbbVie Ireland NL B.V. is a biopharmaceutical company focused on developing leading-edge therapies and innovations. We develop and deliver products and processes from small scale clinical trial supply to larger commercial manufacturing incorporating global research and development activities through to manufacturing of key products that are business critical.


AbbVie is committed to the protection of human health, safety and the environment in the community where we conduct our business. This shall be achieved by:

- Fostering a work environment that promotes employee health and productivity, and is ultimately free of injuries;
- Leading an EHS Culture on site that aligns to the Zero. Believe It. Achieve It. philosophy and sustaining a high performance in EHS by minimizing the potential for incidents through an engaged and safety focused work force;
- Continuously improving the efficiency and sustainability of our business activities and products, resulting in the lowering of greenhouse gas emissions and water use, and minimizing wastes destined for landfill;
- Ensuring that contractors doing work on behalf of AbbVie Ireland NL B.V. conform to regulatory requirements and meet applicable internal EHS standards;
- Continuing to integrate sound EHS practices consistent with our EHS management system into all aspects of the business, in addition to maintaining legal compliance;
- Establishing meaningful goals and strategies for the business, communicating to all persons working under the control of the organization with the intent that they are made aware of their individual EHS obligations and reporting publicly on our progress toward achieving them; and
- Routinely monitoring our operations for accountability to this policy.

This policy applies to all AbbVie employees, contractors and visitors.

It is the responsibility of every employee, contractor and visitor to work safely, to adhere to the letter and spirit of this policy, to report practices or conditions which are inconsistent with this policy or which pose recognized or unacceptable risks to human health or the environment.

In addition, every AbbVie Leader shall promote a workplace climate that enables employees to practice these principles and actively support implementation of this policy.



Russell Benes
Site Director
AbbVie Ireland NL B.V.

22 July 2015
Date



CERTIFICATION EUROPE™



This is to certify that the

Environmental Management System

Of

AbbVie Ireland NL B.V

At

Manorhamilton Road, Sligo, Ireland

Has been assessed by Certification Europe and deemed to comply with the requirements of

ISO 14001:2004

This certificate is valid for the activities specified below:

The management of pharmaceutical products

Certification of Registration remains the property of Certification Europe Ltd.
The validity of this Certificate is maintained on the condition that the Management System is assessed through an on-going surveillance programme and continues to adequately meet the requirements of the standard.
To verify this certificate validity please contact us at info@certificationeurope.com

Date of initial certification: 30th May 2012

This certificate is valid until: 29th May 2018

Chief Executive: Michael Brophy

Chairman: Padraic A. White

Signature:

Signature:

Client Registration No.: 2012/1514
Certificate Reference No.: A/2

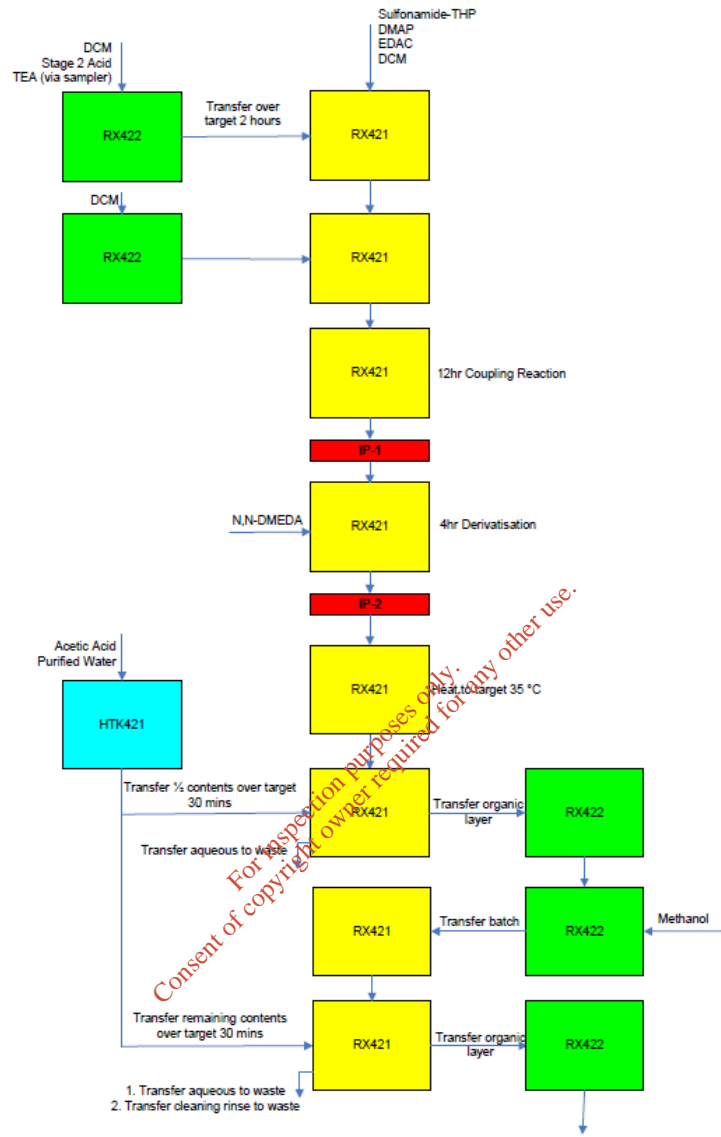
Date of certificate issue: 15th July 2015

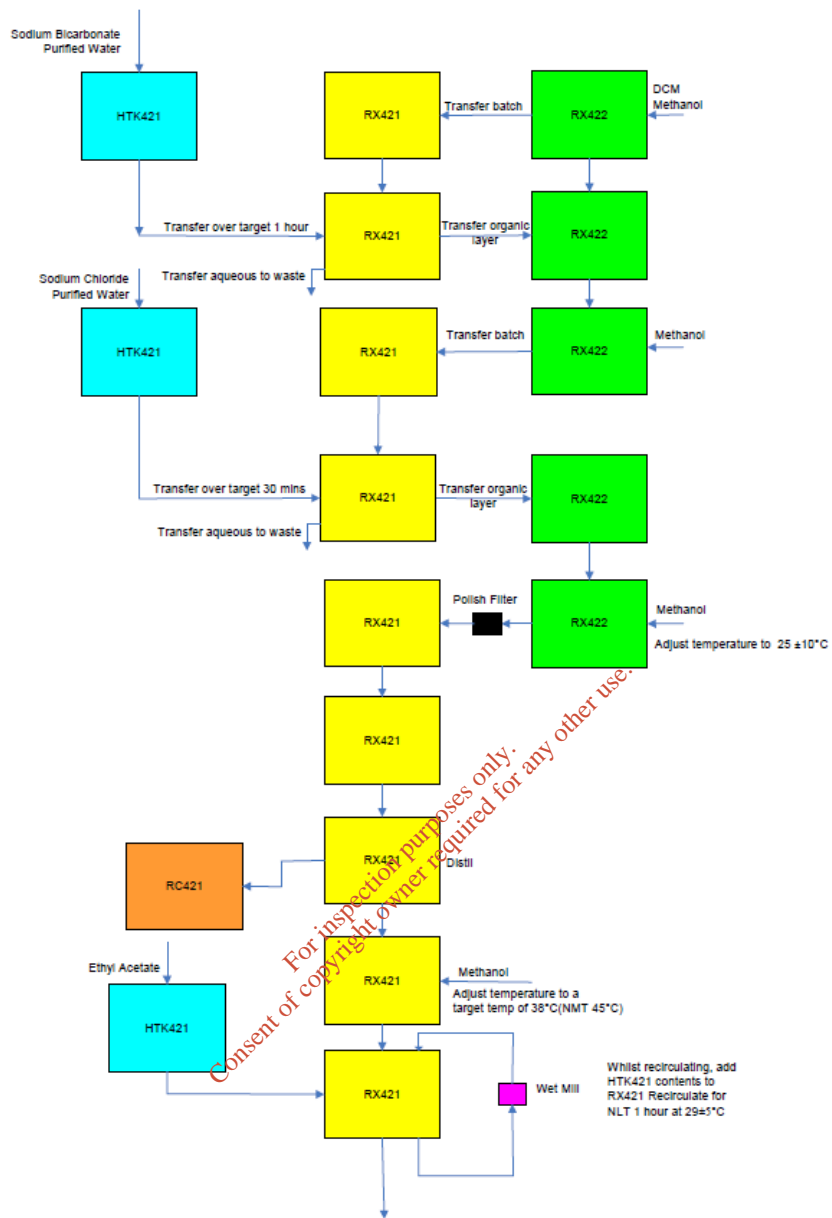


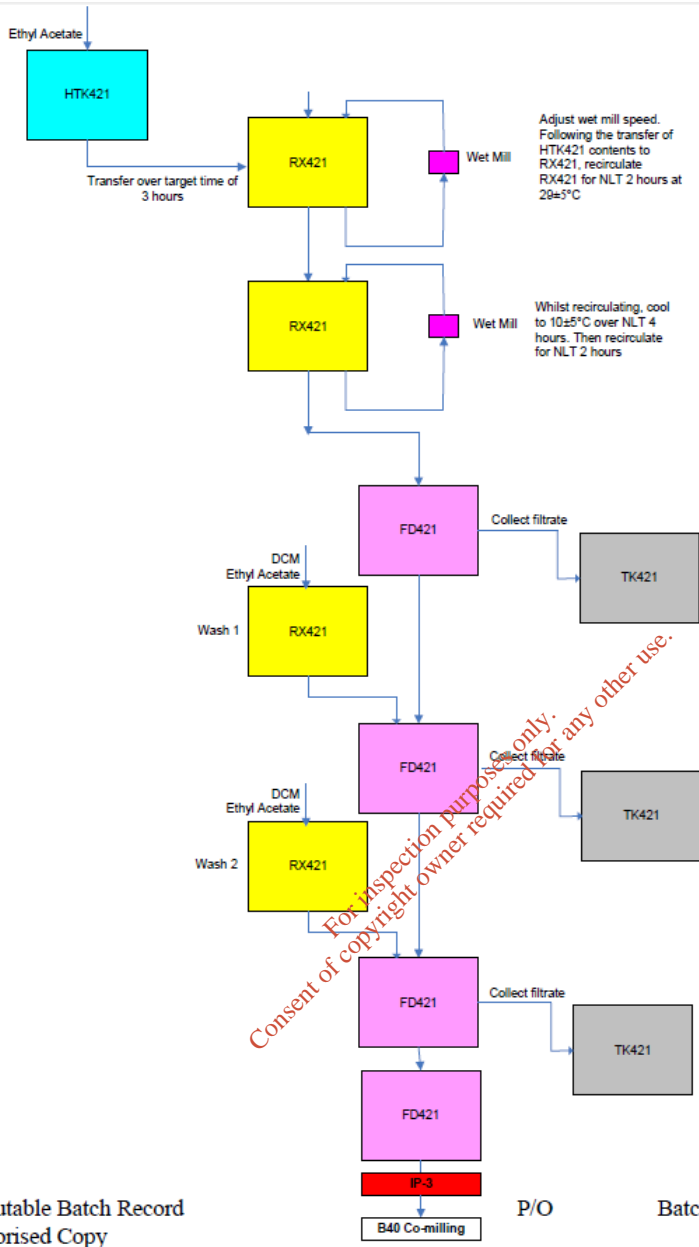
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API Production flow diagram



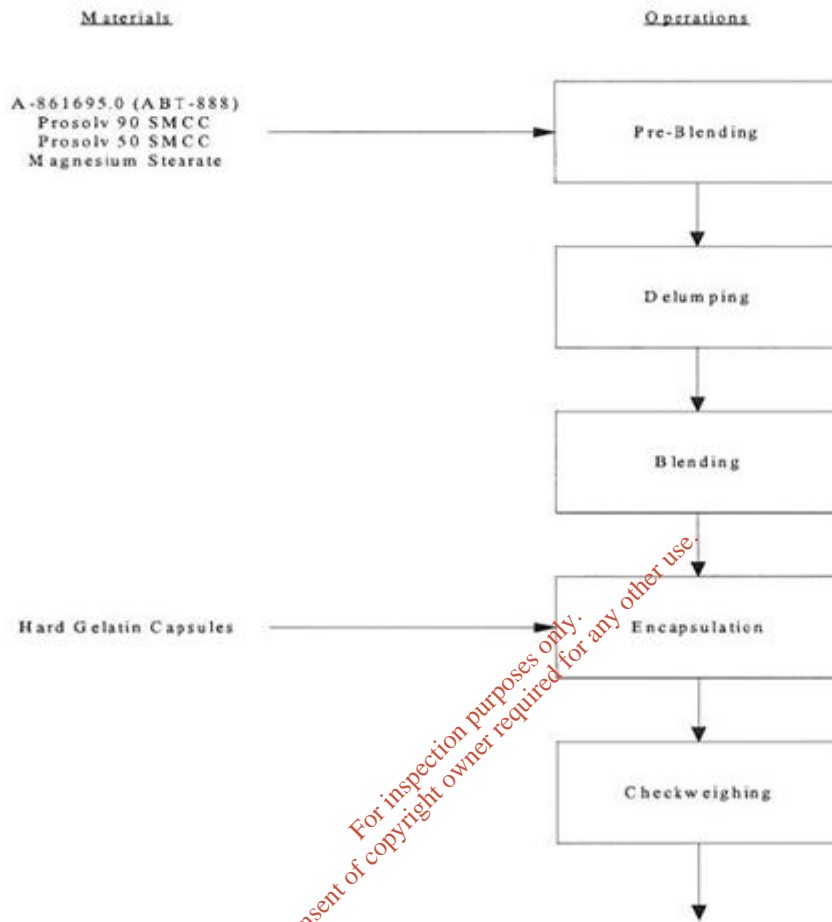




Executable Batch Record
 Authorised Copy

P/O Batch No.

Drug Production flow diagram

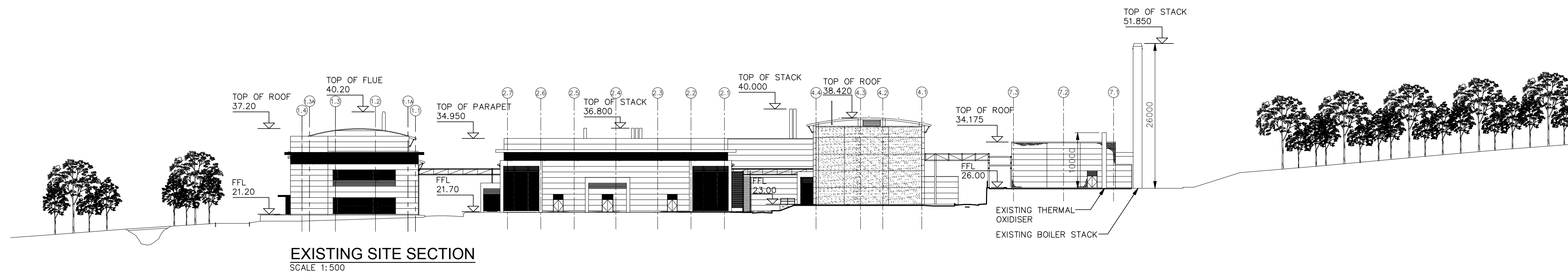


GENERAL NOTES

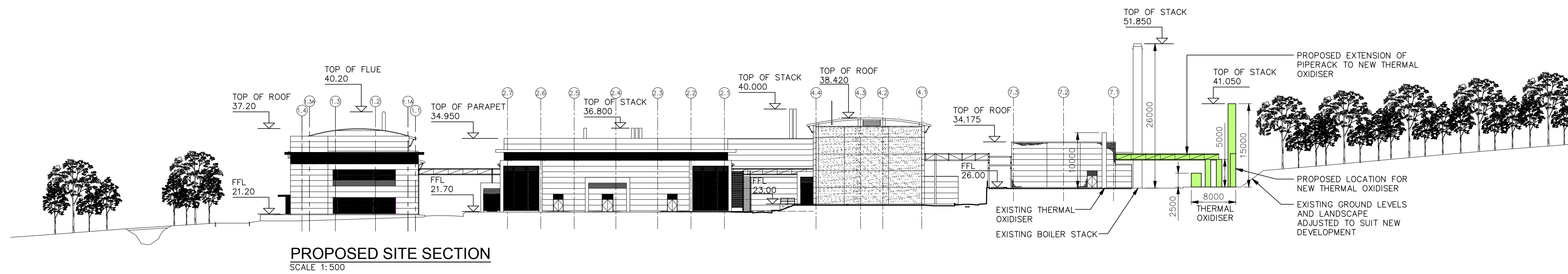
1. THIS DRAWING IS TO BE READ IN CONJUNCTION WITH ALL RELEVANT ARCHITECTS AND ENGINEERS DRAWINGS AND SPECIFICATIONS.
2. DO NOT SCALE, USE FIGURED DIMENSIONS ONLY.
3. ANY DISCREPANCIES TO BE REPORTED TO THE ARCHITECT.
4. ALL DIMENSIONS ARE IN MILLIMETERS.
5. ALL LEVELS ARE IN METRES RELATIVE TO ORDNANCE SURVEY DATUM AT MALIN HEAD.

LEGEND

INDICATES AREA RELATING TO THE NEW THERMAL OXIDISER AND EXTENSION OF PIPERACK



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FORMAL ISSUE
20131210.183427 - LYNCA

A	SECTION 5	DL	DL	PAC	PH	10/12/13
ISSUE	DESCRIPTION	DRN	ORIG	AUTH CHK	APP	DATE

abbvie

CLIENT ABBVIE IRELAND NL B.V. - MANORHAMILTON ROAD

PM
GROUP

PROJECT VOC ABATEMENT

TITLE NEW THERMAL OXIDISER LOCATION
EXISTING AND PROPOSED SITE SECTIONS

CLIENT REF.	CLIENT DRG No.
PROJECT No. IE0311237	DRG No. IE0311237-48-DR-0004
A1 SCALE 1:500	



NOTES

1. ALL BOILER EMISSIONS FLOW TO THE ONE STACK.
 A1-1
 A1-2
 A1-3
 A1-4
 A1-5
 A1-6

LEGEND

- SITE BOUNDARY - FOR FULL EXTENT OF SITE BOUNDARY REFER TO IE0311237-22-DR-001
- AX-XX EXISTING EMISSION POINTS SHOWN IN GREEN
● AX-XX NEW EMISSION POINTS SHOWN IN RED
- MAIN EMISSIONS TO ATMOSPHERE**
- A1-1 BOILERS
 - A2-1 (A) EXISTING THERMAL OXIDISER
 - A2-1 (B) EXISTING CYROGENIC CONDENSOR
 - A2-1 (C) NEW THERMAL OXIDISER
 - A2-2 SCRUBBER
 - A2-3 DUST EXTRACT (BLDG 40)
 - A2-4 DUST EXTRACT (BLDG 20)
 - A2-5 DUST EXTRACT (BLDG 20)
- MINOR EMISSIONS**
- A3-1 LAB FUME HOOD SYSTEM
 - A3-2 AA INSTRUMENT
 - A3-3 CANTEEN
 - A3-4 HYDROGENATOR UNIT
 - A3-5 DRUM CHARGE ROOM
 - A3-6 DISPENSARY GLOVE BOX
 - A3-7 SPP1 AND SPP2
 - A3-8 DRYING AIR EXTRACT FROM IBC WASH
- OTHER EMISSIONS**
- SE-1 SEWER EMISSION POINT
 - MW-1, 2, 3 & 4 MONITORING WELL
 - SW-1 STORMWATER POINT

FORMAL ISSUE
 20150902.163726 - MCMABY

ISSUE	DESCRIPTION	DRN	CRG	APP	DATE
A	PRELIMINARY	BM	CR	MD	02/09/15



CLIENT: ABBVIE IRELAND NL B.V. - MANORHAMILTON ROAD



PROJECT: VOC ABATEMENT

TITLE: INDUSTRIAL EMISSIONS LICENCE REVIEW APPLICATION EMISSION POINTS

CLIENT REF.	CLIENT DRG No.
PROJECT No. IE0311237	
SCALE: A0	DRG No. IE0311237-22-DR-0002

1 Noise Monitoring

1.1 EPA Guidance notes on Noise Monitoring

The following recommendation appears in the FAQ summary issued by the EPA on the Guidance Notes for Noise Monitoring (NG4):

Question 4: If the past noise levels have not been in exceedence of the relevant noise limits, will a 30min reading as required by the license suffice?

Answer: Refer to the amended Table 1.1 (below) for the minimum survey periods required. The noise guidance note (NG4) should be the reference source for any noise monitoring going forward. The intention is to ensure that the requirements are applied on a consistent basis. However, if a particular site is complaint over a number of years, then this annual noise survey requirement could be relaxed or removed with the written agreement of the site inspector, as currently allowed for in the NG4 note.

Table 1.1: Recommended Minimum Survey Durations

Period	Minimum Survey Duration
Daytime (07:00 to 19:00hrs)	4 hour survey with a minimum of 3 sampling periods ^{viii} at each noise monitoring location.
Evening (19:00 to 23:00hrs)	2 hour survey with a minimum of 1 sampling period at each noise monitoring location.
Night-time ^{ix} (23:00 to 07:00hrs)	3 hour survey with a minimum of 2 sampling periods at each noise monitoring location.

The EPA Guidance note for Noise Section 7.2 states:

“If it can be demonstrated, on the basis of historical noise data and complaint history (or lack thereof), that a site is in compliance with its noise limit values and it does not give rise to noise nuisance, the Agency may agree to relax the survey requirements. Any such relaxation must be sought prior to survey work commencing.”

1.2 AbbVie Noise Monitoring Results

There have been no significant changes to the number and nature of noise emissions since the 2005 application for a licence review. The new thermal oxidiser is replacing an existing thermal oxidiser and the associated equipment will be added to the site register of noise emission sources and, once operational, will be monitored as part of the annual monitoring programme.

Note: Noise emissions from site are reported in the AER. Once operational, noise emissions from the new thermal oxidiser will be monitored as part of the annual noise survey. It is proposed to perform one last annual noise survey during the period when the new thermal oxidiser is operational and to cease annual environmental noise monitoring after this if the results are within the limits. The site has conducted annual noise surveys since it first went operational and has an impeccable record with no emission limit failures. Furthermore no complaints have been lodged with AbbVie or the EPA regarding noise emissions from the site during this time.

The following tables are extracts from the AER that AbbVie produced since 2008. These tables represent the results of the noise monitoring on-site.

1.3 2014

Table 2.1.1: Noise Monitoring Results 2014

Date of monitoring	Time period	Noise location (on site)	Noise sensitive location -NSL (if applicable)	LA _{veg}	LA ₉₀	LA ₅₀	LA _{max}	Tonal or Impulsive noise* (Y/N)	If tonal /impulsive noise was identified was 5dB penalty applied?	Comments (ex. main noise sources on site, & extraneous noise ex. road traffic)	Is <u>site</u> compliant with noise limits (day/evening/night)?
29-Sep-14	13:13 - 13:28	B1		43	40	43	69	No	n/a	Road traffic main noise source	Yes
29-Sep-14	14:18 - 14:33	B1		47	41	45	74	No	n/a	Road traffic main noise source	Yes
29/30-Sep-14	23:57 - 00:12	B1		41	39	43	59	No	n/a	Road traffic main noise source	Yes
29-Sep-14	12:51 - 13:06	B2		45	43	46	58	No	n/a	Road traffic main noise source	Yes
29-Sep-14	13:57 - 14:12	B2		49	46	52	58	No	n/a	Road traffic main noise source	Yes
29-Sep-14	23:34 - 23:49	B2		46	44	47	58	No	n/a	Road traffic main noise source	Yes
29-Sep-14	12:31 - 12:46	B3		52	49	53	65	No	n/a	Road traffic main noise source	Yes
29-Sep-14	13:38 - 13:53	B3		52	50	53	66	No	n/a	Road traffic main noise source	Yes
29-Sep-14	23:15 - 23:30	B3		49	49	50	64	No	n/a	Road traffic main noise source	Yes
29-Sep-14	15:34 - 15:49	B4	NSL1	47	41	49	66	No	n/a	Road traffic main noise source	Yes
29-Sep-14	16:39 - 16:54	B4	NSL1	47	41	50	58	No	n/a	Road traffic main noise source	Yes
30-Sep-14	00:35 - 00:50	B4	NSL1	39	33	41	66	No	n/a	Road traffic main noise source	Yes
30-Sep-14	01:43 - 01:58	B4	NSL1	38	31	38	65	No	n/a	n/a	Yes
29-Sep-14	15:55 - 16:10		NSL2	49	43	53	59	No	n/a	Road traffic main noise source	Yes

1.4 2012

Table 2.2.1: Day-time Noise Monitoring Results 2012

Date	Time Period	Location	L _{Aeq} (dB)	L _{A90} (dB)	L _{A10} (dB)	L _{Amax} (dB)	Tonal or Impulsive Noise	L _{Ar} (dB)	Compliant with Noise Limits	Comments
25 th Sept 2012	10:15 - 10:45	NSL1	54.3	45.6	58.7	72.7	No	54.3	Yes	The main source is traffic noise. Plant noise was not audible.
	09:35 - 10:05	NSL2	49.1	40.3	51.8	63.1	No	49.1	Yes	The main source is traffic noise. Plant noise was not audible.
	10:55 - 11:25	NSL3	56.7	40.8	63.1	81.9	No	56.7	Yes	The main noise source is road traffic noise. Plant noise was not audible.
	14:20 - 14:50	BL1	52.3	50.6	54.1	73.1	No	52.3	Yes	Audible plant noise from the external pumps of the tank farms, the extraction fans of the buildings and the compressed air of pneumatic lines. Some road traffic noise from N16 also audible.
	13:45 - 14:15	BL2	47.9	48.2	58.3	59.1	No	47.9	Yes	Audible plant noise from the cooling towers and the utilities building, mainly coming from air compressors and boilers. Some road traffic noise from N16 also audible.
	12:00 - 12:30	BL3	51.2	43.6	47.8	72.9	No	51.2	Yes	Road traffic noise from N16 was audible.

Table 2.2.2: Night-time Noise Monitoring Results 2012

Date	Time Period	Location	L _{Aeq} (dB)	L _{A90} (dB)	L _{A10} (dB)	L _{Amax} (dB)	Tonal or Impulsive Noise	L _{Ar} (dB)	Compliant with Noise Limits	Comments
24 th Sept 2012	22:45 - 23:15	NSL1	48.1	39.8	56.1	61.3	No	48.1	Yes	The main source is traffic noise. Plant noise was not audible.
	23:20 - 23:50	NSL2	42.7	36.3	43.7	67.5	No	42.7	Yes	The main source is traffic noise. Plant noise was not audible.
	23:55 - 00:25	NSL3	51.2	38.1	53.3	75.8	No	51.2	Yes	The main noise source is road traffic noise. Plant noise was not audible.
	02:15 - 02:45	BL1	50.6	48.6	49.7	58.3	No	50.6	Yes	Audible plant noise from the external pumps of the tank farms, the extraction fans of the buildings and the compressed air of pneumatic lines.
	01:40 - 02:10	BL2	49.3	43.1	48.6	56.2	No	49.3	Yes	Audible plant noise from the cooling towers.
	01:00 - 01:30	BL3	48.6	39.6	47.2	61.8	No	48.6	Yes	Road traffic noise from N16 was audible.

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1.5 2011

Table 2.3.1: Day-time Noise Monitoring Results 2011

Date	Time Period	Location	L _{Aeq} (dB)	L _{A90} (dB)	L _{A10} (dB)	L _{Amax} (dB)	Tonal or Impulsive Noise	L _{Ar} (dB)	Compliant with Noise Limits	Comments
25 th Aug 2011	11:35 - 12:05	NSL1	56.2	44.3	59.3	74.3	No	56.2	Yes	The main source is traffic noise. Plant noise was not audible.
	11:00 - 11:30	NSL2	48.2	39.2	52.3	61.6	No	48.2	Yes	The main source is traffic noise. Plant noise was not audible.
	12:10 - 12:40	NSL3	62.6	41.4	66.4	87.8	No	62.6	Yes	Dominant noise source is road traffic noise. Plant noise was not audible.
	15:05 - 15:35	BL1	50.7	48.0	52.5	72.9	No	50.7	Yes	Audible plant noise from the external pumps of the tank farms, the extraction fans of the buildings and the compressed air of pneumatic lines. Some road traffic noise from N16 also audible.
	14:30 - 15:00	BL2	48.3	45.9	50.2	63.5	No	48.3	Yes	Audible plant noise from the cooling towers and the utilities building, mainly coming from air compressors and boilers. During measurements a metal roller was left open for the boiler house. Some road traffic noise from N16 also audible.
	13:30 - 14:00	BL3	48.7	41.0	46.9	82.4	No	48.7	Yes	Road traffic noise from N16 was audible. Distant plant noise audible in the absence of road traffic noise.

Table 2.3.2: Night-time Noise Monitoring Results 2011

Date	Time Period	Location	L _{Aeq} (dB)	L _{A90} (dB)	L _{A10} (dB)	L _{Amax} (dB)	Tonal or Impulsive Noise	L _{Ar} (dB)	Compliant with Noise Limits	Comments
24 th Aug 2011	22:35 - 23:05	NSL1	52.2	38.7	54.3	72.0	No	52.2	Yes	The main source is traffic noise.
	23:10 - 23:40	NSL2	52.8	35.1	47.1	87.2	No	52.8	Yes	The main source is traffic noise. The L _{Amax} is attributed to some aircraft during the monitoring period.
	23:45 - 00:15	NSL3	57.7	32.6	58.9	78.0	No	57.7	Yes	Dominant noise source is road traffic noise.
	00:55 - 01:25	BL1	49.0	47.0	49.3	82.2	No	49.0	Yes	Audible plant noise from the external pumps of the tank farms, the extraction fans of the buildings and the compressed air of pneumatic lines.
	01:30 - 02:00	BL2	48.0	45.7	49.1	57.0	No	48.0	Yes	Audible plant noise from the cooling towers and the utilities building, mainly coming from air compressors and boilers.
	02:10 - 02:40	BL3	48.3	41.2	46.3	67.7	No	48.3	Yes	Road traffic noise from N16 was audible.

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1.6 2010

Table 2.4.1: Noise Monitoring Results 2010

LOCATION	PERIOD	L _{Aeq} (dBA)	L _{Amax} (dBA)	L _{A10} (dBA)	L _{A90} (dBA)	Tonal noise (1)	Estimated L _{Af} (dBA) (2)	Observations
NSL 1	DAY 26 th July 20:03-20:33	53.7	63.8	57.9	43.3	No	N/A	<ul style="list-style-type: none"> Frequent traffic during daytime readings, occasional during the night-time. Close proximity to roundabout ensures breaking and engine revving to accelerate. Some audible plant noise.
	NIGHT 27 th July 07:19-07:49	56.4	72.1	60.6	44.1	No	N/A	
NSL 2	DAY 26 th July 19:31-20:01	45.2	88.5	47.7	40.3	No	N/A	<ul style="list-style-type: none"> Occasional Traffic noise. Some audible plant noise
	NIGHT 27 th July 06:46-07:16	43.2	63.4	46.6	38.1	No	N/A	
NSL 3	DAY 27 th July 14:18-14:49	63.0	82.7	66.3	44.0	No	N/A	<ul style="list-style-type: none"> Close proximity to N16 and trucks using airbrakes to slow down approaching bend in the road. Frequent traffic during daytime readings, occasional during the night-time dominating the L_{Aeq} readings. No audible plant noise
	NIGHT 27 th July 06:13-06:43	54.4	78.9	48.4	37.7	No	N/A	
BL 1	DAY 27 th July 07:58-8:28	53.0	63.5	53.8	52.2	No	N/A	<ul style="list-style-type: none"> Audible plant noise associated with the tank farm.
	NIGHT 27 th July 23:12-23:49	52.0	55.8	52.5	51.9	No	N/A	
BL 2	DAY 27 th July 15:07-15:37	48.6	56.8	49.8	47.3	No	N/A	<ul style="list-style-type: none"> Audible plant noise from the cooling towers.
	NIGHT 27 th July 22:00-22:30	52.2	62.7	53.1	51.1	No	N/A	
BL 3	DAY 27 th July 15:07-15:37	44.6	65.0	45.9	43.0	No	N/A	<ul style="list-style-type: none"> Audible plant noise.
	NIGHT 27 th July 22:32-23:02	49.0	57.3	50.0	47.9	No	N/A	

1.7 2009

Table 2.5.1: Noise Monitoring Results 2009

LOCATION	PERIOD	L _{Aeq} (dBA)	L _{Amax} (dBA)	L _{A10} (dBA)	L _{A90} (dBA)	Tonal noise (1)	Estimated L _{Af} (dBA) (2)	Observations
NSL 1	DAY 10:20-10:50	56.0	72.8	58.8	45.5	No	56.0	<ul style="list-style-type: none"> Frequent traffic during daytime readings, occasional during the night-time. During night-time readings, a diesel strimmer was in use near NSL3. No audible plant noise.
	NIGHT 22:07-22:37	49.3	67.3	52.2	41.0	No	49.3	
NSL 2	DAY 11:28-11:58	55.9	82.0	57.5	45.8	No	55.9	<ul style="list-style-type: none"> Frequent traffic during daytime readings, occasional during the night-time. During day-time readings, strimmer/lawnmower was in use at a neighbouring house. During night-time readings, a diesel strimmer was in use near NSL3.
	NIGHT 22:39-23:10	54.0	74.6	57.2	39.9	No	54.0	
NSL 3	DAY 10:54-11:25	70.7	90.3	73.3	45.5	No	70.7	<ul style="list-style-type: none"> Frequent traffic during daytime readings, occasional during the night-time dominating the L_{Aeq} readings.
	NIGHT 23:14-23:45	65.5	92.2	55.5	33.8	No	65.5	
BL 1	DAY 12:08-12:42	52.2	67.5	53.0	51.2	No	52.2	<ul style="list-style-type: none"> Audible plant noise from external pumps associated with the tank farm.
	NIGHT 06:07-06:37	52.4	62.0	53.5	51.5	No	52.4	
BL 2	DAY 14:36-15:06	44.0	56.7	45.6	42.3	No	44.0	<ul style="list-style-type: none"> Audible plant noise from the cooling towers. During night-time measurements a metal roller was left open for the boiler house.
	NIGHT 06:48-07:19	48.0	56.5	48.7	46.5	No	48.0	
BL 3	DAY 15:10-15:40	47.7	57.4	49.5	45.3	No	47.7	<ul style="list-style-type: none"> Audible plant noise.
	NIGHT 07:22-07:55	45.4	62.0	47.3	42.2	No	45.4	

1.8 2008

Table 2.6.1: Noise Monitoring Results 2008

Date	Time	Location	L _{Aeq} (30 mins)	L _{A10}	L _{A90}	L _A min	L _A max	Comments
6 th May 2008	18:27-18:57	NSL 1	50.7	52.3	46.0	41.9	72.1	Traffic Noise Predominant No audible plant noise.
	19:06-19:36	NSL 3	68.8	71.8	39.7	35.9	87.8	Traffic Noise Predominant No audible plant noise.
	19:44-20:14	NSL 2	49.7	53.0	42.5	37.1	66.1	Distant sound of garden equipment, Children playing in street with ball No audible plant noise.
7 th May 2008	20:37-21:07	BL1	52.7	54.0	51.2	50.3	62.7	Plant Noise
	21:10-21:41	BL3	51.4	52.4	50.2	48.6	56.4	Plant Noise
8 th May 2008	15:45-16:15	BL2	61.3	55.2	51.0	48.8	80.0	Plant Noise
7 th May 2008	22:00-22:30	NSL3	68.0	66.3	33.9	31.4	92.6	Traffic Noise Predominant; Music/ TV audible. No audible plant noise.
	22:34-23:04	NSL2	47.7	51.7	35.7	34.0	66.4	Traffic Noise Predominant No audible plant noise.
	23:07-23:37	NSL1	52.9	55.9	40.2	38.2	80.9	Traffic Noise Predominant No audible plant noise.