

## Attachment 2.5.3 – Technical Knowledge or Qualifications

### 1.0 Site Management and Control

The high level organisational and management structure for the existing facility is presented in Appendix A. This includes the AbbVie Ballytivnan management team, the engineering team and the Environmental Health & Safety (EHS team). Appendix B includes the updated organisational and management structure for the new bio-chemical pharma production suite ('biologics').

Whilst the entire leadership team has specific responsibilities for environmental and health & safety matters, the primary responsibility for the facilities maintenance and compliance with its Industrial Emissions licence rests with the facility Engineering Services & EHS Manager who reports directly to the Site Director. The Engineering Services & EHS Manager is supported by the EHS Engineer.

### 2.0 Site Operatives Relevant to Licence

#### 2.1 Site Director/Site Lead

The Site Director is responsible for the overall operation of the site including compliance with the conditions of the Industrial Emissions (IE) licence. The Site Director is responsible for ensuring that site safety and environmental compliance objectives are thoroughly embedded in all site personnel and procedures. They are also responsible for formulating and implementing policies (Human Resource, Financial, Safety/Environmental, and Operational) that meet compliance and operational expectations.

The existing Site Director is Columba McGarvey. Columba has over ten years' experience as a Director and a Project Manager including working as the Director of Engineering and as the Site Director at the AbbVie facility in Barceloneta, Puerto Rico.

Columba holds a Bachelor of Engineering in Mechanical Engineering from the National University of Ireland (NUI), Galway.

#### 2.2 EHS and Engineering Teams

##### ***Site Engineering Services and EHS Manager (Maintenance and EHS Manager)***

Directs, coordinates and leads the Environment, Health and Safety functions at the site including the development and implementation of strategies, policies and procedures in order to ensure that the facility operates to the highest EHS standards in compliance with statutory and corporate requirements.

The EHS and Engineering Services Manager is also responsible for the management of facilities and utilities, management of energy and sustainability programmes, management of abatement systems, troubleshooting, and management of plant shutdowns.

The present EHS and Engineering Services Manager is James Leahy. James has a Bachelor of Science in Mechanical Engineering from Trinity College in Dublin and a Masters in Engineering Design from the University College of Dublin (UCD). James also has over 30 years' experience as an engineering and project manager in senior roles and has been working at the Ballytivnan facility since October 2012.

James's responsibility also includes:

- Ensure processes and personnel operate within the requirements of appropriate medical device regulations;
  - U.S. Food and Drug Administration, 21 Code of Federal Regulations Part 820;
  - ISO 13485
  - AbbVie corporate and site policies
- Ensure that the necessary systems and procedures are available and operational to evaluate and control all aspects of facilities engineering. This includes the following:
  - Ensure safety standards are achieved and safe working practices are followed at all times.
  - Drive utilization of Maximo as both compliance and equipment performance monitoring system for PMs, DMs, and calibrations.
  - To ensure the performance of day to day preventative and demand maintenance activity to maintain manufacturing and utility equipment.
  - Drive implementation and performance of site under the Maintenance Excellence Program.
  - Generate and maintain calibration program for the entire site.
  - To maintain records and documentation on relevant Engineering Procedures and preventative/ demand maintenance.
  - To liaise with Internal/External Engineering Personnel and contract maintenance providers in maintaining trouble shooting, and installing/commissioning equipment
  - To monitor and control all site utilities on site, ensuring efficiency of operation and documentation of records
  - Cost control and project management of all site based projects
  - Implementation of robust KPI and metrics reporting process to measure performance of systems & processes.
- Assumes all responsibilities of the energy manager/energy management representative per ISO 50001;
- Responsible for administering as landlord the overall site lease which includes contractual responsibilities to provide facility, utility, and safety services to the third party tenant;
- Cost control and broad project management of all site-based projects via senior engineers;
- Use lean/6-sigma approaches to implement engineering solutions to drive operational/equipment efficiencies;
- Management and leadership of site EHS activities ensuring compliance with all safety & environmental requirements. Management of EHS policies and procedures to ensure that all site based activities are completed to corporate and local safety guidelines and standards & to ensure that safe working practices are followed at all times;
- Maintain an effective site Emergency Response Team;

- Management and leadership of site EHS activities ensuring compliance with appropriate regulations and that routine reporting is conducted with relevant regulatory agencies;
- Site Security Coordinator with responsibility to implementing global security initiatives. Liaise with Global Security Team in Chicago and France;
- Management and coordination of internal and external audits for Utility, Facility and EHS related activities;
- Maintenance of site Utility and Facility drawings;
- Active involvement in New Product Introduction to assess the necessary facility requirements;
- Drive cost improvement initiatives annual thru team of engineers to delivers annual Gross Margin Improvements for site;
- Budgetary control of annual site facility/utility engineering budget of 600M USD;
- Responsible for execution of capital budget of 1.5MM USD annually;
- Responsible for execution of lease agreement of 1.3MM USD annually;
- Responsible for ISO 14001, ISO 55001, OHSAS 18001-ISO 45001, and ISO50001 certification and program compliance; and
- Management and leadership of site EHS activities ensuring compliance with Industrial Emissions licence conditions and that routine reporting is conducted with relevant regulatory agencies.

### **EHS Engineer**

The Environmental, Health and Safety Engineer is responsible for having and maintaining programs and management procedures in place to ensure that operations at the facility are conducted to the highest standard in compliance with local, national, and European Union (EU), legislation and regulations and meeting EPA requirements, supported by relevant certifications.

The specific functions of the EHS Engineer that are relevant to the IE licence include:

- Support and continuously evaluate policies, procedures and systems within the plant to ensure compliance with local, national and EU legislation, EPA compliance, other external regulations and corporate requirements. Local country legislation takes preference over corporate requirements.
- Ensures compliance with all policies, procedures and guidelines to meet current Good Manufacturing Practice (cGMP) and Health Products Regulatory Authority (HPRA)/ Food and Drug Administration (FDA) regulations.
- Conduct risk assessments and identify preventative and corrective actions.
- Management of the facility's Industrial Emissions licence requirements.
- Preparation and submission of regulatory reports for the EPA, Irish Water, Sligo County Council etc.
- Auditing to ensure compliance with the sites Industrial Emissions licence, ISO 14001 & OHSAS 18001, and with the corporate management and technical standards.
- Responsible for presenting and taking ownership of own area during regulatory inspections, corporate audits and external interaction with the EPA.
- Ensure training programs are in place to support

The existing EHS Engineer for the IE licence is Breda Rafter. Breda has a Bachelor of Science (ordinary) in Health Science and Physiology and a Bachelor of Science (ordinary plus honours) in Occupational Health and Safety from the Institute of Technology Sligo.

Breda has over 8 years' experience in EHS including 4 years as the EHS Engineer for AbbVie Ballytivnan.

### ***Pharma Operations and Engineering Manager***

The Pharma Operations and Engineering Manager is responsible for the management of the new pharma suite including the engineering systems and processes, plant equipment, process development, and project improvements. Their contribution to the IE licence relates specifically to the control of processes and the prevention of un-controlled releases.

Michael Gallagher has a Bachelor of Engineering (Mechanical) from NUI, Galway. He has been employed as the Pharma Operations and Engineering Manager for AbbVie Ballytivnan, prior to which he was the Drug Product and IT/Automation Manager for AbbVie Manorhamilton. Michael has 20 years' experience in engineering and EHS including over 11 years in a management role.

### ***Pharma Quality Site Lead***

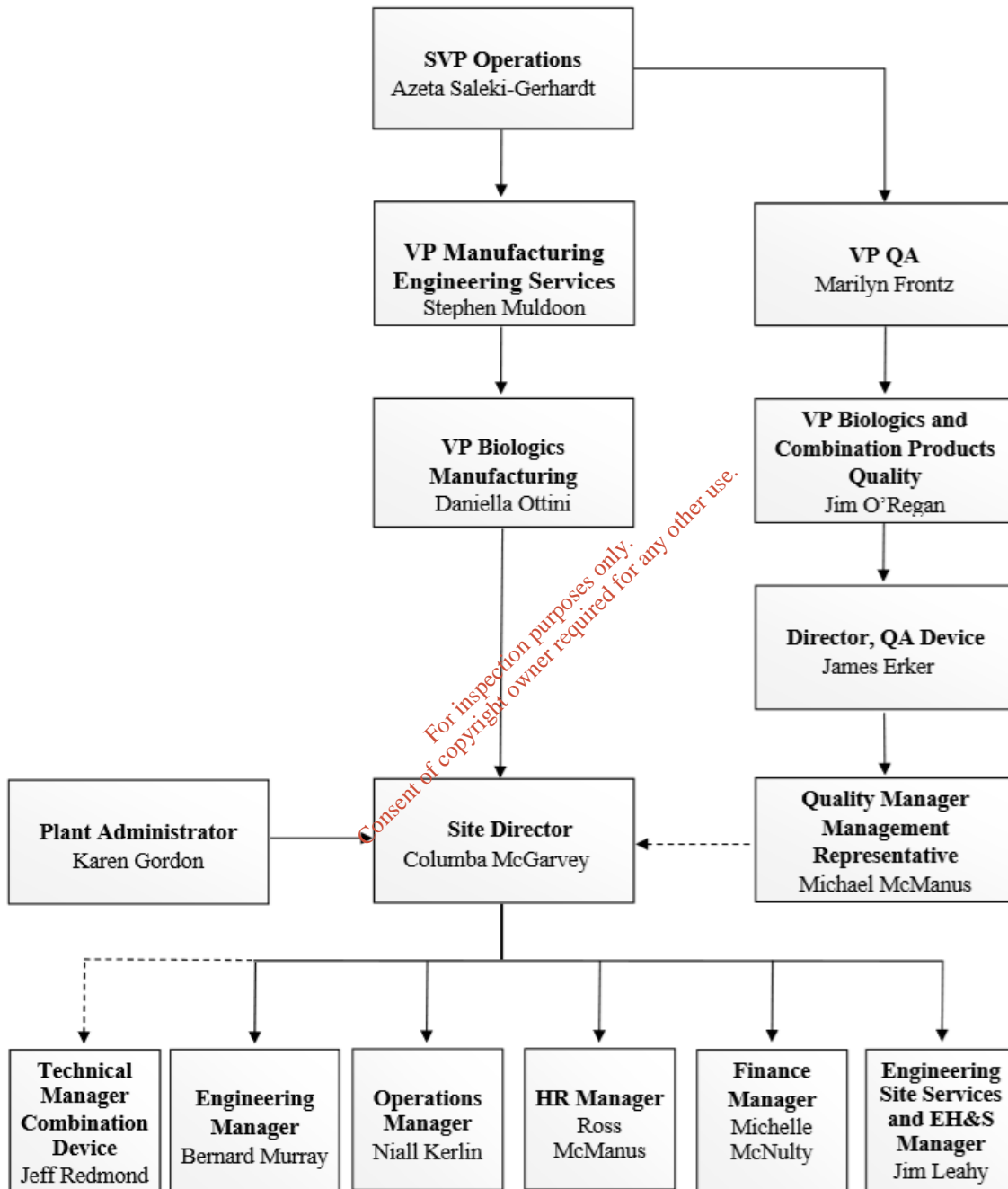
The Quality Site Lead is responsible for the overall operation of the quality system, ensuring compliance by all departments and personnel with all applicable Regulatory and AbbVie requirements. They also develop and maintain the company's quality system in compliance with all applicable regulatory requirements and to ensure that products manufactured at AbbVie Ballytivnan meet the requirements of end users, of regulatory authorities and of the company.

The Pharma Quality Site Lead for AbbVie Ballytivnan is Georges El-Damaa. Georges has a Master of Engineering, Chemistry from the University of Applied Sciences in Aalen, Germany, and a Master of Science in Pharmaceutical Manufacturing Technology from Trinity College in Dublin.

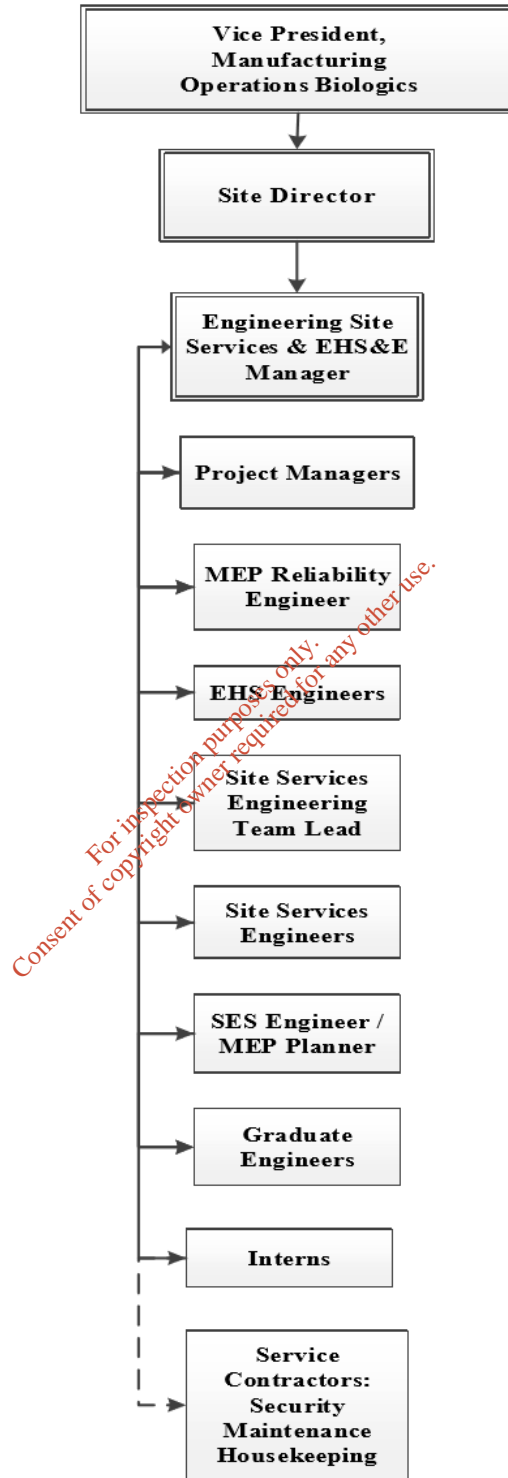
Georges has 9 years' experience working as a Quality Manager in both Switzerland and Ireland and has been a quality manager with AbbVie Ireland since 2015.

### Appendix 2.5.3-A

#### AbbVie Ballytinvnan High Level Organisational Chart



### AbbVie Ballytivnan EHS Organisational Chart

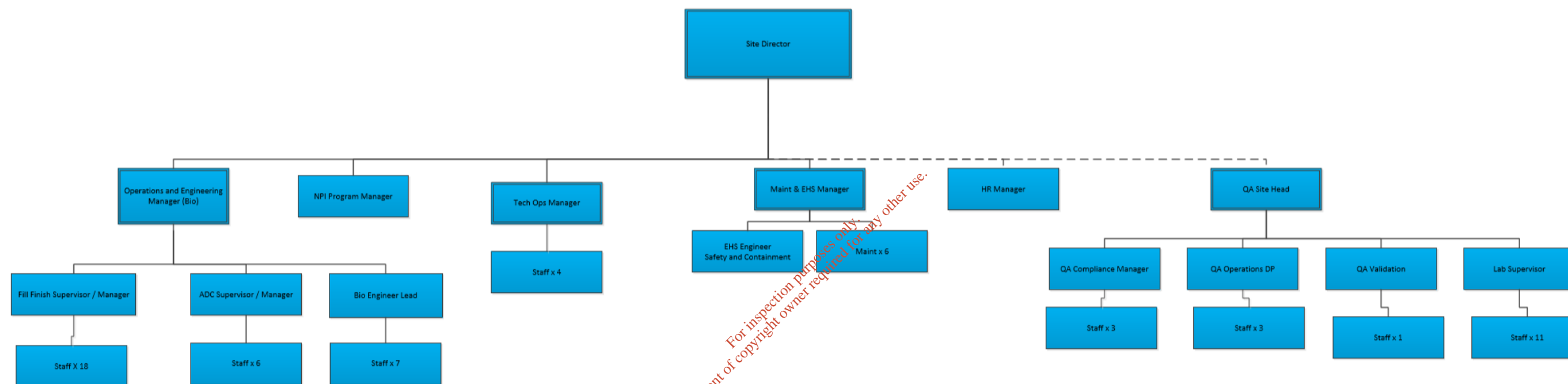


## Appendix 2.5.3-B

### AbbVie Ballytivnan Biologics Organisational Chart

*For inspection purposes only.  
Consent of copyright owner required for any other use.*

### AbbVie Ballytinnan Biologics Organisational Structure



For inspection purposes only.  
Consent of copyright owner required for any other use.