

Job Description

Job Title	Production Engineer; Engineering
Job Holder	
Reports To	Operations Chief of Staff
Location	Manufacturing, Billingham
Date	Nov 2020
Grade	33/34

Job Purpose

To lead the Management of Continuous Improvement within the engineering group and support the wider Operations Team in deploying Bio Manufacturing Excellence.

Dimensions

No of staff reporting to individual	None
No. of projects (per annum)	Support of 80+ batches across all facilities
Forward work plan	Up to twelve months
Key Techniques	<ul style="list-style-type: none"> • Root Cause Analysis • Coaching and development • Lean tools; 5S, 5C • Office skills: Word, Excel, PowerPoint, Trackwise

Principal Accountabilities

1. Develop a sound working knowledge of engineering processes and supporting Quality systems through experience and theoretical understanding of the purpose of each system.
2. Ensures any improvement projects implemented in the FDBK engineering functions consider the relevant Environmental, Health and Safety and cGMP regulations.
3. Has a deep understanding of the bio manufacturing excellence programme and the FDBK operations vision. Demonstrates practical application of the vision using deployment plans and performance measures.
4. Promotes use of potential problem analysis (PPA) where applicable to predict and mitigate against potential deviations affecting quality or schedule adherence.
5. Regularly spend time in the workshops and facilities (GEMBA), coaching the team to uphold the standards (Production Technologist Mind equivalent). Spend time in the manufacturing facilities to provide a 'fresh pair of eyes' to ensure standards are upheld across Operations.
6. Observes the performance of the engineering functions, determining trends and driving investigations to root cause. Uses observation to coach and mentor the teams to improve standards, deploying tools such as 5S and 5C to promote good control.
7. Develops and implements error proofing solutions to simplify day to day operations and support the goal of leaving no doubt.

8. Leads investigations into STOP and DELAY time using appropriate root cause analysis and the 5C system. Supports implementation of countermeasures and preventative actions as required.
9. Develops and deploys visual management tools to support the goal of status-at-a-glance.
10. Assists in development and owns roll out of the FDBK production technologist mind project, equivalent for engineering personnel, supporting the desired behaviours and coaching the team in their understanding.

Any other duties commensurate with the roll.

Competencies:

Level: Manager / Team Leader

Assessed: Business Standards & Integrity, People Development, Analytical Thinking, Change Leadership, Relationship Building, Planning, Achievement & Results Orientation, Process Management



Special Features

The Fujifilm Diosynth Biotechnologies manufacturing facilities at Billingham produce biopharmaceuticals from microbial or mammalian cell cultures for use in clinical trials or commercial supply.

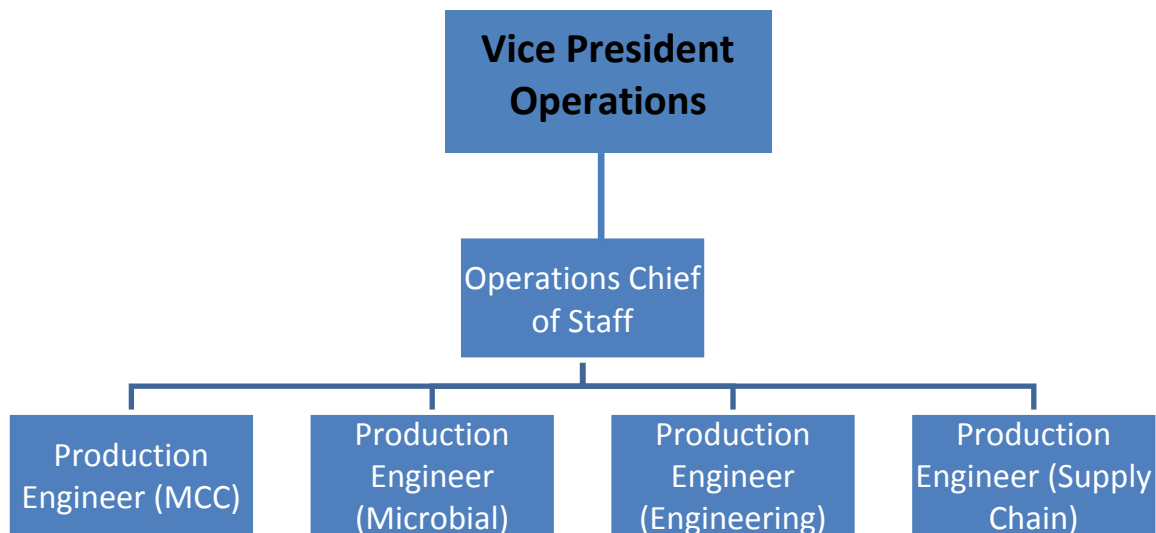
The FDBK manufacturing facilities are multi-functional, comprising of multiple manufacturing streams with supporting services and cleanroom infrastructure which operate to the standards of current Good Manufacturing Practice (cGMP), and may be audited at any time by Regulatory Agencies (e.g. MHRA, FDA) or customers.

The engineering function supports all of these facilities, and in addition the Process Development department also, therefore this person needs to be highly skilled to work cross functionally and understand the impact of any improvement projects or change management

The job holder is expected to continue developing systems that will support the current needs of the company, and future needs, which includes the identification of capital spend requirements and making business cases to seek approval for funding.

Communication needs to be effective and this job holder will need to maintain credible relationships with key stakeholders across all areas of the business.

Organisation Chart



Signatures

Job Holder: Date:

Manager: Date: