

Job Description

Job Title	Production Technologist / Cell Production Technologist
Job Holder	
Reports To	Lead Production Technologist
Location	Manufacturing, Billingham
Date	
Grade	31

Job Purpose

To contribute to a culture of manufacturing excellence through participation in Technology Transfer into and execution of manufacturing operations within FFDB production facilities.

Dimensions

No of staff reporting to individual	None
Forward work plan	Up to one week
Key Techniques	<ul style="list-style-type: none"> • Operation of Upstream, Downstream and analytical equipment as required by role • Aseptic technique as required by role • Environmental Monitoring if required • SAP interaction Office skills: Word, Excel, Powerpoint, Trackwise

Principal Accountabilities

1. Interact with R&D and Engineering personnel as part of a programme team to support Technology Transfer of projects into the manufacturing facilities and to conduct plant and process troubleshooting during manufacture.
2. Execute Technology Transfer and manufacturing activities to achieve manufacture schedule targets, this will include:
 - Ensuring facility readiness to manufacture in accordance with relevant checklists and procedures.
 - Understanding and executing production plans with limited guidance.
 - Execution of manufacturing operations according to Batch Manufacturing Records and associated Work Instructions.
 - Ensure accurate management of Raw Materials and consumables in SAP.
3. The job holder will understand the requirements of GMP (e.g. Purpose of a BMR, role of a Witness, Good Documentation Practice) and ensure accurate data recording of executed tasks and activities in Quality documentation including but not limited to Batch Manufacturing Records, Logbooks and Qualification Protocols.
4. Ensure appropriate training status for all tasks and activities to be undertaken and ensure these tasks and activities are performed in a safe and compliant manner.
5. Identify and appropriately report all potential safety risks and violations.
6. Identify and appropriately report all deviations from defined operating procedures.

7. Demonstrate ownership of designated equipment and systems.

8. Any other duties commensurate with grade.

Competencies:

Level: Core

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



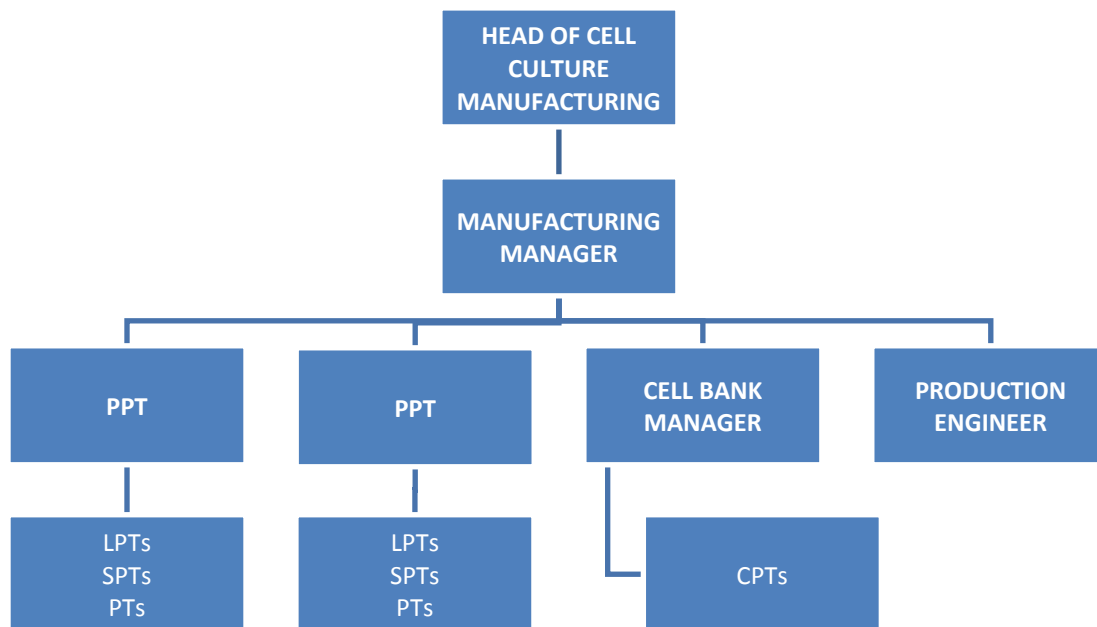
Special Features

The Fujifilm Diosynth Biotechnologies manufacturing facilities at Billingham produce biopharmaceuticals from microbial or mammalian cell cultures, these products will be used in clinical trials or for commercial supply.

The FFDB 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.

Personnel working in the manufacturing facilities therefore must be highly skilled to ensure successful process transfer and execution and flexible to the needs of the manufacturing schedule.

Organisation Chart



Signatures

Job Holder: Date:

Manager: Date: