

Job Description

Job Title	Lead Production Technologist
Job Holder	Vacant
Reports To	Principal Production Technologist
Location	Manufacturing, Billingham
Date	October 2019
Grade	33

Job Purpose

To lead Technology Transfer into and manufacturing operations within FFDB GMP production facilities whilst exemplifying the core values of the Biomanufacturing Excellence Mission Statement

Dimensions

No of staff reporting to individual	Up to 6
No. of projects (per annum)	Up to 20 – 25 manufacturing batches per year made and dispositioned, representing 8 – 10 different products.
Forward work plan	Up to one month
Key Techniques	<ul style="list-style-type: none"> • Line Management of manufacturing team members • Technology Transfer • Customer interaction • Root-Cause Analysis Office skills: Word, Excel, Powerpoint, Trackwise

Principal Accountabilities

1. Demonstrate ownership and leadership within the manufacturing environment by ensuring relevant EHS and GMP standards are continually maintained. The job holder will lead by example and demonstrate the ability to challenge and change unacceptable practices to continually improve ways of working in manufacturing.
2. Has extensive knowledge of the manufacturing process and operation of associated production equipment, acts as the primary manufacturing contact throughout the lifecycle of Technology Transfer and process execution (GMP preparation, manufacture and batch disposition).
3. Collaborates within programme teams to create all documentation required to execute a manufacturing process, ensures processes transferred to the manufacturing facility are designed to operate safely and compliantly.
4. Creates, monitors, executes, adjusts, and communicates manufacturing plans and co-ordinates associated production team resource to achieve manufacturing schedule targets.
5. Provides appropriate decision making and assessment of impact on product quality through a thorough understanding of the theoretical concepts and principles relating to cGMP manufacture.
6. Leads process related investigations in collaboration with development and engineering teams to establish the root cause of failures.

7. Interacts with customers and regulatory agency personnel during visits, audits and manufacturing status communications.

8. Any other duties commensurate with grade.

Competencies:

Level: Manager / Team Leader

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



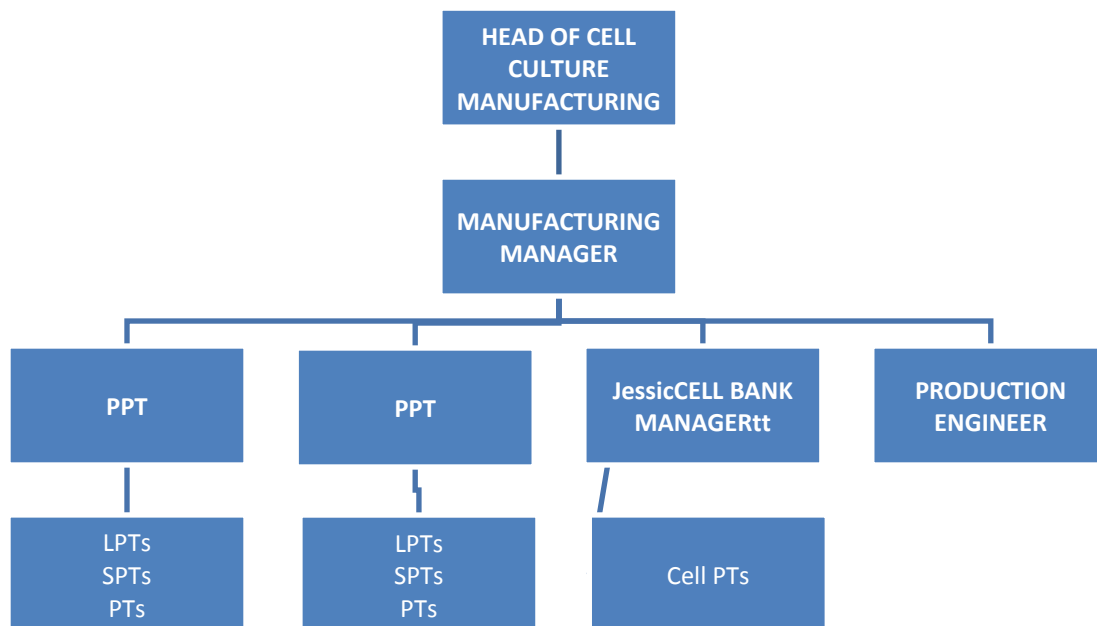
Special Features

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 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: