

Job Description

Job Title	Senior Production Technologist / Senior Cell Production Technologist
Job Holder	
Reports To	Lead Production Technologist
Location	Manufacturing, Billingham
Date	
Grade	32

Job Purpose

To lead manufacturing activities and support technology transfer as an active part of the manufacturing excellence culture.

Dimensions

No of staff reporting to individual	Up to 4
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 1 Week
Key Techniques	<ul style="list-style-type: none"> • Supervision of manufacturing team • Operation of Upstream, Downstream and analytical equipment as required by role • Aseptic technique as required by role • Environmental Monitoring • SAP interaction • Office skills: Word, Excel, Powerpoint, Trackwise

Principal Accountabilities

1. Is trained in all key activities (e.g. Aseptic technique, Bioreactor operation, Chromatography, Environmental Monitoring etc.) and has demonstrated a high level of competence in one or more areas.
2. Interact with R&D and Engineering personnel to ensure accurate Technology Transfer of projects into the manufacturing facilities and to conduct plant and process troubleshooting during manufacture.
3. Undertake EHS Advocate role to support resolution of identified EHS risks and violations. Maintain authorised status to Issue and Accept Permit-To-Work.
4. 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.
 - Ensure safe and compliant execution of manufacturing operations according and accurate completion of supporting documentation.
5. Takes the lead during manufacturing operations, determines how best to achieve the overall production schedule through appropriate use of authority and assertiveness. Communicates status of a manufacture including the cause and potential consequences of any delay.

6. Is able to identify and appropriately report all deviations from defined procedures, make a preliminary assessment of impact on product quality and suggest possible courses of action. Can explain deviations observed to members of the QA department including potential consequences or issues which may result from a particular response.
7. Exemplify the “FDBK Production Tech Mind” by taking ownership of areas of the manufacturing assets and ensuring EHS and GMP standards are maintained and by coaching junior members of the Manufacturing team whenever a potential need is identified.
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



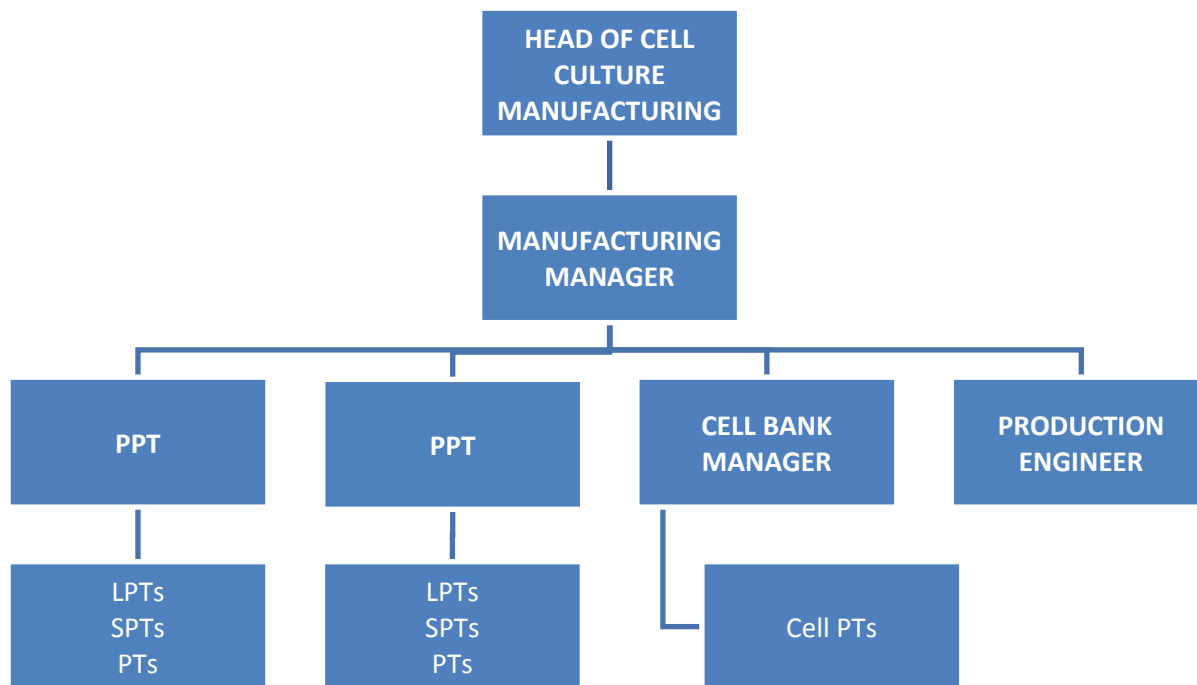
Special Features

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: