

JOB DESCRIPTION	
JOB TITLE:	Lead Production Technologist
JOB HOLDER:	
REPORTS TO:	Principal Production Technologist
LOCATION:	Manufacturing, Billingham
<u>JOB PURPOSE</u>	
To lead Technology Transfer into and manufacturing operations within FFDB GMP production facilities whilst exemplifying the core values of the Biomanufacturing Excellence Mission Statement.	
<u>DIMENSIONS</u>	
NO. OF STAFF REPORTING TO INDIVIDUAL:	Up to 6
NUMBER 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 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	
<ol style="list-style-type: none"> 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 coordinates 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

KEY COMPETENCY	DEMONSTRATED BEHAVIOURS	PERFORMANCE INDICATOR
Analytical Thinking	<ul style="list-style-type: none"> Identifies root causes Understands and evaluates numerical data, tables charts or graphs to get to the cause of a problem Performs calculations and combines quantitative information in order to diagnose and solve a problem. Thinks through priorities. 	Investigations completed
Positive Self-Image	<ul style="list-style-type: none"> Is confident in his or her ability to overcome obstacles Is confident in dealing and working with others Displays confidence while taking on new responsibilities Deals positively with situations that could be seen as stressful or threatening 	Positive feedback from PM / TPL
Independence	<ul style="list-style-type: none"> Takes a stand on critical issues Is prepared to disagree with colleagues or more senior people Raises problems openly Is prepared to question established systems, organisational norms and values 	Feedback from PM / TPL
Development Orientation	<ul style="list-style-type: none"> Gives people assignments or training to develop their abilities Gives specific feedback to help improve performance Gives people latitude to do more challenging or interesting tasks to help them develop 	Total movement of team on training matrix
Results Orientation	<ul style="list-style-type: none"> Organises and brings resources together to help achieve an objective Delegates tasks to ensure the job gets done Eliminates unnecessary risks 	Number of overdue Quality actions
Concern for Standards	<ul style="list-style-type: none"> Takes firm action on sub-standard performance Checks on projects to make sure they are being done properly 	Total number of comments/deviations raised per batch

Note: This is not an exhaustive list and further information on behaviours can be found by reference to the Competency framework.

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.

Signed / Dated (Individual)	
Signed / Dated (Line Manager)	