FUJIFILM Diosynth biotechnologies

Job Description

Job Title	TPL
Job Holder	
Reports To	sTPL / Head of the TPL Group / Head of Technical Support/
Location	UK
Date	Sept 2019
Grade	34

Job Purpose

The Jobholder sits within the TPL group and is accountable for the delivery of challenging technical elements of a PD program by the application of scientific knowledge, project management and leadership skills.

The Jobholder directs the work of multi-disciplinary teams and ensures that project milestones are met on time and to budget, thus ensuring that program margins are achieved.

The Jobholder is the primary technical point of call for the Customer on a program, and guides and informs them through the Project stages from Tech Transfer through to GMP manufacture.

Dimensions

Turnover	£100 million
Site Numbers	500
No of staff reporting to individual	None
Turnover per project	£1 million to £5 million
No of project staff reporting to individual (per project)	3-7
Forward work plan	6 to 24 months

Principal Accountabilities

● To have substantial theoretical and practical knowledge in the fields of Biochemistry, Protein Purification, Biochemical Engineering and associated analytical techniques.

● Must possess excellent interpersonal skills to deal with both international customer programme managers and multifunctional internal programme teams.

● To maintain a close working relationship with the Program Manager, keeping them regularly informed or progress and any problems which may cause a deviation from the SOW or the program timeline.

● As the primary technical contact with the customer, the jobholder must build excellent customer relationships through the use of customer management skills, attentiveness to the technical needs of the customer and a prompt response to any customer requests.

● Be proficient in the generation of summary presentations and the delivery of these to customers either Face to Face, or during telecoms.

● To manage one standard program, and occasionally a second partial technical program in parallel.

● To co-ordinate the technical activities of multidisciplinary teams (upstream, downstream and analytical) to ensure that key project activities are kept on track.

● Is accountable for the technical oversight and delivery of a customer program, from the Tech Transfer stage through to GMP manufacture.

● To be accountable for technical milestones on a program, ensuring that they are all completed on time and to budget.

● To ensure that work performed is within the boundaries of the original SOW, thus maintaining the expected program margin.

● To manage project resources and amend levels commensurate with the volume of work being performed, thus maximising program profitability.

● To attend functional Tier meetings in order to report progress of the Technical work program against the stage deliverables.

● To ensure that the principles of Good Project Practice (GPP) are adhered to (regular Project Meetings, Project Plans, Tech Review)

● To ensure that members from each PD function team attend the Project Meetings and review current technical progress, thus ensuring that they a clear picture on the project requirements, timelines and deliverables.

● To ensure that the Project Teams follow the principles of Good Research Practice (GRP) where experimental work is documented effectively in laboratory note books, proformas, and as raw data files (either as paper or in electronic format).

● To ensure that the Project Team works safely at all times by performing the required COSHH and risk assessments before performing any laboratory work.

● Using skills in leadership and people management, to be empathetic to the needs of individual team members, and therefore build motivated and highly productive teams.

● To review Proposals and SOWs (Statements of Work), assimilate knowledge of customer processes, and translate them into detailed technical plans.

● Preferably have experience in the operation of lab scale and manufacturing scale equipment used in the purification of Biologics.

● Be proficient in overcoming technical problems by the application of sound scientific expertise and past project experience, as well as by the employment of innovative solutions.

● Be experienced in reviewing and interpreting experimental data, and adapting experimental plans to suit.

● Capable of authoring accurate and compliant summary reports for various stages of project work.

● To use scientific process knowledge and awareness of GMP and large scale manufacturing requirements to identify scale-up issues and solutions, and to develop robust manufacturing processes suitable for GMP manufacture.

● To produce a Process Specification document to be used to generate BMRs for GMP manufacture.

● To provide technical guidance to MEG through GMP and HAZOP reviews and other activities occurring prior to GMP manufacture.

● To liaise with QC in the generation of the QC document which summarises the product specification determined in PD.

● To provide Technical Support to Asset Operators during GMP manufacturing, and offer sound technical advice should processing issues be encountered.

● To be concerned with the adherence of the GMP manufacture to the specified technical process designed in PD (the Process Specification).

● To be prepared to chaperone the customer in the Asset during GMP manufacturing.

● To assist QA in the GMP review of executed BMRs, and to provide technical guidance in the closing of comments, events, deviations and non-conformances.

● To be prepared to perform practical lab-work when required, and perform on shifts, particularly during large scale demo runs.

● To interact with the Process Design Group on later phase programs during the design and delivery of FMEA and LPC studies, and the support of process validation activities when required.

● To be prepared to provide technical input to regulatory inspectors during Health Authority audits.

● To engage with the PD Technical tools (Tech Review Process, Standard Work Elements, Process Model, and Process Specification) in order to ensure on time delivery of robust, scalable GMP processes.

● To ensure that their TPL training compliance is kept up to date, reportable on a monthly basis.

Competencies: People Development
Level: Manager / Team Leader
Assessed: At interview

Competencies: Customer Focus
Level: Manager / Team Leader
Assessed: At interview

Competencies: Analytical Thinking
Level: Manager / Team Leader
Assessed: At interview

Competencies: Relationship Building
Level: Manager / Team Leader
Assessed: At interview

Competencies: Planning
Level: Manager / Team Leader
Assessed: At interview

Competencies: Achievement and Results Orientation
Level: Manager / Team Leader
Assessed: At interview

Special Features

- TPL experience should be one the following:
    - Coming from an internal route, will be a graduate typically having 3 years experience as a Lead Scientist, plus management of between 1 to 5 significant programs.
    - Coming from an external route, will be a PhD typically having 5 years post-graduate experience in a relevant biochemical field

- To provide Technical Support to a program on which the individual worked on directly in a previous iteration of the project, or to support a program where the individual has expertise in a particular area (e.g. pegylation chemistry, similar molecule).

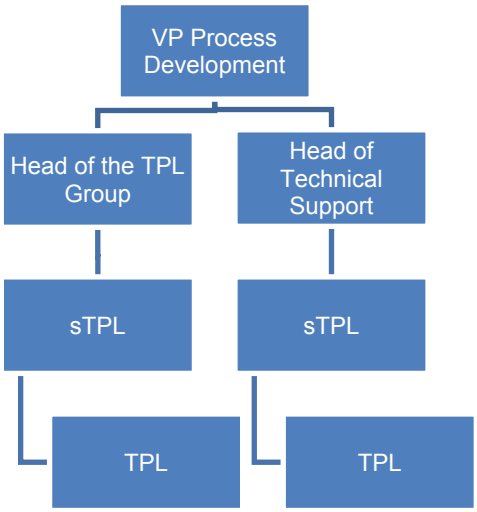
- To be able to travel to customer sites for Face to Face visits, either as commercial support, or as part of the technical program of work.

- To support the Program and Commercial functions during customer visits, or to help in the reviews of Proposals and Statements of Work.

- To engage with the SMEs (Subject Matter Experts) and assess new technologies within the scope of a program, or feedback any novel technical discoveries to the SMEs in order to consolidate core process knowledge.

- To aid the Head of the TPL group in continuous improvement activities such as the generation or evolution of Project tools (Process Specifications, Process Models, Report templates), as well as any other activities that improve the efficiency of the TPL Group (TPL delegates).

Organisation Chart



Signatures

Job Holder: . . . . . Date: . . . . . .

Manager: . . . . . Date: . . . . . .

Revision Table

Revision History	Date of Update	Authoriser
Revision 1	May 2017	A Razzaq
Revision 2	24Sept19	R Quin

Revision History – Amended due to revised Behavioural Competency Framework. Also changed R&D to PD.