ViroCell Biologics Ltd - Job Description			
Job title	Principal Project Engineer – Pharmaceutical Manufacturing	Reports to position	Director, Manufacturing
Supervisory organisation	Manufacturing	Grade	Principal
Job description summary (Primary responsibilities)	• Responsible for leading the execution of Capital / Equipment Projects in conjunction with ViroCell Validation & Great Ormond Street Hospital (GOSH) • Lead development and implementation of documented policies and procedures related to equipment / system / process implementation • Lead new equipment / process introduction and operational excellence activities including ownership of associated change documentation (e.g. Change control, Quality Risk Assessments) • An extensive 'hands on' approach is essential • Take ownership of any equipment based capacity improvement projects, including improvements to the maintence activities and equipment reliability • Responsible for ViroCell's equipment and facility project tracking/management, leading status meetings and mentoring staff from other departments in conjunction with ViroCell Validation & GOSH • Accountable for ensuring that these projects meet scope, schedule and budget • Act as principal point of contact between Virocell and GOSH Engineering / Calibration / PPM / Estates activities related to facility, equipment and systems for manufacturing • Support procurement of fit for purpose equipment / facilities for manufacturing and generating URS documents		
Key accountabilities			
Location	On site / London		
Qualifications			
Degree	Minimum BEng or Equivalent accreditation	Field of study	Engineering or related discipline
Certifications	N/A		
Work experience			
Area	Pharmaceutical (GMP)	Level	Mid >6 years
Competencies and Behaviours			
Leadership	Leadership of ViroCell Facilities and Equipment Engineering Matrix management / indirect people management responsibilities		
Driving results	Leadership of Engineering based activities related to ViroCell Facilities and Equipment. Responsible for on target delivery (milestones, time, cost)		
Agility	Technical agility and flexibility, working on multiple aspects of Facility / Equipment. Creativity in problem solving		

Effective communication	Strong communication and interpersonal skills Capable of representing Engineering function in cross interactions with other functions within ViroCell, as well as with external collaborators / vendors / stakeholders
Issue resolution	Able to raise, report, prioritise and resolve issues in a timely manner and effectively Able to proactively identify potential issues problems and ensure preventative steps are taken
Customer focus	Strong customer focus, responsible for timely execution of projects and effective resolution of issues to ensure minimum manufacturing down time
Collaboration	Strong collaboration culture ensuring effective working cross functionally within ViroCell and in engagements with collaborators / vendors / stakeholders
Negotiation	Strong negotiation ability in cross-functional activities and for collaborators / vendors / stakeholders expectation management
Influence	Strong influencing ability in cross-functional activities and for collaborators / vendors / stakeholders expectation management
Functional responsibilities	
People	Indirect people management in the short term through matrix teams; may have direct line management in the future
Budget	Responsible for procuring the budget for Facilities / Equipment / Engineering spend
Quality	Ensure that facility, equipment and process are maintained in qualified and validated state
Safety	Responsible for safe working within GMP areas including that of 3rd party engineers

Job Description

- Responsible for the direction and management of all engineering project / ppm activities specific to Virocell for GMP operations. This includes:
    - Input into maintenance / development of asset register of all ViroCell equipment in conjunction with ViroCell Validation & GOSH
    - Responsible for establishing service contracts with 3rd party vendors for Virocell systems
    - Responsible for raising permits to work, collating engineering service reports, input into controlled drawings etc
    - Continuous improvement of liaison strategy between PPM / Projects / Manufacturing / Validation to ensure projects delivered On Time In Full
    - Ensure compliance with EU GMP & regulatory expectations,safety policies and good housekeeping
    - Ensure that HS&E practices are understood and followed
- Responsible for ensuring smooth operations of facility and equipment:
    - Out-of-hours call out for facility / equipment issues for Virocell activities
    - First line of response for facility / equipment issues / breakdown
    - Responsible for contacting and liaising with 3rd party vendor for trouble shooting in the event that the issues cannot be resolved internally. Ensure that response time is per SLA
    - Maintenance of equipment spares for Virocell
    - Ownership of facility / equipment CAPA

- Support new process / product introduction through:
    - Generate URS
    - Key Stakeholder in organisation of FAT / SAT / Commissioning and ensuring equipment is installed as per installation plan / URS
    - Overseeing procurement, installation, operation and maintenance of facility / systems / equipment together with Manufacturing & Validation Groups at ViroCell and 3rd party teams
- Drive continuous improvement through:
    - Responsible for identifying and driving programmes for reduction in plant down time
    - Contribute to the development of ViroCell Capital Project plan and budget
    - Drive continuous improvement and lean manufacturing
- SME Engineer for Regulatory Inspection and / or customer audits relating to Virocell activities

Experience, knowledge and skills

Essential

- A minimum of 6 years Engineering experience in GMP pharmaceutical manufacturing environment; experience in biopharmaceutical / ATMP / CGT environment
- Familiarity with equipment including but not limited to isolators, incubators, bioreactors, chromatography, tangential flow filtration systems, temperature controlled units and filter integrity test systems
- Familiarity / Knowledge of Qualification and Validation principles and practice
- Knowledge / Experience of regulatory guidelines - EU GMP/ICH/FDA/EMA/ISO/ISPE and other requirements
- Famiiarity with facilities manufacturing sterile products
- Project management experience
- Experience in operational excellence

Desirable:

- Experience with MES / SCADA systems and automation
- Experience with plant systems found in pharmaceutical GMP facilities including HVAC, electrical supply, and sterile utilities

This job description has been developed based upon the expected and current duties, responsibilities and requirements for the position. Job requirements evolve with the changing needs of the company, this job description is subject to change and may be modified in line with business requirements.

Please send us an email with your CV / resume to apply@virocell.com

Thank you!

August 2023