ViroCell - Job Description			
Job title	Scientist, Quality Assurance	**Reports to position**	Manager, Quality Assurance
Supervisory organisation	Quality Assurance	**Grade**	N/A
Job description summary (Primary responsibilities)	• Support the creation, maintenance, and continuous improvement of ViroCell's quality management system (QMS), ensuring compliance with applicable regulatory requirements. • Support operational QA duties to ensure EU GMP compliance and other regulatory requirements relating to ViroCell's manufacturing activities. • Support and deliver ViroCell's training programme.		
Key Accountabilities			
Location	On site / London		
Qualifications			
Degree	Minimum of BSc or equivalent	**Field of study**	Life sciences
Certifications	N/A		
Work Experience			
Area	Pharmaceutical (GMP)	**Level**	Entry/Mid >2 years
Competencies and Behaviours			
Leadership	Display leadership where required; not essential to role.		
Driving results	Ensure that all tasks and projects are executed within established timelines. Self-motivated and willing to accept temporary responsibilities outside of initial job description.		
Agility	Ability to think critically and demonstrate troubleshooting and problem-solving skills. Ability to function efficiently and independently in a fast-paced, changing environment.		
Effective communication	Strong verbal/written communication and interpersonal skills. Capable of representing ViroCell QA in engagement with internal and external stakeholders and auditors/inspectors.		
Issue resolution	Able to prioritise, raise, report and resolve issues in a timely manner and effectively. Able to proactively identify impending problems and ensure preventative steps are taken.		
Collaboration	Strong collaboration culture ensuring effective working within cross-functionally within ViroCell and in engagements with collaborators.		
Negotiation	Able to negotiate on projects when necessary.		
Influence	Strong influencing ability in cross-functional activities, stakeholder and collaborator expectations.		
Functional Responsibilities			
People	To train peers and work collaboratively.		
Budget	N/A		

Quality	To drive quality culture across team.
Safety	To maintain safe working standards at all times.

Job Description

- Operate within and provide training on the principles of data integrity, intellectual property, and quality management system (QMS) operation.
- Work cross-functionally, fostering teamwork and cooperation to achieve quality outcomes and objectives.
- Generate and review GMP documentation and data in line with regulatory requirements and local guidance.
- Generate and review different types of quality records (e.g.: deviations, Change Controls, Risk Assessments, CAPAs, etc).
- Demonstrate ability to write and review SOP's in line with regulatory and local guidelines.
- Review and approve Batch Manufacturing Records.
- Provide guidance and assistance on qualification/validation activities, as required.
- Technical knowledge of quality requirements for aseptic manufacturing processes and laboratory techniques.
- Support Quality data collection and trending.
- Support and deliver ViroCell's staff training programme.
- Demonstrate ability on training staff, including cross functional team members.

Experience, Knowledge and Skills

Essential

- Relevant QA experience in a GMP setting.
- Knowledge of EU GMP and relevant regulatory agencies.
- Experience authoring, reviewing, and implementing methods and/or SOPs in a GMP environment.
- Good command and proficiency in MS Word.
- Knowledge of regulatory agencies and bodies, eg, MHRA, FDA, EU Pharmacopoeia etc.
- Knowledge/awareness of Data Integrity guidelines ie. ALCOA

Desirable

- Understanding of clinical trial regulations/directives.
- Experience with equipment qualification and validation plans.
- Experience with electronic quality management systems (e.g.: Q-Pulse).

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