ViroCell Biologics Ltd - Job Description			
Job title	Scientist, QC Analytics	**Reports to position**	Principal Scientist, QC Analytics
Supervisory organisation	Quality	**Grade**	tbc
Job description summary (Primary responsibilities)	☐ Responsible for the development up to qualification and validation of a wide spectrum of analytical assays to support product characterisation during and upon GMP manufacture. ☐ Creating GMP Documents ☐ To become SME in various methods ☐ Organise and execute *in-house* QC testing activities. ☐ Participate in Project Managing the outsourcing to third parties of QC assays that are not performed *in-house*. ☐ Mentoring and training junior team members. ☐ Liasing with 3rd parties for GMP testing and QC batch release		
Key Accountabilities			
Location	On site/London		
Qualifications			
Degree	Minimum of BSc or equivalent	**Field of study**	Biological/Biomedical Sciences or related discipline
Certifications	N/A		
Work Experience			
Area	Pharmaceutical (GMP)	**Level**	Entry/Mid >3 years
Competencies and Behaviours			
Leadership	Display leadership when required.		
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.		

Issue resolution	Able to raise, report and resolve analytical QC 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	Responsible for ensuring that all analytical testing activities are performed in line with regulatory expectations, and that quality culture is embedded.
Safety	Responsible for safe working within QC lab areas.

Job Description

- Work with the team to determine testing requirements for GMP raw materials, starting materials and manufactured products.
- Assist with the qualification and validation of analytical testing methods and processes to ensure their suitability to support GMP product manufacture.
- Support method development with external testing providers.
- Work closely with GMP Manufacturing, PD, R&D Analytics and other teams to ensure knowledge transfer in regards to process and testing.
- Participate in equipment qualification and preventative maintenance activities.
- Log and track samples for QC testing.
- Perform infectious titre and/or potency assays via cell transduction and end point PCR/Flow Cytometry.
- Support clinical product manufacturing through QC testing across multiple disciplines, including flow cytometry, qPCR/ddPCR and other cell culture, bioassays and molecular techniques.
- To assist in designing, optimising and developing methods.
- Review, approve/sign-off and report QC testing results.
- Mentor and train other users on how to perform QC analytical testing.
- Ensure the QC lab is maintained to adequate standards, with regular cleaning and equipment checks.
- Organise and oversee outsourced testing performed by third parties.
- Author and review SOPs/Forms and other GMP documentation, as needed.
- Provide deviation and investigation support, including unexpected or OOS results, and CAPA design/implementation.
- Participate in Batch release of ViroCell's manufactured GMP material.
- Participate in ViroCell's control of incoming materials programme, as needed.

- Ensure appropriate GMO risk assessments are implemented per product type and liase with the client appropriately to derive information.

Experience, Knowledge and Skills

Essential

- Experience in QC testing of Biologics/ATMP sterile products.
- Good working knowledge and usage of cell-based assays (flow cytometry, cell culture, PCR) and bioassays (ELISA).
- Practical QC laboratory experience within a GMP environment.

Desirable

- Method Development and Method Validation experience.
- GMP Batch Release Experience
- Experience in working with external suppliers and organisations.

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!