



## QC Cell Bank Analyst Job Description

**Job Title:** QC Cell Bank Analyst  
**Report to:** QC Cell Bank Manager  
**Location:** Billingham - Teesside  
**Date:** August 2018  
**Grade:** 30

### JOB PURPOSE

An Analyst provides analytical support to Biologics manufacturing and ASG projects. The job holder is responsible for following management direction and complying with the technical, operational, SHE and cGMP of their work to generate high quality, relevant, accurate and timely data to support the production, characterization and allied studies on products. The job holder will be expected to identify anomalies with data and contribute to team and site objectives.

The job holder will be laboratory based and be responsible for performing release and stability testing for both microbial and mammalian cell banks. In addition, the jobholder will be responsible for ensuring laboratory systems are maintained and adhered to, enabling compliant cGMP analytics to proceed expeditiously.

### DIMENSIONS

<b>Planning window</b>	Self-management 1-7 day timeframe
<b>Analytical knowledge</b>	Competency in a range of microbiological, analytical and wet chemistry techniques.
<b>Number of programmes</b>	Support to 3-5 at one time
<b>Value of Technical Group Income</b>	£1-2M per annum >15%
<b>Subject of inspection by regulatory agencies</b>	FDA, MHRA and EMA

### GMP RESPONSIBILITIES

1. To ensure all laboratory work undertaken is performed in accordance with cGMP quality system. The consequences of getting this wrong can range from the loss of data to support the use of material in clinical trials, to the loss of marketed batch of material. This could lead to lengthy delays for client programs and potentially to loss of business and company reputation.
2. Identify concerns with processes, methods or data and where possible develop or contribute to the development of solutions with management support.

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### **EHS RESPONSIBILITIES**

1. To ensure that all work undertaken complies with safety assessments contained with analytical methods and risk assessments.

### **PRINCIPAL ACCOUNTABILITIES**

1. To follow management advice and guidance and act as a team player.
2. To follow plans & objectives set for the team.
3. To have own work plan over period 1-7 days.
4. To generate data following applicable quality systems and local procedures to ensure accurate, well recorded, high quality data.
5. When required peer review of other data as part of the data checking processes.
6. To identify and raise concerns with management re: data anomalies or opportunity for continuous improvement.
7. Maintenance of key lab systems and processes (e.g. KanBan, 5S, etc.).
8. Good communication skills demonstrated within team.
9. Self-starting demonstrated willingness to research subject areas under development.
10. Flexibility to adapt to changing plans.

### **SPECIAL FEATURES**

1. The jobholder must have the willingness to seek out knowledge and to develop their competence as they gain experience.
2. The jobholder must possess the ability to clearly communicate within their team.
3. The job holder must have the ability to generate data following local procedures and Quality process to assure the data.
4. The jobholder must be able to critique data/processes and identify concerns.
5. The jobholder will be a graduate level scientist or have a minimum of 2 years of relevant experience.

### **CRITICAL COMPETENCIES**

1. Concern for standards
2. Results orientated
3. Ability to learn
4. Interpersonal awareness
5. Thoroughness
6. Flexibility
7. Tenacity
8. Rational persuasion
9. Analytical thinking

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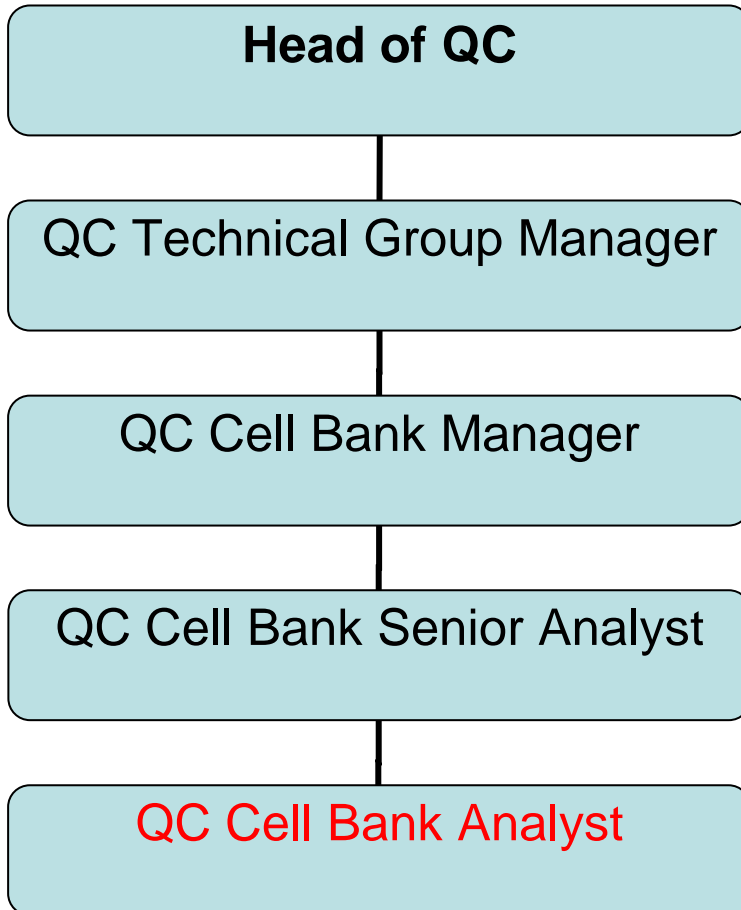
### **DESIRABLE COMPETENCIES**

1. Self-development
2. Excellent communication skills
3. Innovativeness
4. Initiative

### **ROLE SPECIFIC COMPETENCIES**

1. Support writing of cell bank QC doc & spec rationale doc
2. Peer review of cell bank analytical data based on competency
3. Routine testing of microbial cell bank (release & stability)
4. Maintain standards in areas used for cell bank testing
5. Support QIP's, Change Controls and Section 2 LI's
6. Raise Events , Section 1 LI's and AIM's (as required)
7. Inventory management of cell bank vials (e.g. stock checks, vial removal)
8. Ordering and preparation of special media & reagents for cell bank testing
9. Maintenance of relevant instrumentation used for cell bank testing (e.g. spiral plater)
10. Ensuring own training is timely completed and records appropriately maintained
11. Execute Microbial Purity testing without close supervision
12. Execute Viability testing without close supervision
13. Execute API Identity testing without close supervision
14. Execute Plasmid Retention testing without close supervision
15. Execute Lytic Bacteriophage testing without close supervision
16. Execute Growth Promotion testing without close supervision
17. Execute V&H analytics without close supervision (If applicable)
18. Perform routine cell bank dispatches (customer and outsource labs)
19. Support drafting of stability report and CoA / CoT's
20. Deputise for Senior Analyst
21. Yellow Belt and RCA trained (if applicable)

ORGANISATION CHART



**Signatures**

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

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