QC ELISA / Cell Assay Analyst Job Description

Job Title: QC ELISA / Cell Assay Analyst
Report to: QC ELISA / Cell Assay Manager
Grade: 30
Location: Billingham - Teesside
Date: MAR-2020

PURPOSE OF JOB

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 responsible for executing analytical and cell culture activities associated with ELISA and cell assay method establishment and validation, product stability and batch release testing. In addition, the job holder will be responsible for ensuring laboratory systems are maintained and adhered to, enabling compliant cGMP analytics.

DIMENSIONS

Planning window	Self-management 1-7 day timeframe
Analytical knowledge	Competency in a range of microbiological, analytical and wet chemistry techniques. Specialise in cell culture and *in vitro* plate assay techniques.
Number of programmes	Support to 3-5 at one time
Value of Technical Group Income	£1-2M per annum >15%
Subject of inspection by regulatory agencies	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.

EHS RESPONSIBILITIES

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

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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

DESIRABLE COMPETENCIES

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

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ROLE SPECIFIC COMPETENCIES

1. Creation of cell assay AMWB's
2. Peer review of ELISA and cell assay data/test records/WI's
3. Manufacture cell assay MCB's and WCB's and execution of associated contamination testing
4. Support ELISA and cell assay method establishment/qualification/validation
5. Maintenance of cGMP laboratories
6. Support QIP's, Change Controls and Section 2 LI's
7. Raise Events and AIM's as required
8. Reagent preparation and cell line maintenance
9. Execution of *in vitro* ELISA's and cell-based assays for product release, characterisation and stability
10. Inventory management of consumables and reagents
11. Creation of laboratory risk assessments
12. Support and lead (if applicable) laboratory 5S
13. Maintenance (e.g. performance checking) of laboratory instrumentation
14. Ensuring all training is completed in accordance with role requirements.
15. Maintenance of own training records

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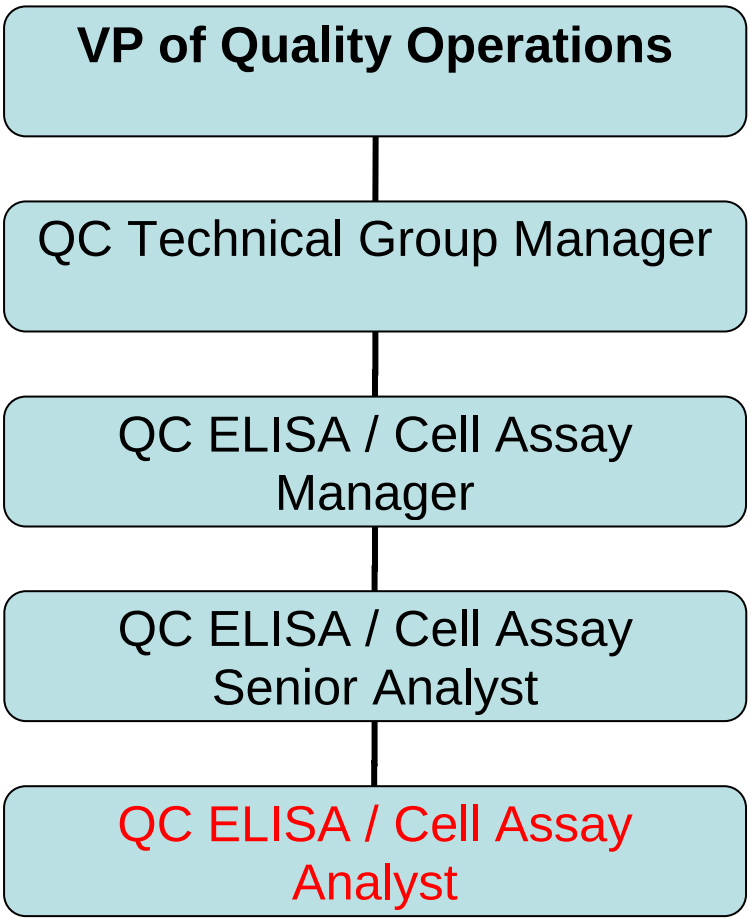
ORGANISATION CHART



SIGNATURES

JOB HOLDER:

Name .....

Signature .....

Date .....

MANAGER:

Name .....

Signature .....

Position .....

Date .....