FUJIFILM Diosynth biotechnologies

Job Description

Job Title	**Stability Study Owner (QC Team Manager)**
Job Holder	
Reports To	**Stability Group Manager (QC Manager)**
Location	**Billingham**
Date	**September 2019**
Grade	**33**

Job Purpose

The Study Owner provides a management, technical and quality role within the Analytical Services Group (ASG) to plan and deliver high throughput, high quality, GMP compliant and scientifically sound data to support ASG customer analytical strategies for Drug Substance, Drug Product and Placebo.

Dimensions

Turnover	£100 million
Site Numbers	500
No of staff reporting to individual	3 to 6 staff
Forward work plan	6 to 12 months

Principal Accountabilities

1. Manage and develop a Study Team of up to 6 Senior Analysts and Analysts.
2. Fully oversee and program manage Stability Studies to deliver scientifically sound and GMP compliant analytical data driven by predefined protocols.
3. Client manage Stability Studies and provide client management support to all members of the stability Team
4. Critically assess study data to identify data anomalies, trends, concerns, etc. and define appropriate responses such as trouble shooting or escalating.
5. Pace-set work processes and practices, seek to reduce inefficiency drive streamlining of work in the lab to speed up delivery to maximize throughput.
6. Self and Study Team respond to OOS/OOT in a timely manner and conduct routine quality investigations to root causes and arrive at meaningful and business improving CAPA. Complex investigations to be owned.
7. Own, develop and maintain trackers to ensure that all work owned by Study Team is planned on a gross scale (6 months +)
8. Own, develop, and maintain local planning processes for the day to month period that allocate work to Study Team members. Respond flexibly, proactively and innovatively when plans need to change.
9. Laboratory management – setting the EHS, quality and throughput standard for the Study Team and ensuring that the Study Team utilise and maintain equipment.
10. Implements, develops and qualifies/validates new techniques when required.
11. Identify defective FDBK processes, systems, analytics, approaches, etc and have the willingness to flag and the tenacity to drive innovative solutions when required.
12. Own the laboratory KPI's, monitors and respond to findings from laboratory metrics to enhance compliance and throughput. Devise new metrics as appropriate to changes laboratory practices/workflows.
13. Can draft PAO's and scope of work packages, as well as generating study protocols for new studies and protocol amendments for mature studies for review and approval. Therefore must be commercially aware and able to track scope creep and identify the need for contract amendments.

14. Responsible for establishing, owning and re-qualifying Reference Standard. Along with managing stock levels.

15. Own, develop and maintain Stability indicating Analytical Methods.
16. Responsible for delivery ASG income.

GMP, Quality and Regulatory Responsibilities

1. To ensure all activities performed by Study Teams are in accordance with cGMP quality systems, and is continually inspection ready. This includes quality data, peer review process, training and scientific understanding/knowledge about tests being performed.
2. To be able to front Study Team activities (eg: systems, protocols, data, non-complex and complex investigations etc.) at client audits and during regulatory inspections.
3. Guide and/or author the generation of key ASG documentation to support ASG activities (eg: protocols, reports, CoA's, CoT's, etc) and to maintain this documentation in agreement with contracts. Review and approve Quality documentation such as SOP's, WI's,etc. Without such key documentation ASG studies cannot occur.
4. Lead timely investigation (ie: LI's and deviations) and rapid reporting of out-of-specification/trend results ensuring that where required meaningful CAPA are established. Escalate and or manage more complex issues that cannot be resolved to QC Manager in a timely manner.
5. Maintain up to date knowledge of the regulatory requirements pertaining to ASG activities.
6. Approve and disseminate data from the group

Planning Responsibilities

1. Using the information provided by QC Manager and planning staff, establish and implement detailed 6-12 month plans for Study Teams to ensure that ASG programme deliverables are achieved according to procedures and within the timelines contractually agreed. This is critical for ASG studies when on time delivery of quality data is paramount to the integrity of the study, and building and maintaining customer confidence in ASG to deliver the analytical strategy (eg: data for filings, etc). As part of this interact with programs, program managers and clients directly
2. Establish, maintain and improve a tracker system for all ASG studies. Produce accurate slot definition plan for business planning meetings and defining when more work can be taken on.
3. Using the tracker system generate monthly S&OP milestones, test these at a monthly meeting for deliverability ahead of supply to the site S&OP process.
4. Represent the ASG at the departmental, site or customer meetings to discuss milestone setting/delivery and to represent operational aspects at business meetings when required.
5. Influence, drive change and motivate within own team and with senior management. Proven ability to mentor, train and trouble shoot.
6. Deputise for Stability Group Manager as required.

Management & EHS Responsibilities

1. Line management of up to 6 Analytical Staff (Seniors, Analysts and Tecnicians). To build motivated and achieving teams by good management practices, good decision making, good planning and on time quality delivery of studies.
2. Accountable for ensuring that the Study Team demonstrate scientific knowledge in their techniques/competencies and deliver high quality, GMP compliant data.
3. Responsible for identifying discipline and reward within their greater team after agreement from QC Manager.
4. Responsible for ensuring cover is in place to meet workload during holidays, regular 121's and PRP process within teams is met.
5. To ensure that specific analytical and product experience is disseminated and acted upon within the Study Teams and provide this to the QC Manager to aid with the wider discussion/decision making on the analytical strategy.
6. Laboratory manager, ensuring the laboratory and storage areas under your jurisdiction are safe and organised places for work, 5S manager
7. Accountability that all staff are operating in accordance with site and QC specific procedures and risk assessments relating to EHS.
8. Identification of opportunities to reduce EHS related risk and when required drafting the additional risk assessment as required by changing workload.

Customer, Technical & Commercial

1. Maintain, enhance and use knowledge of analytical techniques in use to interpret data and draw logical and scientifically sound conclusions. Use knowledge to empower Study Teams and to enhance their understanding of the techniques in day to day use.
2. Perform critical reviews to all stability studies using negotiation, innovation, troubleshooting and problem solving
3. Act as representative for the activities of the Study Team during customer correspondence relating to manufacturing and ASG programmes.
4. To maintain a routine working dialogue with customers in providing and finalising protocols, providing data and discussion on LI's and deviations.
5. To identify changes in scope to existing work packages and to draft suitable PAO's to cover scope changes and gain approval via QC Manager, financial and legal review.
6. For ASG activities overcome technical problems by scientific understanding and logic deduction and recommend/deliver good solutions based on testable theory.

Competencies:

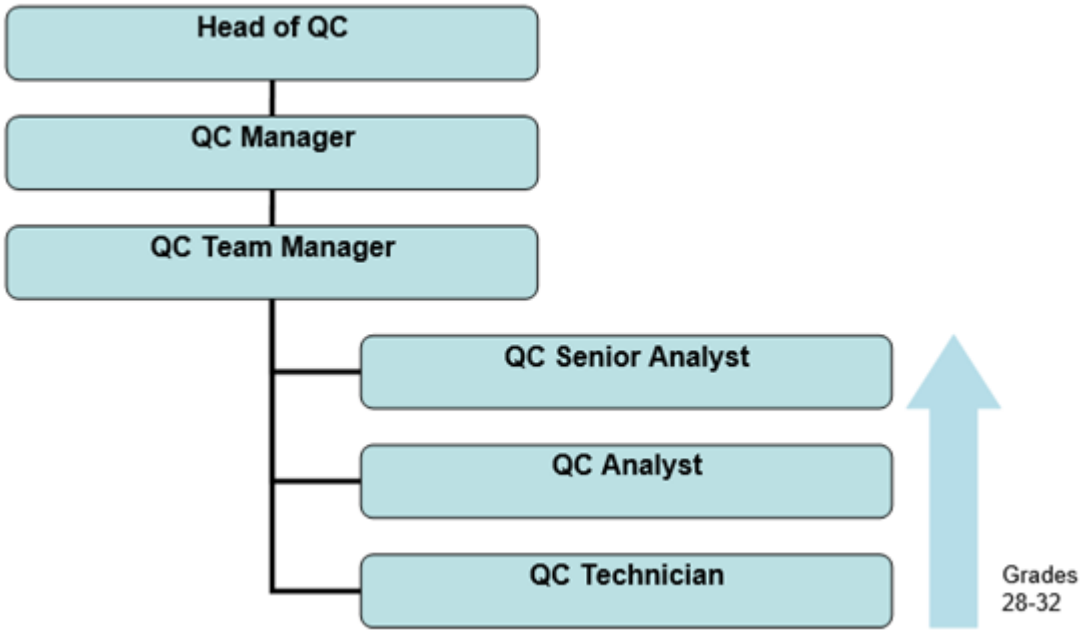
Level: Manager/Team Leader

Assessed: Business Standards & Integrity, People Development, Customer Focus, Analytical Thinking, Change Leadership, Relationship Building, Planning, Achievement and Results Orientation, Process Management

Special Features

1. The jobholder must have a sound knowledge of all ASG activities, team structure and interactions to support ASG studies such as and reference standard, stability and forced degradation as examples.
2. The jobholder must possess the interpersonal and strong communication skills required to ensure confidence in their abilities and their Study Teams capabilities across the ASG function, within wider QC/AD and with both international customers.
3. The jobholder must be able to manage, develop and motivate others, self-manage, have excellent organisational and time-management skills and respond appropriately to numerous requests and prioritise accordingly, within tight deadlines.
4. The jobholder must demonstrate the ability to execute studies reliably at high throughput, critique data, draw valid and valuable conclusions from the data and persuade and influence others on such conclusions.

Organisation Chart



Signatures

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

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

Revision Table

Revision History	Date of Update	Authoriser
Revision 1	11 July 2018	D Chesworth
Revision 2	01 April 2019	A Dickson

Revision History – Amended due to revised Behavioural Competency Framework