Senior Quality Assurance Specialist – Job Description

Role Purpose:

Quality is a key foundation of our business and through effective quality management, CPI will continue to add value to the company and help achieve its business goals.

The focus of this role is to lead the quality assurance activities promoting and integrating quality into every aspect of our business, providing quality assurance expertise and input on the quality management system (QMS) compliance for the CPI Biologics RNA Centre of Excellence at Darlington. In this role, you will perform a variety of tasks in support of specific areas of the site quality assurance function mainly focusing on the development, sustainability and continued improvement of the CPI Biologics RNA Centre of Excellence QMS to meet Good Manufacturing Practice (GMP) requirements.

Projects within CPI encompass a broad range of process technologies and novel measurement and analytical techniques, and this is reflected in the diversity of customers and their expertise.

Responsibilities and expertise specific to role:

To implement, monitor and maintain the CPI Biologics GMP QMS to support GMP manufacturing activities. Responsibilities and expertise include:

- Significant experience and understanding of the requirements of GMP and have the ability to apply knowledge in implementation, monitoring and maintenance to ensure the effectiveness of the GMP QMS.
- To support the development and ongoing maintenance of the control strategy and site master file for CPI Biologics GMP facilities to ensure they are current and appropriate to the activities being undertaken.
- To support, guide and advise on all aspects of manufacturing , QC and supporting operations within RNA CoE as the GMP SME
- Support the technical transfer of projects into the CPI Biologics GMP facilities to ensure compliance to GMP requirements and the CPI Biologics control strategy.
- Play a lead role in regulatory inspections, including the coaching and development of other SMEs and establishment of 'back room' processes and documentation flow
- Support as co-host any customer audits of the facility
- To ensure the skills required to deliver the quality assurance of the business are in place and to make recommendations where skills and equipment gaps exist.

Key Responsibilities:

- To maintain consistent and documented compliance with all relevant Safety, Health and Environment (SHE), Quality and best practice requirements.

- Lead and perform first line management for the other Quality Specialists and Quality Officers providing strong leadership, direction and continuous development opportunities.
- Perform all Quality Assurance duties and tasks in accordance with relevant GMP guidelines.
- Manage outsourced Quality activities with third parties.
- Manage the site Pharmaceutical Quality System including routine review and approval of change controls, deviations, OOS, action plans and CAPA
- Lead in the resolution of manufacturing, testing and packaging issues to support the release of products.
- Perform root cause investigations and quality risk assessments to GMP standards.
- Author, review and approval of policies, SOPs, work instructions and other quality documentation.
- Support both internal and external audits including leading audits, writing reports, agreeing CAPA and following these up as required.
- Oversee the supplier assessment program including audits, supplier evaluation and technical quality agreements
- Review and approval of risk assessments and validation documentation as required.
- Conducting Product Quality Reviews as required.
- Management customer product quality complaints received at site.
- To actively contribute to a culture of continuous capability development through coaching, mentoring and/or developing colleagues within the team and business unit, providing insights into areas of specialism. This may include coaching and developing junior colleagues (both technically and behaviorally) to help them reach their potential.
- To keep up to date with external developments in areas of specialism, and/or legislative, quality and SHE related changes, ensuring application of new best practice and/or knowledge.

Good Manufacturing Practice - GMP

CPI have a responsibility to manufacture medicinal products of the requisite quality, fit for their intended use and be in accordance with the relevant Manufacturing and Marketing Authorisations, Clinical Trial Authorisation, Product Specification, Drug Master File or CEP Dossier as appropriate and which do not place patients at risk due to inadequate safety, quality or efficacy. The Pharmaceutical Quality System, which incorporates Good Manufacturing Practice, is designed to deliver this quality objective, the attainment of which requires the participation and commitment of all staff across departments and at all levels within the company.

Good Manufacturing Practice is the part of Quality Management which ensures that products are consistently produced to the correct quality standards. To comply with the principles of GMP, it is required that clearly defined procedures are adhered to when performing operations across CPI.

Data Integrity - DI

Data Integrity is the degree to which data are complete, consistent, accurate, trustworthy, reliable and that these characteristics of the data are maintained throughout the data life cycle. The data should be collected and maintained in a secure manner, so that they are attributable, legible,

contemporaneously recorded, original (or a true copy) and accurate. Assuring data integrity requires appropriate quality and risk management systems, including adherence to sound scientific principles and good documentation practices.

CPI, as a GXP organisation, have developed a Pharmaceutical Quality System, which incorporates a DI Governance System – a series of arrangements to ensure that data, irrespective of the format in which they are generated, are recorded, processed, retained and used to ensure the record throughout the data lifecycle.

To comply with the principles of DI, it is required that clearly defined procedures are adhered to when performing operations across the site. All staff are actively encouraged/supported in the reporting of errors, omissions and undesirable results.

Direct reports: Up to 5 direct reports

Education / Qualifications:

Essential:	Desirable:
Educated to HNC or Foundation Degree level (or equivalent) in a Scientific/Engineering discipline plus significant industrial experience at a senior level Or Educated to Degree level (or equivalent) in a Scientific/Engineering discipline plus significant industrial experience Or Educated to Master Degree level (or equivalent) in a Scientific/Engineering discipline plus significant relevant industrial experience Or Educated to PhD level (or equivalent) in a Scientific/Engineering discipline plus industrial experience in a relevant field	Chartered status with a relevant professional institution

Competencies and behaviours	
Leadership (Enabling)	**Decision Making (Influencing)**
• Builds and leads groups, communicates a compelling and inspired vision or sense of core purpose to arrive at an agreed schedule of work for a project, including agreed success criteria. • Demonstrates commitment to common goals, integrity and trust in all dealings with colleagues and customers.	• Confidently draws reliable conclusions from diverse and sometimes incomplete data. • Proactively sources and refers to how others have tackled similar problems previously. • Considers risks, and consequences, and takes accountability for, the impact the decision has on the business including costs/ benefits.
Communication (Enabling)	**Developing self and others (Enabling)**
• Presents complex issues/ data with a high level of clarity and impact, using the appropriate format and driving action. • Is able to write clearly and succinctly recommendations and messages that have the desired effect. • Is aware of the impact of their communications and pro-actively seeks feedback for improvement. • Is able to influence others by preparing a reasoned argument to adopt a specific tactics or plan, in line with strategy, and persuade other of the merit.	• Supports others in their development. • Is personally committed to, and actively seeks, opportunities to improve continuously. • Provides honest helpful feedback to others on their performance. • Insightful about self, strengths and limitations, and how to maximise contribution.
Collaboration (Influencing)	**Delivery (Influencing)**
• Blends people into teams, leveraging the use of talents available from any part of the organisation that result in the most innovative solution. • Fosters a sense of energy, ownership, and personal commitment to collaborative work. • Understands priorities and deeper needs of different stakeholders groups. • Supports and enables people to work together to meet objectives.	• Prepares and maintain schedules for activities and events for projects. • Delegates responsibilities for tasks and decisions to the appropriate staff; sets SMART objectives and monitors progress. • Researches capabilities and constraints, in advance of a project, which could affect its approach and outcomes. • Holds people accountable for achieving results.

Knowledge and Experience:

Essential:	Desirable:
Will possess significant quality assurance expertise and experience of managing and operating within a GMP environment, developing, implementing and applying routine systems for quality assurance activities.	Is a member of a relevant professional body. Knowledge of ISO 9001 Quality Management System Standards. Knowledge of EU GMP Guidelines inc Annexes 11 & 15.

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Essential:	Desirable:
Will exhibit professional mastery of principles and practices in GMP quality management systems, gained in industrial environments. Strong attention to detail with a thorough approach and good organisational skills. Ability to work in fast paced environment, flexibility to adjust with moving priorities and ensuring attention to detail remains first class. Can demonstrate evidence of knowledge sharing and network building practice across teams or groups. Has ability to apply theoretical and practical quality tools and techniques to contribute to business activities. Can provide examples of actively utilising cross-team collaboration to achieve desired results. Has confidence to use own judgement and initiative within standard quality practices, as well as an understanding of when to seek advice from colleagues. Knowledge of EU GMP Guidelines Annexes 1, 2 & 13. Experience of operating and implementing safe systems of work and implementation of COSHH regulations and other Health and Safety procedures. Management and coordination of facilities and people.	Knowledge of EU Pharmacopeia standards. Experience in the use of Electronic Document Management systems and QMS.