Senior Quality Control Scientist

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 quality control support to the quality function, promoting and integrating quality into every aspect of our business, providing technical expertise and input on analysis 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 control function mainly focusing on the development, sustainability and continued improvement of the CPI Biologics RNA Centre of Excellence quality control function to meet 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 set up and run the CPI Biologics RNA Centre of Excellence QC and Analytical Lab to support development and routine GMP analysis. Responsibilities and expertise include:

- To understand the state-of-the-art of tools and knowledge in the application of analytical science in the Pharmaceutical sector
- To design, validate and utilise analytical methods for characterisation of pharmaceuticals.
- Support process technology development through timely completion of analytical techniques.
- To perform analytical characterisation of pharmaceuticals and data analysis to the highest standards and is delivered in compliance with CPIs GMP quality certification.
- To ensure the skills required to deliver the analytical needs 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.
- Support/supervision of other Quality Control Analysts and Technicians providing strong technical leadership, direction and continuous development opportunities.
- Perform all Quality Control duties and tasks in accordance with relevant GMP guidelines.
- Qualification, calibration and monitoring of analytical equipment.
- Manage outsourced QC activities with third parties.
- Support the site Pharmaceutical Quality System including input into investigations and/or CAPAs.
- Perform laboratory investigations and out of specification investigations to GMP standards.

- Author, review and approval of SOPs, methods and specifications.
- Support both internal and external audits including writing reports, agreeing CAPA and following these up as required.
- Review and approval of risk assessments and validation documentation as required.
- Conducting Product Quality Reviews as required.
- Support of 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 behaviourally) to help them reach their potential.
- To keep self 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.

Senior Quality Control Scientist

Direct reports: Up to 5 direct reports

Education / Qualifications:

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

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.	• Supports others in their development. • Is personally committed to, and actively seeks, opportunities to improve continuously.

Senior Quality Control Scientist

Competencies and behaviours	
• 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.	• 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 control expertise and experience of managing and operating within a GMP environment, developing, implementing and applying routine systems for quality control activities. Will exhibit professional mastery of principles and practices in GMP quality control 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.	Knowledge and experience of the application of at-line, on-line/in-line analytical technologies relevant to data collection and process control. Knowledge of ISO 9001 Quality Management System Standards. Knowledge of EU GMP Guidelines inc Annexes 1, 2 & 15. Experience in the use of Electronic Lab Notebook (ELN) systems.

Senior Quality Control Scientist

Essential:	Desirable:
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 Pharmacopeia standards. Knowledge of EU GMP Guidelines Annexes 11 & 13. Experience in the implementation and use of Laboratory Information Management Systems (LIMS). In-depth knowledge and practical experience in the development and application of analytical techniques and methodologies for characterisation methods of biological products and cleaning studies including and not limited to UPLC/HPLC, qPCR and UV Photometry. Competent in the development, validation and routine application of analytical methods for biological product analysis utilising a broad range of analytical technologies. 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.	