

#### **Role Purpose:**

To act as the recognised CPI domain knowledge expert in the development of robust, scalable processes to recover and purify products from a range of biological and chemical processes, providing deep technology capability that enables the development of CPI's scientific knowledge and practice and contributes to the realisation of project objectives.

#### **Key Responsibilities:**

- Embrace and role model the desired behaviours to exemplify our Company values, promoting an ethical, positive company culture.
- To maintain consistent and documented compliance with all relevant Safety, Health and Environmental (SHE), Good Manufacturing Practice (GMP), Data Integrity (DI), quality and best practice requirements.
- To contribute expert knowledge to inform CPI's technology strategy and translate this into deliverable plans to achieve business objectives.
- To anticipate new technology developments and to work in partnership with Commercial team and TIO colleagues to assess new areas for capability building.
- To work collaboratively with Business Development and technical colleagues to develop a
  process that assesses both the technical and commercial aspects of new business
  opportunities.
- To build and influence a value adding network of relevant external stakeholders.
- To represent CPI as a domain knowledge technical expert in industrial and academic forums to add to the body of UK technology knowledge and capability.
- To develop and retain relevant knowledge and capability to support UK industry in the translation of state of the art ideas into commercially viable processes and products.
- To build CPI's capability base by identifying and developing potential through coaching and motivating colleagues.
- To mentor CPI colleagues and people in partner organisations, building collaborative knowledge sharing relationships.
- To lead a culture of continuous technology capability development within teams in alignment with CPI strategy and project deliverables.
- To partner Bid Development teams, providing insight and expertise to bid creation.
- To formulate and present technology solutions to complex applications using deep technical knowledge.
- To analyse, interpret and report impact and translate data into commercially relevant information.
- To model best practice in relation to knowledge management providing clearly documented records of technical data, decisions, methodologies, calculations and software use in an agreed format.

#### **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:** No direct reports

#### **Education / Qualifications:**

Essential:	Desirable:
At least one of the following in a relevant, technical discipline:	PhD /CEng / FIChemE plus experience of operating at an expert level
HNC / Foundation degree plus significant and in-depth industrial experience of operating at an expert level	
Degree level qualification plus significant experience of operating at an expert level	
Master plus significant and in-depth experience of operating at an expert level	



Competencies	and behaviours
Leadership (Guiding)	Decision Making (Guiding)
<ul> <li>Leads people with confidence and is empathetic.</li> <li>Displays flexibility in leadership styles in order to tell/sell/involve and delegate.</li> <li>Empowers others to constantly achieve and strive to exceed personal and company objectives, ensuring that they feel comfortable to push boundaries.</li> <li>Demonstrates an entrepreneurial mindset by talking beyond today, about future</li> </ul>	<ul> <li>Leads and facilitates a group to a decision from complex, inconclusive or contradictory data, prioritising the needs of CPI.</li> <li>Evaluates options by considering short term consequences and long-term gains.</li> <li>Uses correct communication method to present a case so that it has greatest persuasive impact.</li> <li>Is regularly sought out by colleagues for advice and solutions.</li> </ul>
possibilities optimistically, showing others how they can benefit and contribute to the business.	
Communication (Guiding)	Developing self and others (Influencing)
<ul> <li>Personally takes the lead in creating an environment that encourages open and honest communication at all levels in the organisation.</li> <li>Motivates and influences others via their communications.</li> <li>Adapts communication style and format recognising individuals' different needs/ motivations.</li> </ul>	<ul> <li>Assesses the skills and competence of others within the organisation and recommends development activities.</li> <li>Brings diverse people together for collaboration, ensuring that employees are open to new ideas and effective collaboration.</li> <li>Gives performance feedback in a timely manner on an informal basis regularly.</li> </ul>
<ul> <li>Communicates corporate message with conviction and enthusiasm, with knowledge and understanding of internal communications messages and branding, and thereby promotes commitment and belief in others.</li> </ul>	<ul> <li>Actively shares expertise and learning across the organisation.</li> <li>Takes personal accountability for success or failure of direct reports</li> </ul>
Collaboration (Guiding)	Delivery (Shaping)
<ul> <li>Displays a collaborative style in day-to-day working whilst motivating others to achieve optimal performance and results.</li> <li>Fosters an inclusive atmosphere throughout</li> </ul>	<ul> <li>Maintains the clarity of reporting and decision-making processes, the governance structures and the staffing, during the progress of projects.</li> </ul>
their teams where ideas and creativity can	Monitors progress against the benefits and plan taking account of risks and changes in

plan, taking account of risks and changes in

the environment and takes action to amend the project where appropriate to maximise

thrive, and people feel empowered to be their

whole selves.



- Develops relationships which facilitate the resolution of complex tasks and can apply different techniques to effectively mitigate any conflict.
- Can negotiate skilfully in tough situations with all stakeholders.
- achievement of the planned benefits/outcomes.
- Investigates externally to CPI and brings in knowledge to improve CPI's performance.

#### **Knowledge and Experience:**

Essential:	Desirable:
Will possess significant, technical expertise, as well as a compelling evidence of highly complex technical problem solving.	Be an active member of a professional body, engaging with peers beyond CPI.
Will have deep experience of exploiting, generating and breaking new ground in area of expertise.	Familiarity with continuous bioprocessing  Experience contributing to UK or international biologics and biotechnology programmes or
Will exhibit professional mastery of principles and practices gained through career in area of expertise.	networks.
Can demonstrate evidence of building cross- industry and organisational knowledge sharing and network building.	
Is practiced in taking responsibility for diverse or complex technical activities where it is necessary to use own initiative and judgement, implementing innovative solutions in business critical situations.	
Evidence of cross-modality knowledge, spanning microbial and mammalian processing.	
Experience in translating laboratory processes into pilot or GMP manufacturing.	



Signature of Job Holder By signing this you confirm you have read, understood, and agree to work in		
alignment with the above job description.		
	aligniment with the above job description.	
Printed		
name		
Signature		
Date		