

Manager – Digital and Automation (Biologics) – Job Description

Role Purpose:

To provide high-level leadership and expertise in the area of Digital and Automation and how it relates to the Technology Teams vertical market. Acts as technical lead in medium / large scale and highly complex projects, drawing upon a broad range of technical know-how from the Biologics Technology Team and core teams to provide carefully thought-through advice and expertise to a range of stakeholders across the organisation. The Manager offers innovative solutions at Technology Team level, contributing extensively to development and improvement activities, identifying and addressing future needs in order to deliver on the Biologics Technology Team and CPI digital strategies.

Specifically, with this role, the Manager will own and drive the Biologics Technology Team Digital and Automation strategy, to define, refine and resource its implementation plan in conjunction with the Technology Team and core team resources. They will be responsible for working with the core teams to develop and ensure compliance to CPI Digital and Data management policies and standards. This is a client/partner primary contact role and will provide solutions to complex technical problems and specify new digital assets in support of business development activities.

Key Responsibilities:

- To manage with PRIDE; leading by example and role modelling the desired behaviours to exemplify our Company values and line manager principles, promoting an ethical, positive company culture. To empower our people to challenge the status quo to deliver incredible work.
- 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 effectively manage the team's goals and performance, sharing and translating area strategy, ensuring identification and delivery of departmental goals, through utilisation of appropriate management styles, providing feedback and motivation to team members and enabling individuals to meet their potential. This includes providing strong managerial support, performance management, and recruitment, development and allocation of resource to ensure project delivery and longer-term planning of deliverables.
- To undertake all management activities to ensure the smooth running of the group. This will include:
 - Medium term forecasting and planning of activities and objectives
 - Setting team and individual objectives to meet departmental, technology team, and company objectives, contributing to the wider strategy
 - Identifying and conducting performance management activities to ensure behaviours and performance of team meet required expectations, providing training and/or relevant support where needed
 - Act as a point of contact for team members' queries and escalations with regards to more complex matters
 - Conduct regular meetings, one to one sessions and performance development

Manager – Digital and Automation (Biologics) – Job Description

conversations with team members to ensure high levels of communication, feedback and performance across team

- Accountable to the Technology lead - Biologics for appropriate CPI Digital & Automation digital asset provision and use for Technology Team.
- Have ownership of Digital and Automation strategy implementation to define and resource its implementation plan, coordinating with other Technology Teams and central areas of expertise.
- Functionally lead, manage, support and actively participate in the work required to deliver project goals on collaborative research & development, commercial and internal projects.
- To support or develop plans for the training of the technical, operation and engineer teams to achieve effective use of Digital and Automation Assets and related systems and expand its capabilities over time in keeping with the business needs and strategy.
- To keep up with knowledge, new developments and trends in Data, Digital & Automation as applied to the industry vertical
- To ensure development, transfer and retention of new and state of the art scientific & digital knowledge within the Technology Team.
- To contribute to a culture of continuous capability development within teams in alignment with company strategy and project deliverables.
- To provide leadership to the integration of technologies, applications, processes and equipment into CPI Digital & Automation Assets and capabilities
- Contributing to the definition and delivery of CPI's overall Digital & Automation strategy.
- To provide leadership and guidance in the design and implementation of policies, workflows, standards and templates in their area to ensure the development of digital excellence in CPI work.
- Lead the integration of control software solutions and automation technologies to support bioprocessing operations, including for continuous processing
- Oversee connectivity between analytical (including PAT) tools, bioreactor control systems and chromatography equipment to enable real-time monitoring, feedback loops and automated process adjustments
- To collaborate with technical and IT teams to ensure the implementation and/or integration of Biologics and CPI wide information management tools, communicating effectively during the stages of consultation, requirements definition and system design, development and testing.
- Supporting the creation of bids through smart use and novel application of digital technologies
- Developing new revenue streams from use of Digital & Automation Assets
- To represent Biologics and CPI at relevant conferences and events, building a network of relevant (inter)national external stakeholders, customers, partners, research organisations and authorities.

Manager – Digital and Automation (Biologics) – Job Description

- To promote technological innovations and to open opportunities for collaborative and commercial projects.
- To provide specific technical support to the Business Development Teams relating to proposal/project development and direct customer engagement.

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

Manager – Digital and Automation (Biologics) – Job Description

Person specification

Education / Qualifications:

Essential:	Desirable:
Educated to Degree level (or equivalent) in a relevant Science, Engineering or Data Science discipline with significant experience.	Educated to PhD level (or equivalent) in a relevant Science, Engineering or Data Science discipline.

Competencies and behaviours	
Leadership (Guiding)	Decision Making (Guiding)
<ul style="list-style-type: none"> Leads people with confidence and is empathetic. Displays flexibility in leadership styles in order to tell/sell/involve and delegate. Empowers others to constantly achieve and strive to exceed personal and company objectives, ensuring that they feel comfortable to push boundaries. Demonstrates an entrepreneurial mindset by talking beyond today, about future possibilities optimistically, showing others how they can benefit and contribute to the business. 	<ul style="list-style-type: none"> Leads and facilitates a group to a decision from complex, inconclusive or contradictory data, prioritising the needs of CPI. Evaluates options by considering short term consequences and long-term gains. Uses correct communication method to present a case so that it has greatest persuasive impact. Is regularly sought out by colleagues for advice and solutions.
Communication (Guiding)	Developing self and others (Guiding)
<ul style="list-style-type: none"> Personally takes the lead in creating an environment that encourages open and honest communication at all levels in the organisation. Motivates and influences others via their communications. Adapts communication style and format recognising individuals' different needs/ motivations. Communicates corporate message with conviction and enthusiasm and thereby promotes commitment and belief in others. 	<ul style="list-style-type: none"> Intervenes to address sources of lagging performance. Provides challenging and stretching tasks and assignments to develop others. Highly effective at supporting high performers and addressing underperformance through effective, constructive and open dialogue. Collects information on performance and evidence of behaviours and uses it effectively to improve individual and team performance.
Collaboration (Guiding)	Delivery (Guiding)
<ul style="list-style-type: none"> Displays a collaborative style in day-to-day working whilst motivating others to 	<ul style="list-style-type: none"> Demonstrates the ability to prepare, gain approval of, refine and update

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<p>achieve optimal performance and results.</p> <ul style="list-style-type: none"> • Fosters an inclusive atmosphere throughout their teams where ideas and creativity can 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. 	<p>business cases that justify the initiation of a project.</p> <ul style="list-style-type: none"> • Displays the ability to manage stakeholders, taking account of their levels of influence and particular interests. • Ensures actions and decisions within the team are aligned with CPI's priorities. • Anticipates how team objectives must adapt and stretch to respond to change.
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Knowledge and Experience:

Essential:	Desirable:
Expertise in sample, process and data analysis in a CPI pursued industry vertical development setting	Expertise of the deployment of GMP software solutions in a pharmaceutical/ Biopharma manufacturing operation
Experience of operational and scientific data measurement, collection and information management	Lean 6 sigma and 5S understanding and application
Knowledge of data acquisition, data analysis, statistics and data modelling relevant to scientific research	Experience of working in highly regulated environments
Knowledge of control and automation concepts and their application to the industry vertical	Experience and expertise in the use of operational and scientific equipment in the industry vertical
Experience of software tools covering areas of simulation for process control, modelling, automation and scheduling	Working knowledge of simulation tools including process control and modelling software, such as Labview or Matlab
Working knowledge and broad experience of IT packages, particularly Outlook, Word, Excel, PowerPoint, Visio	Working knowledge of advanced process control software e.g. Pharma MV and integration of data models for process control

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<p>Have significant technical expertise in the design of development of analytical technologies, advanced control, automation and data collection projects including data acquisition, equipment integration</p> <p>Comprehensive track record of complex technical problem solving and the delivery of physical/life science research projects.</p>	<p>Working knowledge of industrial control software such as PCS7 and development of control strategies</p> <p>Experience of working in regulated environments working to standards such as ISO9001 and GMP as applicable to the industry vertical</p> <p>Have expertise of the functional management and development of collaborative interdisciplinary teams</p> <p>Knowledge and skills in programming and scripting languages, such as Python, C or Javascript</p> <p>Working knowledge of planning/ scheduling software tools.</p>
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Signature of Job Holder	
<p>Printed name</p> <p>Signature</p> <p>Date</p>	