Senior Engineer 2 – Automation - Job Description

Role Purpose:

This role focuses on delivering digital automation projects at the Medicines Manufacturing Innovation Centre (MMIC) and the Oligonucleotide Manufacturing Innovation Centre of Excellence (OMICE). A key aspect of the role is maintaining the process automation systems for one of MMIC's grand challenges (Grand Challenge 2)—a fully digital oral solid dose filling line designed for clinical trial supply.

The Senior Engineer – Automation will leverage their technical expertise to provide leadership and serve as a subject matter expert in reviewing design documentation for the construction of OMICE, a new facility dedicated to manufacturing oligonucleotides. They will be recognized as an authority in automation, offering innovative solutions and contributing to development and improvement initiatives, including the integration of digital manufacturing approaches beyond traditional automation boundaries.

The Senior Engineer will work under the technical supervision of their line manager and senior technical colleagues.

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.

Role Specific Responsibilities:

- Responsible for maintaining and operating a novel automation platform in the development phase for the delivery of clinical trial supplies and pharmaceutical manufacturing. This includes routine equipment maintenance, troubleshooting bugs and operational issues, optimizing system performance, and ensuring seamless integration with automation communications and data management strategies.
- To translate the Automation for Pharma strategy into deliverable plans and practice within the OT team to achieve business objectives.
- To maintain clearly documented records of technical data, decisions, methodologies, ensuring the experimental testing plans align with the validation masterplan and other relevant quality documents within the MMIC GMP framework.
- To identify new technical developments and trends, translate these into building blocks for opportunities within the business unit, initiating the creation of technological innovations/applications.
- To build, maintain and exploit a network of relevant external stakeholders, customers, partners,

research organisations and authorities, to represent the business unit and self as a credible expert, identifying opportunity for future projects and developments.
- To actively contribute to a culture of continuous capability development through coaching, mentoring and/or developing colleagues across the business unit and organisation, providing insights into areas of specialism. This may include coaching and developing colleagues (both technically and behaviourally) to help them reach their potential and acting as a mentor to colleagues across the organisation, providing an expert-level perspective.
- To keep self-up to date with external developments in areas of specialism, and/or legislative 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.

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Direct reports: No direct reports

Education / Qualifications:

Essential:	Desirable:
Educated to HNC or Foundation Degree level (or equivalent) in a relevant Scientific/Engineering discipline plus significant industrial experience Or Educated to Degree level (or equivalent) in a Scientific/Engineering discipline plus relevant industrial experience Or Educated to Master Degree or PhD level (or equivalent) in a role related discipline	Chartered/registered status with a relevant professional institution Industrial experience within a GMP environment

Competencies and behaviours	
Leadership (Influencing)	**Decision Making (Influencing)**
• Promotes commitment to CPI's strategy, vision, values, and direction. • Motivates, inspires and build resilience in others by making the vision shareable by everyone. • Rewards and celebrates success with colleagues and teams. • Future proofs work practices. • Trusts others' judgment and demonstrates a willingness to try new things, even at the risk of failure.	• 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. • Thinks ahead, ensuring that the potential of teams and projects are unlocked and making future focused decisions
Communication (Influencing)	**Developing self and others (Enabling)**
• Comfortably employs a wide range of communication styles and approaches to suit different situations and audiences (external and internal stakeholders) in diverse situations. • Builds effective two-way communication channels within the business area and across departments whilst maintaining credibility and securing commitment.	• Supports others in their development. • Is personally committed to, and actively seeks, opportunities to improve continuously. • Is comfortable learning from the experiences of others and recognises the differing strengths of team members. • Provides honest helpful feedback to others on their performance.

	• Insightful about self, strengths, and limitations, and how to maximise contribution.
Collaboration (Guiding)	**Delivery (Influencing)**
• Displays a collaborative style in day-to-day working whilst motivating others to achieve optimal performance and results. • 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.	• Prepares and maintains schedules for activities and events for projects. • Delegates responsibilities for tasks and decisions to the appropriate staff; sets SMART objectives and monitors progress, fostering an atmosphere of purposeful empowerment in order to allow teams to function efficiently. • 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 technical expertise in automaton and data integration approaches as well as compelling evidence of complex technical problem solving. Actively demonstrates in-depth technical and theoretical knowledge in automation and is viewed as an authority in this area by peers and managers. Can demonstrate evidence of building knowledge sharing and network building practice across teams and organisations to achieve desired results. Takes responsibility for diverse or complex technical activities, using own initiative and judgement, implementing innovative solutions in complex situations.	Is an active member of a professional body, engaging with peers beyond CPI. Demonstrable experience in drug or medicines development. Experience using Siemens TIA Portal and WinCC 7.5. Knowledge of PCS7 In depth knowledge of IEC 61131-3 programming languages. Knowledge and experience of applying a GAMP 5 approach to GxP Computerised System Validation. Demonstratable knowledge of functional safety systems within automated machinery. Knowledge of industrial networking and OT cybersecurity

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