

Research Scientist 2 – Bioprocess Automation – Job Description

Role Purpose:

To contribute to the delivery and realisation of process automation project work through development, design, and testing, and through the use, development, and design of digital technologies and approaches. Additionally, as required, to contribute to the delivery and realisation of broader digital and automation project work and internal capability building.

The RS2 will work both within their individual team and the wider technology team to support digital and automation work as required. The RS2 will work using their own initiative and with some technical supervision from their manager and senior colleagues.

Key Responsibilities:

- To maintain consistent and document compliance with all relevant Safety, Health and Environmental (SHE), Good Manufacturing Practice (GMP), Data Integrity (DI), quality and best practice requirements.
- Embrace and role model the desired behaviours to exemplify our Company values, promoting an ethical, positive company culture.
- To build and maintain a network of relevant internal stakeholders, to represent self and the wider team as a credible professional in networks and groups.
- To keep self up to date with developments in areas relevant to role, and/or legislative and SHE related changes, ensuring understanding of these and any associated new best practice, methods, or techniques.
- To support in Business Development and Bid Proposal activities, to contribute to proposal / project development and direct customer engagement.
- To present and formally report experimental and design conclusions and supporting data for internal peer review and submission to clients, to agreed timescales and standards.
- To actively engage in hazard studies / SRA studies and discussions, as appropriate to role level.
- To set up, plan and execute experimental / pilot scale runs and analyse, interpret, and report the results of these within agreed timescales and standards and in accordance with project requirements.
- To be responsible for providing clearly documented records of technical data, decisions, methodologies, calculations, and software use in an agreed format.
- To take ownership in agreeing weekly workplans with line manager, project manager(s) and other relevant stakeholders, and delivering plan to agreed schedule.
- To be responsible for the maintenance and calibration of equipment to ensure it operates in a safe and efficient manner and is available to meet customer needs.

Role Specific Responsibilities:

- To have and continually develop theoretical and practical knowledge of process automation and related digital technologies
- To design, develop, and implement process automation workflows, for both batch and continuous processes
- To integrate lab equipment for custom automation solutions

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- To design, develop, and implement advanced process control (APC) solutions for continuous processes
- To contribute to hardware engineering, as required
- To analyse and interpret results from automated processes
- To contribute to the design, development, and implementation of digital tools and technologies, especially as related to process automation
- To contribute to data architecture design and realisation as it relates to general bioprocessing and biologics work
- To provide support and training in automation and digital skills to more junior members and the wider technical team
- To support the wider technical team in digital, automation, and bioprocess work
- To aid with data science and data engineering efforts within project work, as required

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

Person specification

Education / Qualifications:

Essential:	Desirable:
Educated to HNC or Foundation Degree level (or equivalent) in a Scientific/Engineering discipline plus significant relevant industrial or academic experience. Or Educated to Degree level (or equivalent) in a science/engineering/computing discipline plus relevant industrial or academic experience.	Chartered status with a relevant professional institution.

Competencies and behaviours	
Leadership (Core)	Decision Making (Enabling)
• Respects and values the diversity of talents, skills, and backgrounds that others bring to joint projects / work. • Has a positive influence on those in contact with. • Gains the respect and confidence of colleagues and supports them in achieving their goals and targets. • Aligns own behaviours and actions to CPI's values, vision, and goals.	• Pro-actively identifies and prioritises the key issues involved to facilitate the decision-making process. • Seeks input from the relevant stakeholders when appropriate, considers risks, and takes accountability for the impact a decision may have on others. • Makes decisions in a timely manner. Identifies the key factors in a complex problem.
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	• 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.

tactics or plan, in line with strategy, and persuade others of the merit.	
Collaboration (Enabling)	Delivery (Enabling)
• Understands the value of establishing effective and supportive relationships, and collaborative working. • Actively listens, questions, and observes body language so as to understand communication from others. • Cultivates and maintains partnerships across departments to deliver value for the business	• Prioritises activities based on their impact and strategic importance. • Takes responsibility and monitors own performance. • Can articulate how their work feeds into projects. • Creates and exploits useful metrics. • Displays commitment and engagement to own work. • Pursues everything with energy, drive and a need to finish, even when faced with setbacks or resistance.

Knowledge and Experience:

Essential:	Desirable:
Will possess technical expertise through theory, a good underpinning technical knowledge base, and evidence of technical problem solving in at least one of: • Automation workflows • Continuous process automation • Advanced Process Control (APC) • Equipment integration • Industrial automation software Will exhibit professional mastery of principles and practices in process automation and/or advanced process control, gained in academic or industrial environments. Will possess an awareness of digital technologies, specifically as they apply to process automation. Experience with Python programming.	Is a member of a relevant professional body. Direct experience in one or more of: • Siemens PCS7 • PharmaMV • WinCC • Closely related equivalent of one or more of the above Experience or familiarity with digital twins and/or other computational modelling techniques. Knowledge of C/C++ programming. Knowledge of data/network architecture and/or data science principles/skills. Familiarity with statistical analysis/modelling and DoE/QbD. Experience and/or knowledge related to one of mammalian/microbial upstream or downstream processing.

Experience of planning and delivering technical work

Experience of data analysis & reporting findings (documentation and/or presentations)

Can demonstrate evidence of knowledge sharing and network building practice across teams or groups.

Has ability to apply theoretical and practical scientific/engineering methods 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 engineering / scientific practices, as well as an understanding of when to seek advice from colleagues.

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