

12 Month Placement Student – Biologics

Role Purpose:

To contribute to the delivery and realisation of project work through preparation, development research and analysis work in line with the requirements of the Biologics business unit. This will involve applying scientific knowledge and learning new skills on a variety of process and analytical equipment. The work will range from small scale development work, analytical method development, process scale up, and digital technologies.

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 be responsible for discussing project needs; set up, plan, and execute scientific experiments and report results to agreed timescales.
- To be responsible for agreeing weekly work plans with line manager and project manager(s) and delivering plan to agreed schedule.
- To contribute to the delivery of projects through the delivery of scientific/engineering knowledge.
- To support the development and potential scale up of processes to maximise product quality and recovery.
- To be responsible for providing clearly documented records of technical data, decisions, methodologies, calculations, and software use in an agreed format.
- Responsible for general laboratory housekeeping to contribute to a safe and healthy workplace.
- Responsible for liaising with the warehouse for collection of deliveries.
- Responsible for the purchasing of chemicals, equipment, and other items as and when required.
- To share professional knowledge with colleagues and be responsible for own continuous professional development.
- Contribute to a culture of continuous capability development within teams in alignment with company strategy and project deliverables.

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

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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

Person specification

Education / Qualifications:

Essential:	Desirable:
Educated to A-Level level (or equivalent) in Biology, Chemistry, or related subject.	Educated to HNC, Foundation degree or degree level (or equivalent) in a Scientific discipline.
Currently enrolled in a relevant degree course.	

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Competencies and behaviours	
Leadership (Core)	Decision Making (Core)
- Respects and values our diverse people and the differing talents, skills and backgrounds that they bring to projects and day-to-day work. - Has a positive influence on those they are in contact with. - Gains the respect and confidence of colleagues and supports them in achieving their goals and targets. - Aligns their behaviours and actions to our PRIDE values, vision and goals.	- Within area of expertise recognises, identifies and defines problems. - Generates and evaluates alternatives, draws conclusion and analyses risk. - Takes timely and correct action using established methods to ensure effective solutions are implemented by working as a team and with and focused outcomes to be delivered.
Communication (Core)	Developing self and others (Core)
- Communicates in a clear and concise manner, covering all relevant points in a timely manner. - Uses the appropriate route and format to communicate. - Confirms understanding of others communication. - Asks questions to understand other people's viewpoints, keeping an open mind and embracing new ideas.	- Knows own career aspirations and clearly communicates them to relevant colleagues whilst actively working to achieve goals. - Sets personal development goals and deploys strengths to achieve them. - Takes responsibility for one's own performance and actions, and invites and incorporates feedback from a variety of sources. - Regularly reflects on own capabilities to identify development priorities.
Collaboration (Core)	Delivery (Core)
- Establishes effective working relationships with other colleagues. - Builds and maintains a network of internal and external contacts. - Actively seeks, values and incorporates different views and ideas to broaden their prospective, embracing differing perspectives and unconventional ideas.	- Plans, prioritises and leads own area of work to deliver specified and agreed outcomes (time and standard). - Accurately scopes out length and difficulty of tasks, and repeatedly estimates correct amount of time needed for tasks. - Refers to lessons learnt from other projects/ tasks with related scope. - Acts with minimal supervision or direction by being purposely empowered to make decisions when needed. - Pays attention to detail and delivers accurate and high quality outputs.

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Knowledge and Experience:

Essential:	Desirable:
Working knowledge and broad experience of IT packages, particularly Outlook, Word, Excel, and PowerPoint. Will have demonstrated, laboratory experience in Biology, Chemistry, or a related field.	Possess knowledge of different steps involved in biologic process development and analysis.

Signature of Job Holder	
Printed name Signature Date	