

QC Manager

Location: Babraham Research Park, Cambridge

Type: Full time, permanent /

Start: Immediate

Salary: Competitive / Hours: 40 p/w

Laboratory Based Position

Cambridge Start Up of the Year 2018

bit.bio is an award-winning spinout from the University of Cambridge. Our breakthrough technology combines synthetic and stem cell biology for the precise, efficient and consistent reprogramming of human cells used in research, drug discovery, and cell therapy. At bit.bio, we are passionate about engineering human cells that will enable the medicine of the future. To do this we need talented and curious people who want to make an impact on the future of science and therapeutics.

As a team of individuals, we value science, collaboration, openness, curiosity and creativity. We are united by trust and respect for each other.

Your role in our team:

We are looking for an experienced QC Manager to join our Quality team. Working closely with both Manufacturing and Quality team leaders, the initial aim of this role will be to help build the QC team and establish key processes for a growing portfolio of commercial off-the-shelf products for research and drug discovery purposes, and assets undergoing clinical development. As a senior member of the team, you will be a key player in executing this workflow within the company, responsible for the execution and reporting of experimental work; supervision and training of junior staff; as well as contributing to SOP and assay development.

This is an opportunity to join one of the best stem cell reprogramming labs and conduct research with real-world impact. The QC Manager will work closely with the R&D, Manufacturing, Logistics and Commercial teams to deliver quality products to market. There is therefore a requirement to be diplomatic, collaborative, customer focused, change agile and comfortable in adapting to changing priorities in a rapidly growing business.

Your key responsibilities will include:

- **Lead the set-up of a QC function to support in process QC testing and final product release for a pipeline of cell products for both research purposes and those in the clinical development pipeline**
- **Lead the development of the QC strategy in terms of generation and validation of analytical test methods, acquisition and qualification of laboratory equipment and reporting and release of materials and final product**
- **Schedule and management of the QC workflow, both for off-the-shelf products, client projects and products in clinical development**
- **As principal QC contact, in liaison with relevant departments, in the handling & reporting of quality issues which arise in the manufacture, testing, packaging and supply of materials or product (both internally and through external parties)**

- **Management and oversight of outsourced QC work programmes**
- **Lead out of specification (OOS) investigations of material or product**
- **Establish relevant QC KPI's to monitor conformity and provide status reports to Senior Management at Quality meetings**
- **Provide quality representation at Quality review meetings at local and site level**
- **Ensure quality goals and objectives are cascaded down through the organisation**
- **Manage projects and deliver improvements in QC capabilities, efficiency, throughput and compliance**
- **Assist with writing protocols, reports, SOPs and testing documents**
- **Pro-actively identify and determine current and future resource requirements – both people and systems – lead in the recruitment and establishment of both in a rapidly growing organisation**
- **Support development of personnel by providing relevant training, tools, skills and motivation to provide opportunities for personal improvement and encourage contribution towards continual improvement**

You...

- Have a degree level or equivalent qualification in a relevant discipline
- Are humble – sincere and secure – accepts own mistakes – prioritises team over personal goals
- Are hungry – driven and proactive – goes above and beyond the call of duty to achieve company results
- Are smart – astute and persuasive – uses emotional intelligence to lead and inspire colleagues

With essential experience in...

- QC management within a cGMP environment
- Experienced in working in a scientific/cell therapy environment
- Experienced in cell phenotyping and functional endpoint analysis eg. flow cytometry, karyotyping, qPCR, ICC, MEA, sterility testing
- Demonstrable understanding of Good Manufacturing Practice within a pharmaceutical or related environment
- Experienced in analytical method validation and qualification of laboratory equipment
- Demonstrable understanding of Good Documentation Practice and principals of Data Integrity
- Proficient use of Microsoft Office
- Excellent time management, organisation and communication skills

...and possibly...

- **Experienced in working with human induced pluripotent stem cells, characterisation and culture systems**

- **Experienced in Continuous Improvement Tools eg. Lean, 5S, Kanban, Kaizan, RCA, VSM**
- **Experience working with eQMS eg. Trackwise, MasterControl, Q-Pulse**
- **QESH Management System / ISO9001 / HTA / PDCA training**

More reasons to join us:

bit.bio provides a vibrant and dynamic work environment in an exciting, fast-moving time for biology. We work with cutting edge technologies and with our world-leading scientific advisory board. We conduct pioneering work with real-world impact.

We trust our people to make significant contributions early on with opportunities to be involved in projects that are key to the success and growth of our young company. We invest in people, creating opportunities for personal development in an inclusive multi-skilled team with ambitious goals that provide opportunities to learn on the job from each other.

Creativity and open minds are encouraged for everyone to contribute to the success of the company.

To support bit.bio staff and our culture further, we also offer a competitive salary, highly competitive benefits package including pension contribution scheme as well as health and life insurance.

To be part of our dynamic, growing start-up team and share our vision to build together the leading cell coding company, please send your CV and cover letter to careers@bit.bio