



Quality Engineer

Biocrucible is developing a class-leading molecular diagnostic platform based on its proprietary isothermal nucleic acid amplification technology. This platform has the potential to offer rapid results with PCR-like levels of sensitivity and specificity but in a fully-disposable format usable by both consumers at home and also in low-resource environments. Our technology can significantly improve the performance of many processes already currently in use throughout the life science and diagnostic industries. The acquisition by Sapphiros in July 2021 has provided further investment and operational support to accelerate this next-generation platform to market.

We are looking for a Quality Engineer to help the team maintain, develop and communicate the Company Quality Management System.

Your responsibilities will include

- preparing and implementing the EQMS procedure documents (including SOPs and WIs)
- supporting the R&D team in developing the Design History File and Design Trace matrix
- working with contract manufacturers with respect to their Quality systems
- supporting the manufacturing team in developing and executing the required validation activities (DQ/IQ/OQ/PQ)
- performing internal audits
- supplier auditing/monitoring
- providing daily support to the Production team
- risk assessment and management
- creating and delivering training sessions – QMS, GMP, GDP, GLP
- continuous Quality improvements
- reviewing and maintaining the non-conformance /CAPA process

We need someone with experience of developing a Quality Management System and an understanding of quality and regulatory requirements for IVDs. You would need to be able to influence others and work as a team to deliver goals utilizing strong communication skills.

Should you wish to apply or would like more information, please send a covering email and a CV to careers@biocrucible.co.uk