

Quality Assurance System Manager

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Company: DNA Life Sciences LTD

Location: East Sussex

Category: other-general

Senior GxP IT Compliance Specialist As the Senior GxP IT Compliance Specialist, you will lead compliance efforts for critical systems essential to GxP operations. Your role involves overseeing GxP IT systems from a quality assurance perspective, ensuring adherence to regulations and fostering a culture of data integrity. You'll serve as the Data Integrity SME and contribute to maintaining and developing QMS related to IT. Key Responsibilities: Ensure ongoing compliance of GxP IT systems and processes. Support adherence to GMP/GDP and GCP regulations, including data integrity legislation. Act as System Owner/Administrator for GxP IT systems within QA. Lead Computer System Validation and compliance processes. Review and lead compliance efforts for GxP IT system-related change controls. Provide coaching and support for data integrity adherence. Conduct periodic reviews of data integrity documentation. Assist in other quality systems as needed, such as Non-Conformances and CAPA. Collaborate with IT colleagues for QA oversight of IT systems. Liaise with IT to assess GxP impact and compliance of IT systems. Support training record maintenance and champion GxP adherence. Stay updated on industry legislation and best practices. Act as a key member of the Quality Leadership team. Minimum Qualifications & Experience: Substantial experience in Pharmaceutical Manufacturing or Quality Assurance. Previous IT QA experience with familiarity in GxP IT systems. Proven ability in data integrity and systems validation. Strong communication and stakeholder management skills. Good scientific and technical knowledge. Understanding of GxP regulations and Quality Systems. Basic statistical tools proficiency. Excellent report writing and attention to detail. Proficiency in Word and Excel. Preferred Qualifications & Experience: Familiarity with

QMS systems like TrackWise, LIMS, Documentum. Knowledge of international GxP regulations.

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