Quality Assurance & Regulatory Affairs Manager

Job Reference: JD-500033
Posted: June 2019
Location: London
Weekly Hours: 40

The Role
At DNA Electronics Ltd, we are integrating cutting-edge semiconductor technologies with novel biochemical techniques to develop products for DNA analysis and molecular diagnostics.

The QA & Regulatory Affairs Manager will be based in the London QA team but will work collaboratively with the QA team in the US office. This role will have line manager responsibility for the small team in London.

Primary Responsibilities

- Designated Management Representative as defined in EN ISO 13485 and 21 CFR 820 for the London site and the primary contact and host for all inspections to support these registrations
- Position will report into the VP of Quality and Regulatory Affairs, with a transition to reporting to the Director of Quality Assurance based in the US office
- Responsibility for ensuring the Quality Management System is established and meets its Quality and Regulatory objectives as reviewed by Management; with Executive Responsibility in accordance with appropriate DNAe procedures. The role holder coordinates and chairs the QMS Management Review and ensures appropriate records are maintained.
- Global co-ordination of staff undertaking Design Control and Risk Management activities to ensure compliance to regulatory requirements
- Support Program Management in Risk Management File compilation and maintenance
- Design History File and Technical Documentation compilation and maintenance
- Together with the Vice President of Quality and Regulatory Affairs, ensures the regulatory strategy is implemented in a timely manner and to meet business needs
- Provide Technical Quality and compliance support, guidance and leadership for the Research & Development and QA teams – this includes performance management and development for the QA personnel

- Act as the Subject Matter Expert (SME) and keep up to date on EU Standards and Regulatory requirements and disseminate to appropriate personnel
- Ensure the company has the knowledge, skills and facilitation necessary to maintain compliant and effective working methods and environment.
- Recommend process changes, in conjunction with stakeholders within the business, to ensure that QMS and Regulatory processes meet the needs of the company, regulatory bodies and applicable standards. Changes will include the implementation of appropriate electronic system solutions
- Line Management of QA team for performance and development
- Keep the company updated and aware of Quality and Regulatory changes from an EU perspective and implement training as appropriate
- Lead Risk Management Activities together with other responsible parties as assigned
- The holder is expected to comply with the relevant DNAe Quality System processes and procedures at all times

Required Qualifications & Experience

- Degree or equivalent in an Engineering, Science or Clinical subjects
- Proven leadership qualities relevant to a multi-site IVD development company
- A good knowledge of compliance management of products that have undergone the full design control lifecycle under ISO 13485 and US FDA 21 CDR Part 820 as well as other worldwide regulatory and compliance standards and working knowledge of Health & Safety Management Systems
- Proven ability as an effective people manager with leadership abilities
- Strong organizational and problem-solving skills in a fast-moving pressured environment where changing priorities are the norm.

Experience

- Extensive experience in senior Quality, Regulatory positions in the Medical Device/IVD industry
- Good understanding of Worldwide Quality and Regulatory requirements coupled with a thorough understanding of the Design and Development and new product introduction processes

Desirable Experience

- Understanding of the use of EU harmonised standards and other regulatory requirements for Software validation, Usability, Risk Management
- Knowledge of US FDA and other relevant EU regulations

Location

DNA Electronics is based in West London at White City, London, UK

Apply

If you believe you meet the above criteria and would relish playing a key role in developing a revolutionary technology, we would be delighted to hear from you.

We offer a competitive compensation package to successful candidates.

Please email your CV and covering letter to: careers@dnae.com quoting

Your name and the job title in the subject line.

For more information about DNAe, please visit our website www.dnae.com