QA/QC Senior Manager

Job Reference: QASM
Posted: April 2022

Location: Carlsbad, CA
Weekly Hours: 40

The Role

DNA Electronics (DNAe) is a dynamic company integrating cutting edge sequencing technologies with novel biochemical techniques to create a revolutionary sample-to-answer sequencing platform. We are seeking a strong individual to contribute to the DNAe team. The QA/QC Senior Manager/Associate Director is responsible for ensuring that the quality management system (QMS) is fully implemented and meets relevant regulations and standards. This role will also lead all activities required to direct and control manufacturing quality.

Responsibilities:

- Manage and provide leadership, development, and coaching for the site's Quality organization (Quality Assurance, Quality Control and Quality Engineering personnel)
- Partner with Research and development (R&D), Operations, and Manufacturing to provide guidance as it relates to the implementation of the quality system and to ensure compliance to product, customer, and regulatory requirements QA-Specific Responsibilities
- Ensure the Quality Management System (QMS) is established in accordance with ISO 13485:2016 and 21 CFR 820 and fit for ISO certification
- Primary contact and host for all inspections to support ISO certification and product registrations
- Coordinates and chairs the QMS Management Review and ensures appropriate records are maintained
- Provide guidance to staff undertaking Design Control and Risk Management activities to ensure compliance to regulatory requirements
- Accountable for Risk Management File and Design History File Documentation compilation and maintenance
- Provide quality and compliance support, guidance and leadership for the QA, R&D and Engineering teams
- Accountable for company’s Internal Audit program, performing internal and supplier audits as needed

- 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 QC- Specific Responsibilities
- Create, document, and implement inspection and testing acceptance criteria and procedures to ensure adherence to established quality standards to ensure high productivity and high technical integrity.
- Develop and analyze statistical data and product specifications to determine standards and to establish quality and reliability expectancy of finished products
- Create and direct environmental test functions and applications.
- Oversee, inspection activity for product throughout production cycle
- Provide compliance oversite of site buildout for GMP inventory control and material flow: receiving/sampling/ testing/status labeling/storage, etc.
- Formulate, document, and maintain quality control standards and on-going quality control objectives
- Provide CAPA support for nonconforming product. Propose corrective actions to improve compliance with quality specifications
- Review and approve Contractor and sub-contractor quality control documentation to ensure their planned activities meet contractual requirements
- Ensure a high level of internal and external customer service. Investigate (and correct) customer issues and complaints relating to quality.

Person Specification

We are looking for people with a passion for their work - people who strive for exceptional results, but who can deliver pragmatic solutions on time. DNA Electronics' scientists and engineers enjoy and thrive on working in an interdisciplinary team but can also work independently and use their own initiative. The ideal candidate also likes to contribute to solving problems outside their field of immediate expertise and is an effective communicator.

Qualifications & Experience:

- Bachelor's degree in Engineering or Scientific discipline, and 10 years+ experience in Quality Assurance within the biotechnology, chemical, biological or medical device industry in a GMP environment
- Proven leadership qualities relevant to a multi-site IVD development company
- 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

- Experience with Document Control, NCR, CAPA, Change Management, Quality Audits (internal and supplier)
- Understanding of the use of EU harmonized standards and other regulatory requirements for Software validation, Usability and Risk Management
- Knowledge of US FDA and other relevant EU regulations
- 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
- Some travel to 3rd party suppliers may be required

Location

DNA Electronics Inc., Carlsbad, CA

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 cover letter to: HR-US@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

DNAe, Inc. is an equal opportunity employer that does not discriminate on the basis of race, color, national origin, ancestry, religion, sex, gender, age, marital status, physical or mental disability, military or veteran status, sexual orientation, gender identity, gender expression, genetic information, or any other characteristic protected by applicable federal, state or local law.