Title	Senior Associate, Quality Assurance (Device GMP training)
Department(s)	Quality
Reports to	Manager, Quality Systems/Doc Control
Employee Type	Regular, Full-Time, Non-exempt
Location	West Office, San Diego, CA

Company Profile

Inovio is a late-stage biotechnology company focused on the discovery, development, and commercialization of DNA immunotherapies that transform the treatment of cancer and infectious diseases. Inovio is taking immunotherapy to the next level in the fight against cancer and infectious diseases. Inovio has reported generating T cells in vivo in high quantity that are fully functional and whose killing capacity correlates with relevant clinical outcomes with a favorable safety profile. With an expanding portfolio of immune therapies, the company is advancing a growing preclinical and clinical stage product pipeline. Partners and collaborators include MedImmune, Regeneron, Roche/Genentech, ApolloBio Corporation, The Wistar Institute, University of Pennsylvania, Parker Institute for Cancer Immunotherapy, CEPI, DARPA, GeneOne Life Science, Plumbline Life Sciences, Drexel University, NIH, HIV Vaccines Trial Network, National Cancer Institute, U.S. Military HIV Research Program, and Laval University. For more information, visit www.inovio.com.

Job summary

The Senior Associate, Quality Assurance (QA) performs a wide variety of duties, including but not limited to, supporting the daily QA departmental operations, supporting product flow through the production floor, and performing various types of documentation reviews. The Senior Associate, QA is responsible for supporting the Quality System to ensure compliance to applicable regulations and standards, QSR, ISO, MDD program as needed and is required to possess strong computer skills and a high-level of written and verbal interactive communication skills. The position requires familiarity with Change Control, Temporary Deviation, Engineering Testing and Validation systems. The Senior Associate, QA provides support to ensure Documentation SOPs and practices conform to regulatory standards and that the processes to release and control documentation are defined and controlled. The position is responsible for reviewing, assisting and verifying the generation of metrics for upper management review.

Essential job functions and duties

- Maintain documentation for Quality System.
- Update and create Standard Operating Procedures for Quality System related activities.
- Provide assistance in ensuring that departmental records, Quality Management System procedures, specifications, corporate standards, external standards (e.g. ISO 13485, Vigilance) comply with FDA Quality Systems Regulations (QSR's) and applicable foreign regulations (e.g. Medical Device Directive).
- Manage and maintain the Document Control Archive Room.
- Review and log documents ready for archive.
- Manage and maintain employee training records in the company EDMS
- Perform data input into the computer system for data collection purposes used to identify quality trends and training monitoring.
- Assist with Change Order processing and release activities.
- Communicate change order information and interface with Manufacturing, Engineering, Quality, Clinical and Research & Development.
- Perform other related tasks as assigned.

Minimum requirements

- Associate's degree (AA) from a two year college or an equivalent combination of education, training and/or experience from which comparable knowledge, skills and abilities have been attained. Bachelor's degree preferred.
- 2-4 years of experience in medical device or pharmaceutical/biotech industry, with working knowledge of FDA and ISO regulations.
- 2-4 years of experience on change orders, deviations, complaints and validation process.
- 1-2 years of experience with general QA work and training management.
- Ability to read, analyze, and interpret technical procedures and regulations. Ability to write reports and procedure manuals. Ability to effectively present information and respond to questions from groups of managers, clients, customers and the general public.
- Ability to solve practical problems and deal with a variety of concrete variables in situations where only limited standardization exists.
- Knowledge of Document Control principles.
- Strong organizational, project management and communication skills and the ability to perform varied tasks in a disciplined, consistent manner.
- Must be able to work under minimum supervision individually and in a team environment.

Disclaimer

Inovio Pharmaceuticals, Inc. is committed to a policy of equal employment opportunity. In keeping with our policy, Inovio will recruit, hire, train and promote into all job titles the most qualified individuals, without regard to race, color, creed, gender, religion, marital status, registered domestic partner status, age, national origin or ancestry, veteran status, physical or mental disability, medical condition including genetic characteristics, sexual orientation, or any other consideration made unlawful by federal, state, or local laws.

A current US work authorization is required. The above statements are intended to describe the general nature and level of work being performed by people assigned to this classification. They are not to be construed as an exhaustive list of all responsibilities, duties, and skills required of personnel so classified. All personnel may be required to perform duties outside of their normal responsibilities from time to time, as needed. Inovio offers an attractive benefits package and is an equal opportunity employer.

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