NOVARTIS

Senior Quality Assurance Engineer

Job ID
REQ-10019495
Set 04, 2024
Messico

Sommario

The Senior Quality Assurance Engineer, is responsible for the design, construction, validation, maintenance and overall compliance of facilities, systems and processes at Novartis Gene Therapies, Durham, N.C.

About the Role

Major accountabilities:

- Provides QE expertise to support clinical and commercial gene therapy products. Full audit support of all internal and external audits in support of product manufacturing.
- Ensures Quality and Compliance aspects of design and work in collaboration with Engineering, technical functions, Manufacturing Operations to ensure that the facility is:
  - Compliant with all appropriate regulations (e.g. FDA, EMEA and other major health authorities) for GMP manufacturing.
  - Capable of manufacturing products that are safe, effective and that meet all applied controls and specifications.
  - Capable to meet intended design goals of output volume, turnaround time and operating and product costs.
- Provides strategic quality input on the translation of commercial product requirements into technical solutions that are capable of meeting defined CQAs (product Critical Quality Attributes) and CPPs (Critical Process Parameters).
- Acts as Quality approver on project deliverables, as defined in the project plan.
- Works with validation colleagues to define the initial asset life-cycle model and qualification and validation strategy, to ensure successful validation of the facility. Plays a lead role in the planning, execution and closure of commissioning, qualification and validation activities from a Quality functional perspective.
- Authors and/or approves Standard Operating Procedures in support of project activity and deliverables.
- Provides QA oversight of engineering, validation, and facilities activities related to maintaining a GMP facility in a validated state.
- Acts as the Quality approver of change controls, deviations, and CAPAs required to maintain the manufacturing facility in a GMP state.
- Other related duties as assigned.
- Must be able to travel to the Durham, N.C. site (US) at minimum monthly. Protocols need to be reviewed in person periodically.

Minimum Requirements:

- B.S. degree in preferably engineering, chemistry or biochemistry.
- 5 years of experience in biopharmaceutical based GMP manufacturing operations.

- Experience with viral gene therapies, cell culture technologies and/or orphan disease indications is a plus.
- Strong knowledge and application of the CFR’s and cGMPss.
- Comprehensive knowledge of FDA and EU regulations and experience in US and international regulatory agency inspections.
- Direct experience with commissioning, qualification and validation to meet FDA and other health authority requirements.
- Experience with deviations, CAPAs, and Change Controls.
- Direct experience reviewing and/or authoring standard operating procedures and partnering with operations on product related investigations and deviations.
- Excellent oral and written communication skills with strong technical writing experience required.
- Ability to synthesize data and summarize outcomes to provide recommendations on compliant path forward.

Languages :

- English.

Why Novartis: Helping people with disease and their families takes more than innovative science. It takes a community of smart, passionate people like you. Collaborating, supporting and inspiring each other. Combining to achieve breakthroughs that change patients’ lives. Ready to create a brighter future together? https://www.novartis.com/about/strategy/people-and-culture

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Accessibility and accommodation

Novartis is committed to work with and provide reasonable accommodation to individuals with disabilities. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the recruitment process, or in order to perform the essential functions of a position, please send an e-mail to tas.mexico@novartis.com and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

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