

# Senior Quality Assurance Engineer

Job ID  
REQ-10019495  
Sep 04, 2024  
Mexico

## Summary

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 cGMPs.
- 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.

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Division

Operations

Business Unit

Innovative Medicines

Location

Mexico

Site

INSURGENTES

Company / Legal Entity

MX06 (FCRS = MX006) Novartis Farmacéutica S.A. de C.V.

Functional Area

Quality

Job Type

Full time

Employment Type

Regular

Shift Work

No

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