NOVARTIS

Manager, R&D Quality

Job ID
REQ-10089436
Oct 13, 2026
LOC_IN

About the Role

Major Accountabilities:

- Support maintenance of the regulatory -required files for health authority inspections and assist with health authority inspection management
- Support generation of Quality Plans (and review other plans for quality/safety aspects) for clinical programs
- Support review of Oligonucleotide Analytics, including analytical methods, stability, control strategies, impurities, and quality risk assessment.
- Support cross functional CMC, regulatory, and lifecycle initiatives for oligonucleotide drug substances and drug products.
- Support initiatives to maintain or improve quality performance and compliance of operational activities including risk management, health authority reporting, IT systems
- Support initiatives focused on quality, process and compliance improvement, including identification of opportunities and develop strategies aimed at improving quality while ensuring compliance with regulatory requirements
- Ensure information gained during quality and compliance initiatives, as well as audit and assessment results, are evaluated to identify any regulatory, compliance and QA training needs
- Aid in the identification of quality issues and assist with root cause investigations and support the development of corrective and preventative action plans (CAPA), including monitoring status to Ensure issues are addressed, completed and documented.
- Provide assistance in the remediation of deviations, Ensure follow up and monitoring of associated corrective and preventive actions.
- Manage and Support quality aspects of projects and activities, including those related to third parties, analytical instruments, manufacturing equipment, quality plans, training, IT validations, etc.
- Review and approve quality deliverables to ensure compliance (including procedures, records, third party work, contractors, clinical trial material, components, gap assessments)
- Reporting of technical complaints / adverse events / special case scenarios related to Novartis products within 24 hours of receipt
- Distribution of marketing samples (where applicable)

Minimum Requirements:

- Working knowledge of oligonucleotide modalities and therapeutics (e.g., siRNA, ASO, mRNA, and conjugated oligonucleotides).
- Understanding of oligonucleotide manufacturing, analytical characterization, stability, and control strategy concepts.
- Familiarity with oligonucleotide-specific CMC development, lifecycle management, and regulatory considerations.
- Awareness of critical quality attributes (CQAs), impurity profiles, degradation pathways, and product quality risks associated with oligonucleotide therapeutics.
- Understanding of analytical method lifecycle concepts, including method development, validation, transfer, and ongoing performance monitoring.
- Familiarity with oligonucleotide drug substance and drug product development considerations, including formulation and comparability strategies.
- Ability to assess quality risks and provide quality oversight for oligonucleotide development programs.

- Ability to interpret technical, analytical, and quality data to support risk-based decision making.
- Effective collaboration with technical SMEs across analytical, process, regulatory, pharmaceutical development, manufacturing, and quality functions.
- Ability to support cross-functional discussions on emerging xRNA modalities, platform approaches, and evolving regulatory expectations.

Commitment to Diversity and Inclusion / EEO paragraph

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

Accessibility and accommodation

Novartis is committed to working with and providing 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 diversityandincl.india@novartis.com and let us know the nature of your request and your contact information. Please include the job requisition number in your message

Role Requirements

Division
DIV_GD
Business Unit
Development
Location
LOC_IN
Site
Hyderabad (Office)
Company / Legal Entity
IN10 (FCRS = IN010) Novartis Healthcare Private Limited
Functional Area
FCT_QA
Job Type
Full time
Employment Type
Regular
Shift Work
No
Apply to Job

Job ID
REQ-10089436

Manager, R&D Quality

Apply to Job

Source URL: *https://jobapi.novartis.com/req-10089436-manager-rd-quality*

List of links present in page

1. https://jobapi.novartis.com/req-10089436-manager-rd-quality

2. mailto:diversityandincl.india@novartis.com
3. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Hyderabad-Office/Manager--R-D-Quality_REQ-10089436-1
4. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Hyderabad-Office/Manager--R-D-Quality_REQ-10089436-1