NOVARTIS

QA Compliance Expert - Regulatory CMC Facilitator

Job ID
REQ-10087109
Sep 23, 2026
LOC_IN

About the Role

Key Responsibilities

- Partner with regulatory teams to align Chemistry, Manufacturing and Control strategies across the product lifecycle.
- Evaluate product changes for regulatory impact and support compliant change control decisions.
- Serve as the primary site contact for regulatory matters and cross-functional stakeholder engagement.
- Provide regulatory guidance during quality events, investigations, escalations, and compliance discussions.
- Coordinate timely reviews of Chemistry, Manufacturing and Control documentation for assigned products.
- Support regulatory inspections and audits by identifying and addressing compliance risks.
- Drive initiatives that strengthen regulatory compliance and promote process harmonization.
- Deliver training and knowledge sharing to enhance regulatory awareness across site functions.

Essential Requirements

- Advanced degree in Chemistry, Biology, Pharmacy, Engineering, or a related scientific discipline.
- More than three years of experience in a Good Practice regulated environment.
- Experience in Quality Assurance, Manufacturing, Development, or Regulatory Affairs within the pharmaceutical industry.
- Strong knowledge of biologic drug substance manufacturing processes involving recombinant proteins or nucleic acids.
- Ability to work independently, manage complex priorities, and make sound quality decisions.
- Fluent English communication skills with the ability to collaborate across global teams.

Why Novartis: Our purpose is to reimagine medicine to improve and extend people’s lives and our vision is to become the most valued and trusted medicines company in the world. How can we achieve this? With our people. It is our associates that drive us each day to reach our ambitions. Be a part of this mission and join us! Learn more here: https://www.novartis.com/about/strategy/people-and-culture

You’ll receive: You can find everything you need to know about our benefits and rewards in the Novartis Life Handbook. https://www.novartis.com/careers/benefits-rewards

Commitment to Diversity and Inclusion:
Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.
Join our Novartis Network: If this role is not suitable to your experience or career goals but you wish to stay connected to hear more about Novartis and our career opportunities, join the Novartis Network here: https://talentnetwork.novartis.com/network.

Role Requirements

Division
DIV_TO
Business Unit

Other
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
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