# R&D Quality Specialist

Job ID
REQ-10050616

5月 14, 2025

India

## 摘要

Standard activities or routine tasks e.g. batch records reviewer, etc. Supportive project work. Support the timely release of GMP relevant documents and batches. Support departmental projects and objectives according to agreed timelines and standards in the given area of competency and support adherence to compliance with cGMP in TRD.

## About the Role

**Major accountabilities:**

- 1. Support a discipline and/or provide a service individually or within a team of associates. May provide functional expertise to Line Unit and other QA Units in area of responsibility.
- 2. Write and review GMP-relevant deliverables and/or related tools as per area of responsibility in order to ensure compliance with cGMP and project quality deliverables.
- 3. Support project related activities (e.g. TRD product portfolio, development of new tools,

processes, Quality initiatives, Quality Manual implementation, Quality Plans, Quality Risk Assessments, training activities, qualification and facility upgrade activities, IT validation projects) as per area of responsibility.
- 4. Comply with internal and external guidelines regarding quality and safety (Quality Manual, regulatory cGMP guidelines, Health Authority guidance ' s, SOPs etc.).

**Additional specific roles/tasks**

**Key Responsibilities:**

- Conduct Pre-packaging Batch Record Review to ensure GMP compliance and readiness for IMP packaging activities.
- Manage and process change controls, specifically for Category 1 and Category 3 changes, ensuring timely evaluation and documentation.
- Create Right First Time (RFT) and trend reports to monitor process performance and identify areas for improvement.
- Support temperature excursion assessment activities, including investigation, documentation, and implementation of corrective actions.
- Review and approve deviations, CAPAs, and change controls related to IMPs. Participate in internal and external audits, including preparation, execution, and follow-up of corrective actions.
- Collaborate with TRD, manufacturing, supply chain, and regulatory teams to ensure quality requirements are met.
- Contribute to the development and maintenance of quality management systems (QMS) and standard operating procedures (SOPs).
- Support training initiatives for GMP and quality awareness within TRD IMP teams.

**Qualifications:**

- Bachelor ' s degree in Pharmacy, Chemistry, Life Sciences, or a related field.
- 6-8 years of experience in GMP quality assurance within the pharmaceutical industry, ideally with IMPs or clinical trial materials.
- Strong understanding of Good Manufacturing Practice (GMP) and Data Integrity principles, with the ability to apply these in daily QA activities.
- Demonstrated learning agility and ability to quickly adopt and effectively use IT tools relevant to QA processes.
- Experience with deviation management, CAPA, change control, and batch record review. Proficiency in generating RFT and trend reports.
- Experience with temperature excursion assessments.
- Excellent attention to detail and problem-solving skills.
- Strong communication and collaboration abilities.

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Business Unit
Innovative Medicines

地点
India

站点
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Company / Legal Entity
IN10 (FCRS = IN010) Novartis Healthcare Private Limited

Functional Area
Quality

Job Type
Full time

Employment Type
Regular

Shift Work
No

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