

R&D Quality Manager

Job ID
REQ-10033301

12月 17, 2024

Switzerland

摘要

Location: Basel, Switzerland

Working model: Hybrid working model (12 days per month in the office)

Note: Applications will be reviewed in January 2025.

About the role:

The R&D Quality Manager will independently manage projects and processes to support the technical R&D (TRD) portfolio. Providing quality assurance expertise, guidance and support to TRD project teams, to ensure compliance with cGMP and Novartis procedures and quality standards.

About the Role

Major accountabilities:

- Generation, Review and Approval of GMP relevant documents generated by TRD and/or TRD QA
- Batch release decision-making according to applicable procedures, with the authority delegated by Swiss FvP
- Oversight on the review of master and executed batch records performed by other QA members, including clarification of all deficiencies in GMP documents, and supervision of agreed follow-up
- Support project management functions as a project team member
- Supports audits and inspections in case of questions on assigned projects
- QA contact for assigned third parties, when applicable. In this context, supports on-site visits and audit preparations at CMO, follows up audit CAPAs, and supports review of CMO KPIs and input to Quality agreements.

Minimum Requirements:

- Master degree in scientific discipline (Chemistry / Pharmacy)
- Sound scientific, technical and regulatory knowledge.
- Fluent English both spoken and written
- Fluent German is an advantage.

Work Experience:

- 3+ years of proven experience in n operational Quality Assurance (within a Pharmaceutical environment)
- Good knowledge of cGMP, working knowledge in technical development, production.

Skills:

- Good organizational and decision-making skills
- Influencing skills.
- Resilience
- Self Awareness.

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部门
Development

Business Unit
Innovative Medicines

地点
Switzerland

站点
Basel (City)

Company / Legal Entity
C028 (FCRS = CH028) Novartis Pharma AG

Functional Area

Quality

Job Type
Full time

Employment Type
Regular

Shift Work
No

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