NOVARTIS

(Senior) Quality Manager (m/f/d)

Job ID
REQ-10078724
Июн. 02, 2026
Швейцария

Сводка

Location: Basel, Switzerland #onsite

Role Purpose:
The (Senior) Quality manager is responsible for leading and overseeing quality activities across the TRD portfolio, ensuring compliance with cGMP, regulatory requirements and the Novartis Quality Manual and is conducted according to the relevant Standard Operating Procedures. The (Senior) QAM provides strategic QA oversight, drives quality decision-making, and ensures timely delivery of GMP documentation, batch release (as applicable), and project milestones. Acts as key interface for stakeholders and external partners (CMOs) as applicable, ensuring robust audit readiness, effective CAPA management, and alignment of quality standards. Leads risk-based quality assessments and supports inspections and audits. Contributes expert guidance to cross-functional teams to ensure consistent, compliant, and efficient quality operations.

About the Role

Major Accountabilities

- Manage complex projects and processes to support the TRD product portfolio, development activities, and departmental objectives in line with agreed timelines, quality standards, and regulatory requirements.
- Ensure sustained compliance with cGMP, internal quality standards, and health authority expectations across all assigned activities.
- Act as Subject Matter Expert (SME) and provide QA oversight and functional expertise to TRD line units, cross-functional teams.
- Perform review, approval, and release of GMP-relevant deliverables, can include batch disposition for clinical trial materials (IMP), in accordance with defined authorities.
- Can oversee the review of master and executed batch records, ensure timely clarification of GMP deficiencies, and supervise appropriate follow-up actions.
- Author, review, and approve GMP documentation (e.g., CoAs, BRR checklists, SOPs, Quality Risk Assessments) ensuring completeness, accuracy, and compliance.
- Can provide QA support to project teams and contribute as an active project team member as applicable.
- Can act as QA Single Point of Contact (SPOC) for assigned Contract Manufacturing Organizations (CMOs).
- Ensure alignment and harmonization of QA responses across TRD QA Operations.
- Can serve as SAP/GLIMS key user and QA Operations SPOC for system-related topics.
- Support internal and external audits and inspections, ensuring readiness and effective responses.
- Ensure compliance with all relevant quality, safety, ethical, and information security standards.

Work Experience

- Experience in GMP environment, preferably including QA
- Experience in batch release, documentation review, and inspection support preferred
- Experience in project management and cross-functional collaboration in a global matrix organization is highly desirable.
- Experience with GMP aspects of small molecules, new modality pharmaceutics is a strong asset.
- Experience with external partners (e.g., CMOs) and supplier quality oversight is an asset.

Skills

- Strong knowledge of cGMP and regulatory requirements
- Strong scientific, technical, and quality risk management expertise
- Solid scientific and technical understanding of pharmaceutical processes
- Analytical thinking with proven ability to assess GMP compliance
- Strong decision-making, organizational, and project management skills
- Effective communication, leadership and stakeholder management

Languages

- Fluent English (written and spoken)
- Local/site language (desirable)

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.

Accessibility and accommodation
Novartis is committed to working with and providing reasonable accommodation to all individuals. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the recruitment process, or in order to receive more detailed information about the essential functions of a position, please send an e-mail to inclusion.switzerland@novartis.com and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

Why Novartis: Helping people with disease and their families takes more than innovative science. It takes a community of smart, passionate people like you. Collaborating, supporting and inspiring each other. Combining to achieve breakthroughs that change patients' lives. Ready to create a brighter future together? https://www.novartis.com/about/strategy/people-and-culture

Benefits and Rewards: Learn about all the ways we'll help you thrive personally and professionally.
Read our handbook (PDF 30 MB)

Дивизион
Development
Business Unit
Quality
Место
Швейцария
Сайт
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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(Senior) Quality Manager (m/f/d)

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