NOVARTIS

TRD Sr. QA Specialist

Job ID
REQ-10074537
мар 23, 2026
Италия

Сводка

Location: Ivrea, Italy #onsite

Role Purpose:
Support the pilot plant ramp up and operationalization process through the creation compliant manufacturing and QC-related quality system which comprises master batch records, logbooks, forms, procedures. Support qualification and validation activities managing and reviewing the related documentation.
Ensure the compliance of all the business areas with the Novartis Quality Manual and Policies and all relevant GxP, legal and regulatory requirements, in preparation of external and corporate audits and Health Authority inspections.

Maintain the site compliance through 3rd party management, trainings, change controls, self-inspections, KPIs (Key Performance Indicators) and KQIs (Key Quality Indicators) monitoring.

About the Role

Major Accountabilities:

- Support site qualification and validation activities (advising, review, approval).
- Implementation of Quality Systems (incl. documentation management)
- Supplier management activities (agreements, oversight, audit).
- Preparation/support and coordination of CAPA/follow -up
- Audit and inspection preparation and support, ensure applications, certificate maintenance etc. to local HA
- Change control review/approval
- Ensure local DI and eCompliance oversight (training, inspections, plan, risk ID etc)
- KPI/KQI trending
- Handling of technical complaints, deviations, quality events related to Novartis products, systems or processes.

Key Performance Indicators:

- Successful support of projects with agreed quality and delivery dates, passing of internal & external inspections.
- Meet quality & timelines for all projects
- Act in accordance with Novartis standards.
- The number and severity of cGMP issues identified during internal and external audits
- Year-end figures within budget; Successful coordination of departmental operational activities

Work Experience:

- Change Control Management
- Audit & Inspection Management
- Compliance Risk Management
- Good Manufacturing Practices (cGMP)
- GxP Experience
- KPI Reporting
- Quality Management System

Prerequisites:

- Minimum of 5 years in pharmaceutical industry (sterile preferred)
- Previous experience in HAs inspection support (backroom / SME)
- Experienced in QMS document management
- Fluency in English
- Experience working with electronic quality systems (e.g. change controls, deviations, OOX, complaints, etc.)
- Strong quality mindset, documentation, communication, and cross-functional collaboration skills.

Languages:

- Italian
- English

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.

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
Италия
Сайт
Ivrea
Company / Legal Entity
IT58 (FCRS = IT058) Advanced Accelerator Applications Italy Srl
Functional Area
Quality
Job Type
Full time
Employment Type
Regular
Shift Work
No

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