NOVARTIS

TRD QA Specialist

Job ID
REQ-10074539
мар 23, 2026
Италия

Сводка

Location: Ivrea, Italy #onsite

Role Purpose:
During the pilot plant ramp up and operationalization support line units efforts in developing compliant manufacturing and QC-related quality system, with particular focus on master batch records, logbooks, forms, procedures. Oversee the manufacturing lines initial validation activities (e.g. water runs, engineering batches and eventually APSs) and QC laboratory instruments PQs.

In routine will be responsible to coordinate the QA shopfloor team and perform manufacturing and QC oversight, deviation and OOX review/approval, batch record review and support QP for the release of phase I/II clinical products.

About the Role

Major Accountabilities:

- Support the pilot plant ramp-up and operationalization by contributing to the development, implementation, and maintenance of a compliant manufacturing and QC quality system, with particular focus on master batch records, logbooks, forms, and GMP procedures.
- Oversee and support initial manufacturing and QC validation activities, including water runs, engineering batches, APSs, and QC laboratory instrument Performance Qualifications (PQs), ensuring documentation completeness and GMP compliance.
- In routine operations, coordinate and provide leadership to the QA shopfloor team, ensuring continuous QA presence during manufacturing and QC activities.
- Perform real-time manufacturing and QC oversight, including review and approval of deviations, OOX/OOS events, and execution of immediate quality decisions on the shopfloor.
- Review, approve, and ensure completeness and accuracy of batch manufacturing records, supporting the Qualified Person (QP) in the timely release of Phase I/II clinical trial radiopharmaceutical products.
- Ensure timely collection, monitoring, and reporting of Quality KPIs, supporting management reporting and continuous performance monitoring of manufacturing and QC activities.
- Actively support Health Authority inspections and internal audits, ensuring timely provision of accurate documentation, data, and subject-matter expertise, and contributing to inspection readiness activities.
- Manage and oversee GxP Quality System processes, including Change Control, Deviation Management and CAPA, ensuring full compliance with GxP requirements and the Novartis Quality Manual.
- Ensure effective tracking, escalation, and timely closure of CAPAs, including proactive management of risks related to delayed or ineffective actions.
- Prepare, review, approve, and manage GxP documentation lifecycle activities, including document issuance, filing, archiving, and controlled distribution.
- Actively contribute to continuous improvement initiatives, including optimization of existing processes and implementation of enhanced quality practices aligned with operational maturity of the pilot plant.

Key Performance Indicators:

- Successful support of projects and routine operations in line with agreed quality standards and delivery timelines.
- Positive outcomes of internal and external inspections, with no critical compliance gaps attributable to QA oversight.
- Demonstrated ability to maintain effective collaboration and sound working relationships with manufacturing, QC, technical operations, and QA teams.
- Consistent role modeling of Novartis culture, values, and behaviors within the QA organization and cross-functional teams.

Work Experience:

- Quality Assurance in pharmaceutical sterile manufacturing environments
- Audit and Health Authority Inspection Management
- Quality Management Systems (QMS)
- Sterile Manufacturing Operations (DP or API)
- Aseptic Processing and Contamination Control
- Deviation, Incident, and Escalation Management
- OOX/OOS and Investigation Management
- Corrective and Preventive Actions (CAPA)
- Change Control Management
- SOP and Documentation Management
- Manufacturing and QC Oversight

Prerequisites:

- Proven experience of minimum 3 years working on the shopfloor of a sterile pharmaceutical manufacturing site (Drug Product or API).
- Solid and demonstrable knowledge of Quality Systems, Data Integrity principles, and aseptic processing.
- Experience working with electronic quality systems (e.g. change controls, deviations, OOX, complaints, etc.)
- Strong quality mindset, leadership and cross-functional attitude

- Proactive and continuous improvement mindset

Languages:

- Italian
- English (intermediate level)

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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