NOVARTIS

# TRD QA Specialist

Job ID
REQ-10074539
Mar 23, 2026
LOC_IT

## 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.

## Role Requirements

**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

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DIV_GD
Business Unit
Quality
Location
LOC_IT
Site
Ivrea
Company / Legal Entity
IT58 (FCRS = IT058) Advanced Accelerator Applications Italy Srl
Functional Area
FCT_QA
Job Type
Full time
Employment Type
Regular
Shift Work
No
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