# Quality Assurance Operations Specialist

Job ID
REQ-10058016

7月 23, 2025

Spain

## 摘要

The QA Operations Specialist manages Quality aspects and projects within area of responsibility. This role ensures and supports overall GxP conformity and Compliance with the Novartis Quality Management Systems.

## About the Role

**Major accountabilities:**

- Provide QA support of production, engineering, and supply chain operations through review/approval of test records for batch release, SOPs, C of As (as applicable), CAPAs, Deviations, change controls, and shop floor oversight. Provides the production, engineering, and supply chain teams with QA/Compliance guidance and decisions.
- Review and approve Standard Operating Procedures (SOPs), Quality Risk Assessments (QRAs), Quality Plans related to manufacturing operations, as needed. Contribute to

generation of Annual Product Reviews for production, engineering and supply chain.
- Support continuous quality improvement program for manufacturing operations and partner with the production, engineering, and supply chain teams to implement/optimizes to improve efficiency (right the first time) and monitor/escalate as needed.
- Supports all regulatory inspections related to preparedness initiatives and executions of the inspections.
- Provide cGMP and associated OJT training to any other quality members and other operational areas as needed.
- Perform or support any other tasks necessary to maintain the product quality and site cGMP compliance, as needed.
- Supports QA Operations programs especially related to batch release activities and shop floor programs which includes Visual Monitoring on Surprise (ViMOS), walkthrough program, equipment/area/utility out of service program, QA area release of classified and unclassified areas, QA media fill oversight programs, event triage and support of routine operations.
- Assist in triaging when an event or issue arises during manufacturing operations Follow the scheduling of tasks set forth by the QA operations Lead or Head for shop floor coverage including ViMOS
- Review/approve investigations of excursions in production, engineering, and supply chain operations.
- Support resolution of major and critical quality events, monitor that recurrent events are properly escalated and resolved. Ensure root cause is determined, evaluate impact on product quality, disposition, and corrective actions

**Minimum Requirements:**

- Bachelor ´ s Degree in Science (Preferably in Pharmacy), MSc in Pharmaceutical Industry.
- 2+ years of experience in a GxP (Bio)pharmaceutical or API manufacturing operations up of which 1+ years of experience in a Quality Assurance role.
- QA and/or QC experience in pharmaceutical industry with environmental monitoring & cleanliness zones.
- Experience with investigation and root cause including OOX investigation expertise strongly preferred.
- Fluent English and Spanish, written and spoken.

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部门
Operations

Business Unit
Innovative Medicines

地点
Spain

站点
Zaragoza

Company / Legal Entity
ES45 (FCRS = ES045) AAA Ib é rica S.L.U.

Functional Area
Quality

Job Type

Full time

Employment Type
Regular

Shift Work
No

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