NOVARTIS

# Quality Assurance Officer / Specialist

Job ID
REQ-10037292
Jan 22, 2025
Spain

## Summary

The Quality Assurance Officer / Specialist supports all the activities GMP related (operational and strategic), in order to guarantee the compliance with the regulatory requirements, quality standards and SOP in use, guaranteeing the quality oversight over the entire working time of the facility for all the GMP activities on going.

## About the Role

**We offer fixed-term contract of 1 year.**

**Open Positions: 2**

**Quality Assurance Officer**

**Major Accountabilities:**

- Supervise GMP activities in the shopfloor as to ensure they are carried out in accordance with GMP standards.
- Guarantee the correct document lifecycle management (paper and electronic system).
- Support the QP in the preparation of batch release documents as well as in the batch record closure.
- Support the release for shipment under quarantine process.
- Support the Artwork management process.
- Update the lists of documents related to the Quality Management System based on the indications of the reference SOPs.
- Management of  Deviations, CAPA, change controls  as required.
- Support the Self-Inspections as per approved annual plan.

**Minimum Requirements:**

- 1+ years of experience in a Quality department
- Good organizational skills including attention to details
- Solid knowledge of quality system (GMP) and basic knowledge of regulatory requirements
- Availability to Work in a shift pattern  including night shifts
- Fluent English and Spanish, written and spoken.

**Quality Assurance Specialist**

**Major Accountabilities:**

- Support the the site program for ongoing inspection readiness in conjunction with the quality leadership team, including the site self-inspection program.

- Oversee and contribute to the timely completion of audit/inspection responses and reports, CAPA commitments, and internal/external communications with Health Authorities.
- Support the site level Quality Management Review (QMR) program including monitoring and reporting key performance indicators.
- Support Deviation,CAPA, OOX Management
- Support the following site QMS programs: Annual Product Quality Review (APQR), Compliance Alerts, Escalations, , Health Authority Notifications, Exceptions Handling, Document Control, Training, Data Integrity, and Novartis Global document assessment
- Ensure site program compliance with the legal requirements of the local Health Authorities and the Novartis audit/inspections quality systems.
- Lead/Support both site and global Change Controls and Change Review Boards to ensure consistent application of Compliance requirements and standards.

**Minimum Requirements:**

- 2+ years of experience in a Quality department
- Good organizational skills including attention to details
- Solid knowledge of quality system (GMP) and basic knowledge of regulatory requirements
- Fluent English and Spanish, written and spoken

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Division
Operations
Business Unit
Innovative Medicines
Location
Spain

Site
Zaragoza
Company / Legal Entity
ES45 (FCRS = ES045) AAA Ibérica S.L.U.
Functional Area
Quality
Job Type
Full time
Employment Type
Temporary (Fixed Term)
Shift Work
No
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