## **U** NOVARTIS

## **Quality Assurance Specialist**

Job ID REQ-10037292

3月 13, 2025

Spain

## 摘要

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** 

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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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 Temporary (Fixed Term)

Shift Work No

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