

QUALITY ASSURANCE ANALYST

Job ID
REQ-10060495

8月 28, 2025

Mexico

摘要

-Supports effective GxP Compliance and/or Audit activities, operations and systems to ensure compliance of business areas with the Novartis Quality Manual and Policies and all relevant GxP, legal and regulatory requirements, and through internal audits, KPIs (Key Performance Indicators) and KQIs (Key Quality Indicators). -Supports the preparation and management of external and corporate audits and Health Authority inspections.

About the Role

Major accountabilities:

- Planning and supporting PQR/APQR activities -Support site qualification and validation activities (planning, advising, review) -Implementation of Quality Systems (incl. documentation management) -Supplier management activities (agreements, oversight, audit) -Preparation/support and coordination of CAPA/follow-up -Audit and inspection preparation

and support -Change control review/approval -Ensure local DI and eCompliance oversight (training, inspections, plan, risk ID etc.) -Ensure process quality assurance acc.

- to regulations -QP declaration review and approval -KPI trending -Ensure applications, certificate maintenance etc. to local HA -SPOC for communication with HA, GCA / One voice / consolidated approach / synergies for all sites within same HA jurisdiction / country -Reporting of technical complaints / adverse events / special case scenarios related to Novartis products within 24 hours of receipt -Distribution of marketing samples (where applicable)

Key performance indicators:

- Ensures planning and successfully supports PQR/APQR activities -Successfully carries out site qualification and validation activities (planning, advising, review) -Supports the implementation of Quality Systems (incl. documentation management); Ensure local DI and eCompliance oversight (training, inspections, plan, risk ID etc) -Ensure process quality assurance according to regulations

Minimum Requirements:

Work Experience:

- QC/ QA in pharmaceutical ind./ biotech with environmental monitoring &.
- cleanliness zones.
- Functional Breadth

Skills:

- Action Oriented.
- Continuous Learning.
- Dealing With Ambiguity.
- Functional Skills.
- Gmp Procedures.
- Process Optimization.
- Qa (Quality Assurance).
- Quality Standards.
- Self Awareness.
- Technological Expertise.
- Technological Intelligence.
- GxP.
- Industry standards.
- Compliance requirements.

Languages :

- English.

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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部门

Operations

Business Unit

Innovative Medicines

地点

Mexico

站点

INSURGENTES

Company / Legal Entity

BR03 (FCRS = BR003) NOVARTIS BIOCIENCIAS S.A

Functional Area

Quality

Job Type

Full time

Employment Type

Regular

Shift Work

No

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