Document Management Specialist

Job ID
REQ-10051978

5月 12, 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

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
MX06 (FCRS = MX006) Novartis Farmac é utica S.A. de C.V.

Functional Area
Quality

Job Type
Full time

Employment Type
Regular

Shift Work
No

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Accessibility and accommodation

Novartis is committed to work with and provide reasonable accommodation to individuals with disabilities. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the recruitment process, or in order to perform the essential functions of a position, please send an e-mail to tas.mexico@novartis.com and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

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