Head GxP Compliance and Health Authorities Inspection Support

Job ID
REQ-10033976

2月 18, 2025

Spain

摘要

As Head GxP Compliance and HA Inspection Support you will ensure GxP compliance across Novartis, in alignment to evolving regulatory landscape. You will also ensure availability of required tools and training materials to support preparation for Health Authority Inspections and audits and support Compliance Platform and Function Leaders in the implementation of GxP compliance strategy across Novartis.
In this role you will also support the establishment of a comprehensive GxP compliance framework for the application of Artificial Intelligence (AI) within Novartis. This includes monitoring the AI regulatory landscape and requirements, proactively identifying and mitigating any associated compliance risks within Novartis.

About the Role

Major accountabilities:

- Provide support and training to ensure inspection readiness before and during strategic Health Authority Inspections and audits. Support review of response to HAI observations. Ensure remediation activities are undertaken, implemented, and the effectiveness verified at the respective sites and entities.
- Actively contribute to the Gen AI governance and initiatives. Support building a robust GxP eCompliance framework for application of Artificial Intelligence (AI) within Novartis, using GenAI tools.
- Participate in Global Aseptics and ATMP Expert Network and support reinforcing fundamental prerequisites of the aseptic area training, and practices.
- Actively participate in the category 2/3 escalation meetings as required, provide investigation support for any potential GMP gaps that may result in material impact to Novartis.
- Contribute on the development and deployment of strategic Quality/Compliance related projects including QMS, risk management and Data integrity.
- Liaise with RA Policy team on Regulatory intelligence, emerging guidances including identifying any draft guidance documents for commenting. Assist QMS team to review final guidance documents issued by the HA for gap assessment through the publication of Regulatory Newsflash on monthly basis.
- Support QMS related activities and actively contribute/participate in the QMS governance and network meetings.
- Ensure all applicable SOPs are routinely monitored for updates for the processes owned in line with attached role profile (See attachment 1).
- Support the Quality Systems Programs and other internal compliance initiatives including Novartis Engagement with Industry Forum activities, and projects related topics.

Minimum Requirements:

- Education: Undergraduate Degree in a science discipline; additional knowledge in Pharmaceutical Manufacturing technology and practices; Quality Assurance/ Compliance and Auditing; graduate degree desired.
- Minimum of 15 years experience in the pharmaceutical or biopharmaceutical industry in Operation and QA roles. Significant experience in either operations or QA roles supporting sterile operations and/or ATMPs is required.
- Demonstrated ability to execute detailed and complex investigations, including detection of potential data integrity breaches.
- Knowledge and experience related to eCompliance Regulations and an interest in the developing GenAI landscape.
- Prior exposure to HA inspections / auditing experience required (min. 5 years).
- Strong oral and written communication, social and organizational skills required.
- Availability for min. 25 % travel on a global basis.
- Fluent English, written and spoken, other languages are a plus.

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部门
Operations

Business Unit
Innovative Medicines

地点
Spain

站点
Barcelona Gran V í a

Company / Legal Entity
ES06 (FCRS = ES006) Novartis Farmac é utica, S.A.

Alternative Location 1
Hyderabad (Office), India

Alternative Location 2
Ljubljana, Slovenia

Functional Area
Quality

Job Type
Full time

Employment Type
Regular

Shift Work
No

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