

Quality assurance- Complaints Specialist

Job ID
REQ-10050372

5月 02, 2025

Brazil

摘要

Manages Quality aspects and projects within area of responsibility. Ensures and supports overall GxP conformity and Compliance with the Novartis Quality Management Systems.

About the Role

About the role :

- On-time and GMP
- compliant release of dosage forms
- No complaints about inspections by authorities in your own area of responsibility without these being noticed and communicated beforehand
- Responsible for complaint management, including entry, follow-ups, product analysis, and closure.
- Develop and establish reports for prompt review of new complaints, regulatory reporting

decisions, and follow-up.

- Code events and ensure all required information for a complaint file is obtained and properly documented.
- Evaluate all information from a clinical and technical perspective to ensure appropriate analysis, investigation, root cause, and quality engineering review.
- Track, receive, and ship products as needed.
- Execute daily complaints analysis and failure investigations, documenting results and relevant information.
- Approve complaints in assigned product families.
- Set up complaint meetings and effectively communicate with worldwide complaint groups and internal departments.

Minimum Requirements:

- Functional Breadth
- 3 y of experience in complaints and investigations.
- QC/ QA in pharmaceutical ind./ biotech with environmental monitoring &.
- Collaborating across boundaries.
- cleanliness zones.

Skills:

- Continuous Learning.
- Dealing With Ambiguity.
- Gmp Procedures.
- Qa (Quality Assurance).
- Quality Control (Qc) Testing.
- Quality Standards.
- Self Awareness.
- Technological Expertise.
- Technological Intelligence.

Languages :

- English.

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部门
Operations

Business Unit
Innovative Medicines

地点
Brazil

站点
Santo Amaro

Company / Legal Entity
BR03 (FCRS = BR003) NOVARTIS BIOCIENCIAS S.A

Alternative Location 1
INSURGENTES, Mexico

Functional Area
Quality

Job Type
Full time

Employment Type
Regular

Shift Work
No

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