

Complaint Hub Associate

Job ID
REQ-10031882
Dec 03, 2024
Spain

Summary

In this role will manage Quality aspects and projects within area of responsibility and ensure and support overall GxP conformity and compliance with the Novartis Quality Manual, the law and other policies / procedures in processes like e.g. document management, change control system, training, escalation management, risk management, qualification / validation and CSV.

About the Role

We offer a temporary contract of 6 months, with possibility of extension.

Major accountabilities:

- Responsible for handling of technical market complaints and processing in e-QMS, by completing an initial assessment and closure of the complaints.
- Initiating escalation, when required, and following up with responsible country quality for supplementary data.
- SPoC for stakeholders, e.g. investigation sites, ESO QA, NPS, Med Info-Call Centers, etc...
- SPoC for local cases in Spain supporting and/or participating in NEM cases as required. Member of Local Committee - Quality Assessments.
- Responsible for performing local reconciliation activities with stakeholders as Patient safety/Medical Info with all countries in scope.
- Prepare draft feedback letters and sharing it with stakeholders.
- Responsible for complaint sample management related with Spanish customers (cases).
- Responsible for preparing Quality trends (Spanish cases) and driving continuous improvement for processes and product quality performance.
- Ensure that local Quality System and SOPs are in place for all GxP related activities under complaint landscape and that compliance with cSMP is maintained through training and internal audits.

Minimum Requirements:

Work Experience:

- Degree in a Scientific or Technology field (e.g. Chemistry, Pharmacy or other Life Science).
- Minimum 3 years of experience in Quality or in Quality Assurance department.
- Solid Knowledge on GMP & other regulations as: GCP, GDP, ICH, ISO
- Fluent Spanish and English, written and spoken. **French and German knowledge will be highly valued.**

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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Commitment to Diversity and Inclusion: 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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Division

Operations

Business Unit

Innovative Medicines

Location

Spain

Site

Barcelona Gran Vía

Company / Legal Entity

ES06 (FCRS = ES006) Novartis Farmacéutica, S.A.

Functional Area

Quality

Job Type

Full time

Employment Type

Temporary (Fixed Term)

Shift Work

No

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