Quality Compliance Coordinator

Job ID
REQ-10002173
Nis 17, 2024
Turkey

Özet

-Manage cost 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) -Performs preparation and management of external and corporate audits and Health Authority inspections. -Planning and supporting PQR/APQR activities. -Preparation and archiving of quality agreements and contracts. -Establishment of training system to document all taken trainings and also to retrieve the training status.

About the Role

Major accountabilities:

- Planning and supporting PQR/APQR activities.
- Support site qualification and validation activities (planning, advising, review).
- Performs preparation and management of external and corporate audits and Health Authority inspections.
- 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 e-Compliance oversight (training, inspections, plan, risk ID etc)
- Ensure process quality assurance acc.
- KPI trending
- Establishment of training system to document all taken trainings and also to retrieve the training status. Ensure organization of GMP training for the site and also to track the completion.
- Preparation and archiving of quality agreements and contracts.
- Manage site quality risk assessments and ensure risks mitigated.

Key performance indicators:

- Successful support of projects with agreed quality and delivery dates, passing of internal and external inspections.
- Meet quality and timelines for all projects -Act in accordance with Novartis standards.
- The number and severity of cGMP issues identified during internal and external audits -Year-end figures within budget; Successful coordination of departmental operational activities

Minimum Requirements:

- University degree in Pharmaceuticals, Chemical Engineering or Chemistry
- Minimum 4 years of experience
- Excellent communication skills in English
- Good negotiation skills in English
- Team working and customer oriented mindset
- Good at conflict management
- Knowledge of quality management systems such as deviation, complaint handling, change management
- Knowledge of regulatory systems and CMC processes
- Good analytical thinking and problem solving skills

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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Departman
Operations
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Company / Legal Entity
TR01 (FCRS = TR001) Novartis Sağlık, Gıda ve Tarım Ürünleri San. Ve Tic. A.Ş.
Functional Area
Quality
Job Type
Full time
Employment Type
Regular
Shift Work
No
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