Engineering Standard Manager

Job ID
REQ-10041025

2月 21, 2025

India

摘要

Drive the development, implementation and continuous improvement of Engineering global business processes and systems to ensure adherence to internal Novartis requirements, standards and external regulations improving efficiency and compliance.

About the Role

Key Responsibilities:

- Develop and maintaining simplified decision-making Global Engineering Standards for key Business Processes/Quality Systems ensuring alignment with Health Authority regulations and business requirements. Provide guidance and oversight to manufacturing sites ensuring communicating and implementation tracking.

- Proactively reviews the Quality Systems to identify Engineering trends across the organization and in alignment with industry expectations. Ensures alignment with Novartis Quality System (QMs/QDs/ SOPs). Reviews, and provides feedback of all relevant Quality Modules and Directives. Provides input into the alignment and update of global standards.

- Define and maintain Engineering Systems (e.g., Kneat, Agile ACC, COMOS) (including implementation of new functionalities) by executing defined roadmap in collaboration with IT. Drive its continuous improvement in compliance with Global Engineering Standards processes and benchmarking against internal Novartis and external industry standards.

- Ensure training content is properly updated for Global Engineering Standards and Systems functionalities into applicable Management System (e.g., U4G). Active partnership with sites to ensure proper knowledge and learning capabilities.

- Ensure Engineering Training program (matrix) is in alignment with existing effective and applicable Standards. Define minimum training requests for specific job role to facilitate onboarding process.

- Support sites in preparation, review, and approval of responses to internal and external audits to global and local Engineering organizations. Ensure KQI are under control at global and local organization through monthly reporting.

- Direct Interface with Quality Function to ensure alignment of Global Engineering Standards and Systems with the aim of achieving world class standards and practices, with best practice sharing across the platform sites.

- Support as a Global Process owner for the C&Q & support for implementing the tools as part of engineering process digitalization.

Essential Requirement:

- Degree in Mechanical/Chemical Engineering/M. Pharma with 10 - 12 years of experience in Pharmaceutical/ Chemical/ FMCG Industry.
- Deep understanding of Project Commissioning & Qualification activities, and qualification documentation creation within pharmaceutical OSD / Injectable / API / Oncology / Biotechnology.
- In-depth knowledge of engineering standards: Understanding industry-specific regulations, codes, and guidelines is crucial for ensuring compliance and quality in engineering process & activities.
- Expertise in developing Engineering Standards, Standard Operating Procedures (SOPs), Templates, Work Instructions (WIs), and other technical documentation.
- Technical Skills: Kneat, excel, power point, word

- Proficient in project management, including planning, organizing, and coordinating with global stakeholders to successfully implement engineering programs, initiatives, and projects

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部门
Operations

Business Unit
Innovative Medicines

地点
India

站点
Hyderabad (Office)

Company / Legal Entity
IN10 (FCRS = IN010) Novartis Healthcare Private Limited

Functional Area
Technical Operations

Job Type
Full time

Employment Type
Regular

Shift Work
No

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