NOVARTIS

Manager, R&D Quality

Job ID
REQ-10093439

十一月 25, 2026

Germany

摘要

Manage complex projects (late phase cross sites, high impact). Manage global initiatives, work with cross functional teams independently. Manage projects and processes to support departmental portfolio, projects and objectives according to agreed timelines and standards. Ensure that compliance with cGMP is maintained in TRD

-Provide quality assurance expertise, guidance and support to operational activities in development and research organizations to ensure compliance with applicable regulatory requirements and Novartis procedures and quality standards.
-Manage projects, including Quality Plan initiatives, and processes that support quality objectives to assure their compliance with GxP regulations.

About the Role

Major Accountabilities:

- Support a discipline and/or provide a service individually or within a team of associates. May provide functional expertise to Line Unit and other QA Units in area of responsibility.
- Write, review, decide on approval and/or release of GMP-relevant deliverables and/or related tools as per area of responsibility in order to ensure compliance with cGMP and project quality deliverables.
- Manage project related activities (e.g. TRD product portfolio, development of new tools, processes, Quality initiatives, Quality Manual implementation, Quality Plans, Quality Risk Assessments, training activities, IT validation projects) as per area of responsibility.
- Support Project management functions as a project team member.
- Provide support to TRD line functions in GMP related topics as per area of responsibility.
- Comply with internal and external guidelines regarding quality and safety (Quality Manual, regulatory cGMP guidelines, Health Authority guidance, SOPs etc.).
- Member of the TRD project teams and TRD sub-teams, representing QA for the assigned portfolio.

- Provide QA Oversight to GCS line functions for hot products (investigational radiopharmaceuticals/ ready to use IMPs), incl. qualification and oversight of global Logisitic service providers

- Manages Deviations, Investigations, CAPAs and contributes to or writes trending reports for Deviations / Technical Complaints / Change requests for hot products (investigational radiopharmaceuticals/ ready to use IMPs) and processes of TRD GCS line unit and recommends necessary.

- QA Approver of GMP documentation related to hot products (investigational radiopharmaceuticals/ ready to use IMPs) owned by TRD GCS according to internal procedures, contributing to the review of Quality Modules/Standards, act as backup QP for RLT related releases within EU.

- Write, review and complete GMP-relevant documents.

- Provide support to GCS TRD Line Functions and Country Pharma Organization. Provide training to GCS and TRD QA functions for GMP-related tasks.

- Support the tracking of Key Quality Indicators

- Fulfill SME role as defined in the QA GCS SME matrix. (e.g. Subject matter expert for clinical label related topics and projects).

- Support audits and inspections in case of questions related to RLT portfolio

- Supports internal audits of Novartis and audits of third-party packaging and labelling as required.

- Support initiatives to maintain or improve quality performance and compliance of oper- ational activities including risk management.

- Support the activation of IITs, MAPs and/or RCs within the RLT platform with regards to the clinical supply set up, including contribution to QAA reviews (clinical supply from CDMOs, Pilot Plants and NTO in scope).

- Participate in Quality Escalations for assessment of patient and supply impacts
- Support global oversight of TRD projects and clinical supply chains

Education (minimum/desirable):

- an **Approbation as a pharmacist**, or
- a successfully completed university degree of at least four years in one of the disciplines recognized under § **15(1) AMG** , including: Pharmacy,Chemistry,Pharmaceutical Chemistry and Technology,Biology,Human Medicine, orVeterinary Medicine;
- together with the applicable practical experience required by § 15 AMG (3 years of experience with Radiopharmaceuticals).

Languages:

Fluent English required (oral & written). Good skills in site (local) language desired (oral).

Experience/Professional requirement:

required knowledge and experience to act as a Qualified Person for Radiopharmaceticals in EU, according to §§ 14, 15 German Drug Law

Good knowledge of cGMP, working knowledge in technical development, radiopharmaceutical production or QA.

Sound scientific, technical and regulatory knowledge.

Strong organizational and decision-making skills.

Strong and proven ability to analyze and evaluate cGMP compliance.

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

Benefits and Rewards: Learn about all the ways we ' ll help you thrive personally and professionally. Read our handbook (PDF 30 MB)

部门
Operations

Business Unit
Quality

地点
Germany

站点
Nuremberg (Non-Sales Force) (Novartis Pharma GmbH)

Company / Legal Entity
DE14 (FCRS = DE014) Novartis Pharma GmbH

Functional Area
Quality

Job Type
Full time

Employment Type
Regular

Shift Work
No

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kPlayer.ui.components.Remove }] } }; // Check and add plugins only if they exist if (kPlayer.plugins["download"]) { config.plugins.download = { disable: true }; } if (kPlayer.plugins["transcript"]) { config.plugins["playkit-js-transcript"] = { position: "right", // Default: bottom;('left', 'right', 'top', 'bottom') to enable transcript. expandMode: "over", // Default: alongside;('alongside', 'hidden', 'over') expandOnFirstPlay: false, showTime: true, downloadDisabled: false, printDisabled: false, disable: true }; } if (kPlayer.plugins["preventSeek"]) { config.plugins.preventSeek = { preventSeekForward: false, preventSeek: false }; } config.plugins.floating = { disable: true }; if (kPlayer.plugins["navigation"]) { config.plugins.navigation = { position: "right", expandMode: "over", expandOnFirstPlay: false, visible: false }; } if (kPlayer.plugins["hotspots"]) { config.plugins['playkit-js-hotspots'] = { disable: true }; } if (kPlayer.plugins["moderation"]) { config.plugins['playkit-js-moderation'] = { disable: true }; } if (kPlayer.plugins["info"]) { config.plugins['playkit-js-info'] = { disable: true }; } if (kPlayer.plugins["share"]) { config.plugins.share = { disable: true }; } config.ui.uiComponents = []; if (kPlayer.plugins["googleAnalytics"]) { config.plugins.googleTagManager = {}; config.plugins.googleTagManager.customEventsTracking = {}; config.plugins.googleTagManager.containerId = 'GTM-57RJQ5'; config.plugins.googleTagManager.customEventsTracking.custom = []; config.plugins.googleTagManager.customEventsTracking = { preset: { coreEvents: true, UIEvents: false, playlistEvents: false, castEvents: false } }; }

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