NOVARTIS

Manager, R&D Quality

Job ID
REQ-10093441

十一月 25, 2026

Italy

摘要

Location: Ivrea, Italy #onsite

Role Purpose:
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,

- 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):

Masters

Bachelor/Technician (> 5 years ' pharma)

Languages:

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

Experience/Professional requirement:

Good knowledge of cGMP, working knowledge in technical development, Radiopharmaceutical production, Radiopharamceutical supply chain, clinical supply chain or QA.

Sound scientific, technical and regulatory knowledge (US, EU, Japan guidelines/ regulations).

Good organizational and decision-making skills, solution driven.

Good and proven ability to analyze and evaluate cGMP compliance

Demonstrated/recognized leader of specific GxP; early external/industry engagement

Role Model of Novartis culture, values & behaviours

Benefits & Rewards

At Novartis, we ' re committed to reimagining medicine together - and rewarding the people who make it happen.

Expected Annual Base Salary Range for role: € 38,000 to € 70,600

The base salary offered is determined based on gender-neutral objectives, such as relevant skills, competencies and experience in accordance with the Novartis pay setting policy and upon joining Novartis will be reviewed periodically.

In addition to your base salary, you may be eligible for a performance-based bonus depending on certain performance parameters.

The rewards of being part of our team go far beyond base pay and incentives. We also offer a variety of competitive benefits in kind to help you thrive personally and professionally, such as insurance plans, retirement plans, wellbeing resources and global recognition programs. In addition, we provide flexible and hybrid working options, where possible, and minimum 14 weeks paid parental leave.

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)

Primary location salary range
€ 38,000.00 - € 70,600.00

部门
Operations

Business Unit
Quality

地点
Italy

站点
Ivrea

Company / Legal Entity

IT58 (FCRS = IT058) Advanced Accelerator Applications Italy Srl

Alternative Location 1
Barcelona Gran V í a, Spain

Functional Area
Quality

Job Type
Full time

Employment Type
Regular

Shift Work
No

var kPlayer = KalturaPlayer55802022 || KalturaPlayer; var config = { targetId: "kalturaplayer6b07476ee970b346580582", provider: { widgetId: "10m7rm1pm", partnerId: "2076321", uiConfId: "55802022" }, playback: { autoplay: false, autopause: false, muted: false, loop: false }, sources: { options: {}, startTime: 0 }, disableUserCache: "true", plugins: {}, sources: { options: {}, startTime: 0 }, ui: { showCCButton: false, settings: { showQualityMenu: true, showSpeedMenu: false }, components: { fullscreen: { disableDoubleClick: false } }, uiComponents: [{ presets: ['Playback', 'Live'], area: 'BottomBarRightControls', replaceComponent: 'Fullscreen', get: 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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