NOVARTIS

TRD QA Specialist

Job ID
REQ-10088805

九月 29, 2026

Italy

摘要

Location: Ivrea, Italy #onsite

Role Purpose:
During the Pilot Plant ramp-up and operationalization, provide QA oversight and support for the establishment of a compliant quality system for GMP-relevant IT, OT, computerized, and automated systems. The role focuses on system qualification and validation, data integrity, lifecycle documentation, procedures, interfaces, equipment connectivity, and ongoing compliance.

The QA Specialist will support the implementation and qualification of computerized systems used in manufacturing, QC laboratories, facilities, utilities, and supply-chain processes. In routine operations, the role ensures that these systems remain compliant, fit for intended use, and maintained in a validated state throughout their lifecycle.

Hiring a QA Specialist with IT/OT expertise for the TRD RLT Colleretto Giacosa Pilot Plant is essential to establish local Quality capability for IT/OT system qualification, procedure development, and initial manufacturing-line validation. The role requires hands-on experience with computerized systems in pharmaceutical or regulated environments, strong knowledge of quality assurance and

data-integrity principles, and effective collaboration with all the stakeholders.

About the Role

Major Accountabilities

- Act as the local QA subject-matter expert for GMP-relevant IT/OT systems, providing independent quality oversight while supporting cross-functional execution during project ramp-up.
- Review and approve key validation and qualification deliverables, including User Requirements Specifications, risk assessments, validation plans, test protocols, executed test evidence, deviations, and qualification or validation summary reports.
- Ensure that global applications, locally configured systems, infrastructure components, equipment software, interfaces, and data flows are appropriately assessed, qualified, and released before GMP use.
- Ensure clear definition of responsibilities among system owners, system users, IT, OT, Engineering, Quality, and support functions throughout the system lifecycle.
- Ensure implementation and QA oversight of controls related to user access, audit trails, electronic records, electronic signatures, backup, restoration, archiving, business continuity, system security, and data integrity.
- Review and approve changes, deviations, CAPAs, and risk assessments affecting GMP-relevant computerized systems.
- Coordinate and support periodic reviews to confirm that computerized systems remain compliant, supported, secure, fit for intended use, and in a validated state.
- Support the drafting, review, approval, and maintenance of GxP procedures governing computerized-system validation, system administration, access management, audit-trail review, backup and restore, incident management, change control, periodic review, and system retirement.
- Support internal audits and Health Authority inspections involving computerized systems, data integrity, automation, electronic records, and electronic signatures.
- Contribute to continuous improvement initiatives, including optimization of validation activities and implementation of risk-based quality practices aligned with the operational maturity of the Pilot Plant.

Key Performance Indicators

- Timely qualification and release of GMP-relevant IT/OT and computerized systems in line with approved quality standards and project timelines.
- Timely completion of validation deliverables, periodic reviews, deviations, CAPAs, changes, and access reviews.
- Positive outcomes from internal audits and external inspections, with no critical compliance gaps attributable to QA oversight of IT/OT systems.
- Consistent role modelling of Novartis culture, values, and behaviours within the QA organization and cross-functional teams.

Work Experience

Demonstrated experience across several of the following areas:

- Computerized-system validation and qualification
- IT Quality and eCompliance
- Operational Technology and industrial automation
- Pharmaceutical manufacturing and laboratory systems
- Data integrity, electronic records, and electronic signatures
- IT infrastructure qualification
- System lifecycle and periodic review management
- Change, deviation, and CAPA management
- Supplier and IT/OT service-provider oversight
- Audit and Health Authority inspection support
- Quality Management Systems
- GxP documentation and procedure management

Prerequisites

- Minimum of three years of proven experience in the pharmaceutical or similarly regulated industry in Quality Assurance, computerized-system validation, laboratory computerized-system support, manufacturing automation, IT/OT quality, or a comparable role.
- Familiarity with applicable GxP and computerized-system compliance expectations, including EU GMP Annex 11, 21 CFR Part 11, GAMP 5, and data-integrity guidance.
- Hands-on experience with IT, OT, computerized, automated, manufacturing, or laboratory systems used in a regulated environment.
- Solid knowledge of computerized-system lifecycle management, qualification, validation, Quality Systems, and data-integrity principles.
- Experience preparing, reviewing, executing, or approving computerized-system qualification and validation documentation.
- Ability to understand system architecture, interfaces, data flows, infrastructure dependencies, equipment connectivity, and electronic records.
- Experience working with electronic Quality Systems for change controls, deviations, CAPAs, and related quality processes.
- Strong quality mindset, ownership, analytical thinking, and ability to work effectively in cross-functional teams.
- Proactive approach and continuous-improvement mindset.

Languages

- Italian
- English, intermediate level or above

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: € 29,800 to € 55,300

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
€ 29,800.00 - € 55,300.00

部门
Development

Business Unit
Quality

地点
Italy

站点
Ivrea

Company / Legal Entity
IT58 (FCRS = IT058) Advanced Accelerator Applications Italy Srl

Functional Area
Quality

Job Type
Full time

Employment Type
Regular

Shift Work
No

var kPlayer = KalturaPlayer55802022 || KalturaPlayer; var config = { targetId: "kalturaplayer6af22e7a36385610465039", 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 } }; }

// Ensure the global player registry array always exists, regardless of embed type. window.kalturaPlayerVideos = window.kalturaPlayerVideos || []; try { var thumbEmbedPromise = thumbnailEmbed({config, mediaInfo: {entryId: "1dgfvmafo"}}); // thumbnailEmbed() returns a Promise that resolves with the player instance // when the user clicks the thumbnail. Use .then() to capture the player directly. thumbEmbedPromise .then(function(player) { window.kalturaPlayerVideos.push(player); // Notify kaltura datalayer.js that a new player is ready so it can // attach custom event listeners immediately, regardless of when // the user clicked the thumbnail relative to page load. document.dispatchEvent(new CustomEvent('kalturaPlayerReady', { detail: { player: player } })); }) .catch(function(error) { console.error(error); }); } catch (e) { console.error(e.message) }

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