NOVARTIS

Manager, Quality Systems

Job ID
REQ-10089267

十月 15, 2026

USA

摘要

Location: Carlsbad, California

The Manager, Quality Systems will serve as a Quality subject matter expert, providing oversight to support commercialization readiness and the continued effectiveness of the Quality Management System. This role will develop and maintain statistically sound, risk-based approaches for evaluating quality data, identify emerging trends and risks, and translate regulatory requirements and quality insights into actionable recommendations. The position will also lead cross-functional quality and regulatory training, support CAPA/Issues and Change Control activities, manage the Medical Device Reporting program, and provide Quality guidance during investigations and troubleshooting within a regulated bioanalytical laboratory environment.

#LI-OnSite

About the Role

Key Responsibilities

- Provide Quality oversight to support commercialization readiness, including applicable processes and procedures for the commercialization of IVD devices.
- Provide Quality oversight, review, and approval of statistical frameworks, programs, and deliverables, including manufacturing QC programs and risk assessments.
- Manage the Medical Device Event Reporting process and support CAPA/Issues and Change Control programs in accordance with internal procedures and applicable regulatory requirements.
- Evaluate quality events, including deviations, CAPAs, complaints, audit findings, OOS, NCMR, and OOR, providing guidance on risk assessment, impact, immediate remediation, and preventive actions.
- Analyze quality-related data to identify issues and emerging trends and provide recommendations to management that support the effectiveness and continuous improvement of the Quality Management System.
- Develop and deliver enterprise-wide GxP, CLIA, IVD Manufacturing, ISO, and GCLP training to ensure compliance with regulatory requirements.
- Support clinical laboratory compliance with applicable accreditation requirements and support internal, sponsor, and regulatory audits, including managing assigned audit observations through resolution.
- Maintain current knowledge of applicable industry standards and regulatory requirements, including IVDR, MDCG 2024-4, ISO, CLIA/CAP, QSR, GCP/GCLP, cGMP, and ICH, and promote their consistent application across Quality activities and training.

Essential Requirements

- BS in engineering, medical technology, biological sciences, or related field.
- Minimum of seven (7) years progressively responsible experience in a related Quality Assurance role in a regulated environment.
- Experience, understanding, and familiarity with regulatory and compliance requirements and guidelines, including GxP, Part 11, ICH, ISO, CLIA/CAP, IVDR, and QSR.
- Demonstrated ability to understand and apply risk-based practices, with process analysis and root cause analysis experience and the ability to establish improved processes based on outcomes.
- Experience developing procedures and training, with strong communication and collaboration skills and the ability to present data and substantiate approaches before audiences and inspectors.
- Ability to work as an independent contributor, identifying and executing continuous improvement opportunities.

Desirable Requirements

- Experience with commercialization or commercialized IVD products
- Experience with statistics or statistical frameworks, assay validation, or QC Trending

The salary for this position is expected to range between $114,100 and $211,900 per year. The final salary offered is determined based on factors like, but not limited to, relevant skills and experience, and upon joining Novartis will be reviewed periodically. Novartis may change the published salary range based on company and market factors. Your compensation will include a performance-based cash incentive and, depending on the level of the role, eligibility to be considered for annual equity awards. US-based eligible employees will receive a comprehensive benefits package that includes health, life and disability benefits, a 401(k) with company contribution and match, and a variety of other benefits. In addition, employees are eligible for a generous time off package including vacation, personal days, holidays and other leaves.

To learn more about the culture, rewards and benefits we offer our people click here.

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)

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Accessibility & Reasonable Accommodations

The Novartis Group of Companies are committed to working with and providing reasonable accommodation to individuals with disabilities. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the application process, or to perform the essential functions of a position, please send an e-mail to us.reasonableaccommodations@novartis.com or call +1(877)395-2339 and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

部门
Operations

Business Unit
Quality

地点
USA

状态
California

站点
Carlsbad

Company / Legal Entity
U441 (FCRS = US441) Navigate BioPharma Services, Inc.

Functional Area
Quality

Job Type
Full time

Employment Type
Regular

Shift Work
No

var kPlayer = KalturaPlayer55802022 || KalturaPlayer; var config = { targetId: "kalturaplayer6ae29a94ba0c7906335286", 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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