NOVARTIS

QC Sr. Investigations Expert

Job ID
REQ-10091408

十一月 19, 2026

USA

摘要

The QC Senior Investigations Expert is responsible for leading manufacturing and QC investigation records (DEV, OOS, QE) in support of cell therapy manufacturing operations. This includes execution of thorough root cause investigations, interviewing personnel, hypothesis testing and interpretation of results, authoring investigation reports, identifying corrective and preventive actions (CAPA), and troubleshooting complex problems to support timely release of batches while maintaining compliance and ensuring quality, safety, efficacy and performance of the products in close collaboration with cross-functional teams (i.e. QA, Manufacturing, Planning and Release teams)

About the Role

#LI-Onsite

Location: Morris Plains, NJ

1 position open for: Sun-Wed (4 x 10 hours) OR Wed-Sat (4 x 10 hours)

Relocation Support: This role is based in Morris Plains, NJ. Novartis is unable to offer relocation support: please only apply if accessible.

Key Responsibilities

- Interview personnel involved with QC events and provide quality insight to complete laboratory investigation reports in 1QEM.

- Review/complete routine cell therapy manufacturing nonconformance/deviation investigations.

- Ensure all investigations are completed in a timely manner. Notify stakeholders of any delays in a timely manner.

- Provide technical support for manufacturing investigations / CAPAs / change controls as needed.

- Handle complex issues and solve problems with minimal guidance.

- Provide training to new investigations team members

- Serve as author or technical reviewer of departmental procedures as appropriate.

- Build strong cross-functional and interdepartmental partnerships to ensure seamless execution of investigations and interface closely with different functional organizations, including Quality Assurance teams.

- Collaborate with 3 *rd* parties including contract testing laboratories and CMO clients to ensure seamless execution of investigations

- Present QC Investigations Experts team in local cross functional routine (daily/weekly) meetings and global calls.

Continuous Improvement

- Work with functional teams to propose effective CAPAs, develop CAPA plans and assure CAPA effectiveness.

- Employ lean manufacturing / six sigma principles to continuously improve products, processes and systems.

Compliance

- Assess potential impact and risk to product or process associated changes may have upon change implementation and develop an appropriate mitigation strategy.

- May Initiate change control documentation

- Identify functional area SMEs to perform impact assessments as part of the change management process.

- Support deviation investigation defense during audits and site inspections for QC compliance related inquiries

Key Performance Indicators

- Timely delivery on commitments with and departmental KPIs

- Timely responses and solutions to investigations

- Efficient and flexible usage of the available resources

- Compliance to all relevant company policies and guidelines

- Exhibiting core Novartis values and behaviors and fostering these within the team

Essential Requirements

Education:

Bachelor's degree and 4-6 years of related pharmaceutical / biopharmaceutical work

experience, or master ' s degree and 3-4 years of work experience.

Languages:

- English

Experience:

- Minimum of 4 years of experience in a cGMP environment / commercial manufacturing.

- Extensive experience in a regulated GMP environment, preferably within Quality operations, or in manufacturing in a pharmaceutical or cell therapy company.

- Extensive knowledge of cGMP regulations and quality standards relevant to cell therapy manufacturing.

- Extensive working experience of deviation investigations utilizing root cause analysis tools.

- Working experience in the CAPA process and ability to identify and verify effectiveness.

- Excellent technical writing skills and ability to collaborate effectively in cross functional teams.

- Proven ability to accurately and completely understand, follow, interpret, apply Global Regulatory and cGMP requirements.

- Ability to support health authority inspections.

- Knowledge of data trending and tracking, including use of statistical analysis software a plus.

- Advanced knowledge and implementation of data integrity principles.

Specific Professional Competencies

- Excellent communication, presentation, and interpersonal skills to effectively train diverse audiences.

- Strong analytical and problem-solving skills.

- Ability to function in a rapidly changing environment & handle multiple priorities.

- Ability to set priorities, manage timelines and effectively react/manage changing priorities.

- Ability to work with management (global and site) and support corporate and departmental goals

- Ability to collaborate cross functionally to drive operational and quality excellence.

- Advanced organizational and time management skills.

- Ability to work independently and as part of a team to achieve quality objectives.

- Demonstrated critical reasoning, problem solving, troubleshooting, investigation, and decision-making skills.

- Communicate effectively with management regarding task completion, roadblocks, and needs.

- Ability to work collaboratively in a high-paced team environment, meet deadlines and prioritize work for multiple teams/programs.

The salary for this position is expected to range between . 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

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)

EEO Statement:

The Novartis Group of Companies are Equal Opportunity Employers. We do not discriminate in recruitment, hiring, training, promotion or other employment practices for reasons of race, color, religion, sex, national origin, age, sexual orientation, gender identity or expression, marital or veteran status, disability, or any other legally protected status.

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
New Jersey

站点

Morris Plains

Company / Legal Entity
U014 (FCRS = US014) Novartis Pharmaceuticals Corporation

Functional Area
Quality

Job Type
Full time

Employment Type
Regular

Shift Work
No

var kPlayer = KalturaPlayer55802022 || KalturaPlayer; var config = { targetId: "kalturaplayer6b00041c63e0c415094505", 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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