NOVARTIS

QC Sr. Investigations Expert

Job ID
REQ-10042264
Mar 12, 2025
USA

Summary

The QC Senior Investigations Expert is responsible for leading manufacturing and QC investigation reports 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.

About the Role

Location: Morris Plains, NJ

2 positions open

1 - Sun-Wed (4 x 10 hours)

1 - Wed-Sat (4 x 10 hours)

Major accountabilities:

Position Summary

- Conduct thorough investigations (OOS, OOT, Environmental Monitoring, deviations, etc.) utilizing root cause analysis tools.
- Lead investigations and cross functional investigation teams, and close reports in a timely manner

Core Responsibilities

- Interview personnel within QC 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.

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.

Collaboration

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

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

Ideal Background

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 QC operations in a cell therapy company.
- Extensive knowledge of cGMP regulations and quality standards relevant to cell therapy manufacturing.

Skills:

- 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.

Competency Profile

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.

Why Novartis: Our purpose is to reimagine medicine to improve and extend people's lives and our vision is to become the most valued and trusted medicines company in the world. How can we achieve this? With our people. It is our associates that drive us each day to reach our ambitions. Be a part of this mission and join us! Learn more here: https://www.novartis.com/about/strategy/people-and-culture

The pay range for this position at commencement of employment is expected to be between $89,600 and $166,400/year; however, while salary ranges are effective from 1/1/25 through 12/31/25, fluctuations in the job market may necessitate adjustments to pay ranges during this period. Further, final pay determinations will depend on various factors, including, but not limited to geographical location, experience level, knowledge, skills and abilities. The total compensation package for this position may also include other elements, including a sign-on bonus, restricted stock units, and discretionary awards in addition to a full range of medical, financial, and/or other benefits (including 401(k) eligibility and various paid time off benefits, such as vacation, sick time, and parental leave), dependent on the position offered. Details of participation in these benefit plans will be provided if an employee receives an offer of employment. If hired, employee will be in an "at-will position" and the Company reserves the right to modify base salary (as well as any other discretionary payment or compensation program) at any time, including for reasons related to individual performance, Company or individual department/team performance, and market factors

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

Join our Novartis Network: Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up: https://talentnetwork.novartis.com/network

Benefits and Rewards: Read our handbook to learn about all the ways we'll help you thrive personally and professionally: https://www.novartis.com/careers/benefits-rewards

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.

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