NOVARTIS

Senior Scientist, QC Microbiology

Job ID
REQ-10030340
Nov 21, 2024
USA

Sommario

Manages Quality aspects and projects within area of responsibility. -Ensures and supports overall GxP conformity and Compliance with the Novartis Quality Management Systems.

About the Role

Hours: Monday - Friday 8-4:30pm

Location: This opportunity is located in Morris Plains, NJ and will not have the ability to be located remotely.

Job Purpose:

Independently perform QC Microbiology testing, generate and analyze EM trend reports and other activities supporting the QC department

Major Accountabilities:

- Serve as delegate for Manager for Microbiology.
- Serve as Quality Control representative on cross-functional teams.
- Perform Microbiology testing such as a growth promotion, gram stain, water sampling and testing in support of clinical and commercial manufacturing strategies.
- Document results within electronic and paper-based systems accordingly.
- Execute and follow SOPs and quality policies.
- Generate and analyze trend reports (monthly, quarterly) to determine appropriate course of action.
- Review reports that are generated and take required action based on the data.
- Review/approve data generated by other team members. Adhere to site wide through put times (TpT).
- Reviews laboratory logbooks and laboratory cleaning monthly.
- Verify the accuracy of data generated.
- Review QC documents to ensure completeness, accuracy, consistency and clarity.
- Author and revise documents and quality policies as required.
- Ensure cleanliness of laboratory working areas.
- Ensure all assigned training is completed within-required time frame.
- Complete Train the Trainer course and train others on specified tasks.
- Oversee and maintain the gowning qualification program and ensure program is kept current.
- Lead and implement process improvements.
- Initiate and lead special projects and facilitate any issues that arise.
- Execute method qualification/optimization as needed.

- Independently lead OO S/OOE/OOT and deviation investigations of high complexity.
- Drive complex investigations to understand root cause.
- Implement effective CAPAs in a timely manner.
- Perform required impact assessments and quality risk assessments.
- Expert in quality systems such as 1QE, ESOPS D2, Condor, LIMS, and Subway.
- Knowledge of MODA- EM system
- Support SS and Lean projects.
- Interface with regulatory agencies during audits.
- Perform other job duties as assigned.

Key Performance Indicators:

- Flawlessly delivers quality results on time to all customers, internal and external.
- Recognized specialist in any particular field of laboratory matters and is capable to confidently communicate' technical information to regulatory inspectors.
- Complies with SOPs and GxP’s in a consistent and compliant manner.
- Escalate issues and potential solutions to laboratory management in a timely manner.
- Ensures assigned assays can be executed at all times
- Detail orientated and able to proof work and identify non-standard format-or wording, and errors within documents
- Drafts documents of expected quality
- Problem solve to best of one’s ability.
- Support colleagues as needed
- May need to adapt to changing work shifts, both swing and/or graveyard on very short notice

Ideal Background:

Education: BA or MS or advanced degree in biology, chemistry, biochemistry, microbiology or other related science.

Language: Fluent in English.

Experience:

- 5+ years of relevant experience in the pharmaceutical,biologics, microbiology, sterile or aseptic manufacture, -or medical device industry.
- Knowledge of cGMP and an understanding of the concepts of GLP, good clinical practices and FDA guidelines, applicable state and foreign regulations, and standards routinely used in the industry (i.e. USP ISO, Annex 1 etc.).
- Thorough knowledge of microbiological and environmental monitoring test methods.
- Micro/Environmental knowledge to facilitate investigations.
- Expert knowledge of LIMS systems.
- Able to manage stakeholders to drive projects forward for on-time delivery

Competency Profile

- Recognized expert in execution of cGXP requirements. Superior communication and organizational skills.
- Ensure customer (internal and external) satisfaction and react to customer (internal and external) requests.
- Is an SME and seen as a competent team player.
- Is able to work independently, compliantly and is results driven.
- Is able to multitask and support junior staff members whilst conducting own work Detail Orientated.
- Able to proof work and identify non-standard format or wording, and errors within documents.
- Requires walking/ standing for extended periods (up to 6 hours) throughout the work shift.
- Requires working with commonly used disinfectants/chemicals in the industry such as 70% IPA, Spor-Klenz, and Bleach.
- Requires dexterity for fine motor tasks such as pipetting and sterile manipulations in biosafety cabinets.
- May use a computer and multiple software packages for greater than 4 hours a day.

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 **$97,600 and $146,40/year**; however, while salary ranges are effective from 1/1/24 through 12/31/24, 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

You'll receive: You can find everything you need to know about our benefits and rewards in the Novartis Life Handbook.

Handbook. https://www.novartis.com/careers/benefits-rewards

Commitment to Diversity and Inclusion:
Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patient and communities we serve.

Join our Novartis Network:
If this role is not suitable to your experience or career goals but you wish to stay connected to hear more about Novartis and our career opportunities, join the Novartis Network here:
https://talentnetwork.novartis.com/network

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 who are focused on building and advancing a culture of inclusion that values and celebrates individual differences, uniqueness, backgrounds and perspectives. 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. We are committed to fostering a diverse and inclusive workplace that reflects the world around us and connects us to the patients, customers and communities we serve.

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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