QA Expert

Job ID
REQ-10039684
Feb 10, 2025
Estados Unidos

Resumen

This position will be located at Morris Plains, NJ and will not have the ability to be located remotely.

The QA Operations Expert is responsible for first level, hands on, cGMP facilitator role for all site related GMP activities. They interact directly with site staff, who are performing the daily operational functions in support of their effort to produce quality products. This role ensures that the quality strategy is implemented and that there is a continuous drive to improve product and process quality for make, test, and release as well as all other support functions. They are also responsible to serve as quality project team representatives for continuous improvement initiatives on site, as applicable
#LI-Onsite

Key Responsibilities:
• Execute, lead, oversee, and provide direction for the following QA related daily operations, from a subject matter expertise perspective
o QA Shopfloor activities in the Manufacturing and QC environments providing best practice coaching activities in the production, QC labs and other support areas on site, in accordance to Novartis policies, SOPs, and cGMP requirements. Non-conformance/Quality Event/OOS investigation quality review in accordance with Novartis policies, SOPs, and cGMP requirements.
o Oversight & Governance of aseptic operations including but not limited to ViMOS, Aseptic Process Validation program, walkthrough program, EM monitoring program, etc.
o Deviation handling and Governance. Initiation, review and approval of initials & Impact assessment, deviation and OOS/OOE/OOT investigations and CAPA plan establishment in accordance with applicable SOPs.
o Final Product PP/FP release and disposition activities. Handling and addressing all Patient batch release communications with/from various stakeholders. Add
o QA data review of associated batch records, procedures and related documentation to ensure adherence to Novartis policies, SOPs, and cGMP requirements. Review and audit production-based batch records, procedures, and validation documentation to ensure adherence to Novartis policies, SOPs, and cGMP requirements.
• This role will consult and collaborate, successfully, with Engineering, Facilities, Quality Control, MS&T and Process Unit personnel as deemed necessary by the individual or QA management
o Quality review of validation life cycle documents, including user requirement specifications, plans, protocols and reports in adherence with SOPs, corporate policies, standards and government regulations. Through these reviews/support the individual will provide quality requirements guidance to validation document authors to ensure high-quality documents that demonstrate consistent approach, in compliance with requirements
• Provide support for all Internal, external and, Health authority audits by involvement and interaction with audit

management team and/or inspectors. Provides Quality oversight to complex qualification activities and projects
• Provides timely review and approval of Equipment and Process validation plans, protocols, summary reports and deviations to ensure project timelines are not impacted. Coordinates and develops with PU, QC and MS&T qualification projects and plans and identifies the
• “critical to quality” parameters impacting qualification activitie
• Reviews and approves Site Validation Master Plans, Risk and Impact Assessments as appropriate
• Provides QA review and guidance on asset and Product change request in consultation with change request owners to evaluate validation impact.
• Advises and consults with other departments on equipment, analytical instrument and computer system validation.

About the Role

Desirable Requirements:

- BS degree in Scientific discipline or other related field with significant prior experience (10+ years) or equivalent.
- General, 8+ years of Pharmaceutical industry experience required. 6 + years of Quality Assurance, Process Validation or Facilities, Utilities, Equipment and Analytical Instruments Qualification, CSV experience or applicable experience in a related area in the Pharmaceutical industry.
- Knowledge of cGMPs and understanding of the concepts of GLP, FDA and Health Authority Guidelines, applicable regulations and standards routinely used in the industry (ANSI, ISO, GAMP,ATMP).
- Subject matter expertise in root cause analysis, CAPA governance, and Non-conformance/OOS investigation strategy
- Thorough understanding of environmental control programs for release of manufacturing areas, understanding of aseptic technique as applied to critical manufacturing processes.
- Supervisory or management experience; may include leading teams or projects
- Demonstrated leadership skills in team building and accomplishing complex projects.
- Ability to communicate effectively with cross-functional groups in various aspects of company operations.

Novartis Compensation and Benefit Summary: The pay range for this position at commencement of employment is expected to be between $103,500 and $192,400/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.

Company will not sponsor visas for this position.

Novartis is unable to offer relocation support for this role: please only apply if this location is accessible for you.

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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