

Senior QA Operations Specialist

Job ID
REQ-10016426
Aoû 07, 2024
Singapour

Résumé

Job Description Summary This role support/provide quality oversight in ensuring a smooth manufacturing operation, new product launches/transfer in a compliant/timely manner, drug substance batch review/release are in full gmp compliance to regulatory standards and ensures quality strategy/continuous improvement are driven in alignment to site objective/s.

About the Role

Position Title: Senior QA Operations Specialist

Location – Singapore

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This role support/provide quality oversight in ensuring a smooth manufacturing operation, new product launches/transfer in a compliant/timely manner, drug substance batch review/release are in full gmp compliance to regulatory standards and ensures quality strategy/continuous improvement are executed in alignment to site objective/s.

Key Responsibilities:

- Ensure all activities in compliance with cGxP, incl. data integrity
- Review and approval of analytical data / tests (analytical release)
- Oversight of all production and testing activities, ensures compliance with cGxP, incl. data integrity and eCompliance
- Support exception investigations
- Review and approval of production, QC, and AS & T records
- MBR review. Support OpEx improvement projects. Executes batch release in compliance with registration (if Qualified Person)
- Comply with all HSE guidelines. Detect and report potential accident, risks and propose solutions
- Participate in HSE risk assessments. Preparation and participation to internal HSE audits

Commitment to Diversity & Inclusion: :

We are committed to building an outstanding, inclusive work environment and diverse teams representative of the patients and communities we serve.

Role Requirements :

Essential Requirements:

- 5+ years of experience in pharmaceutical quality control, quality assurance or production
- Operations Management and Execution; Functional Breadth; Collaborating across boundaries; Applied Practice
- Collaboration; result-oriented. Good knowledge of GMP; Continuous Learning; Operational Excellence; Digital & Tech Savvy
- MS Office applications and other standard IT applications supporting Quality activities
- Technological competence; Quality Assurance; Knowledge of GMP, Quality Standards; Quality Control (QC) Testing

Desirable Requirements:

- University degree with a scientific / technological background (e.g. Chemistry, Pharmacy, Biology, Biochemistry, or equivalent)

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>

You'll receive: You can find everything you need to know about our benefits and rewards in the Novartis Life Handbook. <https://www.novartis.com/careers/benefits-rewards>

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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>

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Division

Operations

Business Unit

Innovative Medicines

Emplacement

Singapour

Site

Tuas South Avenue

Company / Legal Entity

SG12 (FCRS = SG012) Novartis Singapore Pharmaceutical Manufacturing Pte Ltd

Functional Area

Qualité

Job Type

Full time

Employment Type

Regular

Shift Work

No

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