

## Specialist - QA Ops - Manufacturing Mgmt

Job ID  
REQ-10016426

9月 03, 2024

Singapore

### 摘要

#### 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: Specialist - QA Ops - Manufacturing Mgmt

Location - Singapore

#### About the Role:

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)

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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>

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Senior QA Operations Specialist

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部门  
Operations

Business Unit  
Innovative Medicines

地点  
Singapore

站点  
Tuas South Avenue

Company / Legal Entity  
SG12 (FCRS = SG012) Novartis Singapore Pharmaceutical Manufacturing Pte Ltd

Functional Area  
Quality

Job Type  
Full time

Employment Type  
Regular

Shift Work  
No

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