

# Senior Specialist, QA Operations Life Cycle Management

Job ID  
REQ-10018413  
Aug 12, 2024  
Singapore

## Summary

Responsible for managing quality aspects within area of responsibility and to ensure that the operational business is in compliance with cGMP (Current Good Manufacturing Practices), the Quality Assurance Agreement, regulatory requirements and the Novartis Quality Manual and is conducted according to the relevant Standard Operating Procedures

## About the Role

Position Title: Senior Specialist, QA Ops - Lifecycle Management

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 objectives.

### Key Responsibilities

Your responsibilities include, but are not limited to:

- Operational
  - o Oversight of all production and testing activities, ensures compliance with cGxP, incl. data integrity and eCompliance
  - o Support exception investigations (complex/critical)
  - o Support change control activities relating to complex changes
  - o Support OpEx improvement projects
  - o Execute batch release in compliance with registration according to local requirements as technical responsible person
- HSE
  - o Comply with all HSE guidelines
  - o Detect and report potential accident, risks and propose solutions
  - o Participate in HSE risk assessments
  - o Preparation and participation to internal HSE audits
  - o Responsible for participating in initial training and retraining

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

Role Requirements :

- University degree with a scientific / technological background (e.g., Chemistry, Pharmacy, Biology, Biochemistry, or equivalent)
- 8-10 Years of relevant experience in pharmaceutical manufacturing in providing operational QA oversight, supporting audits or new product launches/tech transfer
- Several years of experience in pharmaceutical quality control, quality assurance or production
- GMP experience will be an added advantage
- Strong organizational and time management skills
- Quality oriented with attention to details
- Highly proactive, self-motivated, professional and dedicated

Why consider Novartis?

236 million lives were touched by Novartis medicines in 2022, and while we're proud of this, we know there is so much more we could do to help improve and extend people's lives.

We believe new insights, perspectives and ground-breaking solutions can be found at the intersection of medical science and digital innovation. That a diverse, equitable and inclusive environment inspires new ways of working.

We believe our potential can thrive and grow in an unbossed culture underpinned by integrity, curiosity and flexibility. And we can reinvent what's possible, when we collaborate with courage to aggressively and ambitiously tackle the world's toughest medical challenges. Because the greatest risk in life, is the risk of never trying!

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Division

Operations

Business Unit

Innovative Medicines

Location

Singapore

Site

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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