

# Specialist QA Operations

Job ID  
REQ-10026729  
Oct 24, 2024  
Malaysia

## Summary

About this role:

The Specialist QA Operations 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

**Your Responsibilities:**

## Your responsibilities include, but not limited to:

**Major accountabilities:**

- 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 and T records -MBR review -Support OpEx improvement projects Qualified Person – Executes batch release in compliance with registration -Reporting of technical complaints / adverse events / special case scenarios related to Novartis products within 24 hours of receipt -Distribution of marketing samples (where applicable)

**Key performance indicators:**

- On-time and GMP-compliant release of dosage forms -No complaints about inspections by authorities in your own area of responsibility without these being noticed and communicated beforehand -Successfully support continuous improvement projects -Executes batch release in compliance with registration

**What you'll bring to the role:**

- Minimum of 3 to 5 years of experience in quality assurance and GMP in the pharmaceutical / biotech industry is preferred
- Minimum Bachelor degree in a scientific discipline (e.g. pharmacy, chemistry, engineering, life science) or similar education; advanced degree in natural or applied sciences preferred
- Enhanced Computer skills
- Proficient in English Required
- **Required Competencies:**
- Ability to work with tight deadlines as well as strong planning, organizing and time management skills
- Attention to details, dedication to accuracy
- Reliable and with high sense of accountability

- Ability to work independently
- Strong problem solving and analytical skills
- Reliable team-player with strong competence in leading cross-functional teams and operating within a matrix organizational structure
- Strong verbal and written communication skill

#### **Skills:**

- Continuous Learning.
- Dealing With Ambiguity.
- Gmp Procedures.
- Qa (Quality Assurance).
- Quality Control (Qc) Testing.
- Quality Standards.
- Self Awareness.
- Technological Expertise.
- Technological Intelligence.

#### **Languages :**

- English.

**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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#### **Commitment to Diversity and Inclusion:**

Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve

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Operations  
Business Unit  
Innovative Medicines  
Location  
Malaysia  
Site  
Selangor  
Company / Legal Entity  
MY01 (FCRS = MY001) Novartis Corporation (Malaysia) Sdn. Bhd. (19710100054)  
Functional Area  
Quality  
Job Type  
Full time  
Employment Type  
Regular  
Shift Work  
No  
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