

Specialist QA Operations

Job ID
REQ-10026729
Jan 12, 2025
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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