NOVARTIS

QA Specialist

Job ID
REQ-10038248
Jan. 30, 2025
Südafrika

Zusammenfassung

Provide quality assurance expertise, guidance and support to operational activities to ensure compliance with applicable regulatory requirements and Novartis procedures and quality standards.

About the Role

Major accountabilities:

- Batch record review and related activities (e.g., PIT, reference standards ordering and management, import permit application, method transfer, sample and temperature checks) for timely market release of finished goods.
- Product Quality Reviews according to schedule, in order to monitor the quality of products and compliance against the marketing authorization. Compile PQR reports for product renewals.
- Raise, investigate, manage and actively resolve quality investigations as needed e.g., deviations, complaints, CAPAs, non-conformances in conjunction with third parties and operational units to minimize impact on product availability and business.
- Create and maintain GxP documentation
- Self-inspections and supplier / third party assessments according to schedule. Propose and monitor actions to improve/maintain quality standards
- Provide QA/QC support for product launches.
- Deliver on KPI measures in a timely way
- Day-to-day coordination and communication with external functions (e.g distributors, analytical laboratory, customers)
- Manage goods for destruction
- Perform product return evaluations and determine disposition
- Handling of technical product complaints.
- Training to ensure continuous quality maintenance and quality improvement
- Take responsibility for corporate citizenship within the sphere of influence and control, and to enforce the Company Code of Conduct

Key performance indicators:

- Adherence to cGMP and SOPs
- Compliant product supply and business targets are met
- No delay with new product launches caused by QA
- Local GxP Quality systems in place and maintained
- Quality related processes carried out in a timely way
- GxP risks proactively identified and effectively mitigated

- Training conducted according to program
- Delivery of established KPI with regard to quality and performance
- Timely close out of Deviations and corrective and preventative actions
- Compliance with all aspects of the Code of Conduct/ Corporate Citizenship/ Novartis Policies and Procedures

Minimum Requirements:
Work Experience:

- Experience in the pharmaceutical industry (quality assurance, quality control, registration or production) or a directly related field will be beneficial.
- BPharm Degree
- Registered with The South African Pharmacy Council

Skills:

- Knowledge and understanding of GMP, quality systems and quality practices
- Regulations & Guidelines
- Document management
- Analytical thinking and problem solving
- Planning & organizing
- High compliance
- Communication and interpersonal skills.
- Continuous Learning
- Self Awareness

Languages:

English

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Abteilung
Operations
Business Unit
Innovative Medicines
Ort
Südafrika
Website
Midrand
Company / Legal Entity

ZA01 (FCRS = DEL) South Africa
Functional Area
Quality
Job Type
Full time
Employment Type
Regular
Shift Work
No
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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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