Process Expert

Job ID
REQ-10045027
Apr 09, 2025
Malaysia

Summary

You will provide front line technical and scientific expert support for all manufacturing compliance and process-specific issues to ensure execution of processes on-time (business continuity); in compliance to cGMPs, SOPs and applicable guidelines and functional standards (e.g. HSE, NOSSCE) and continuously improve quality, productivity efficiency.

About the Role

Operational Activities

- Provide expert support for all quality and compliance issues related to production, act as a Subject Matter Expert (SME) for quality processes, and ensure real-time shop floor support for compliance or quality problems
- Coordinate and ensure the completion of all production operations on time, perform real-time batch follow-up and technical review, manage change-over activities, and ensure all production documents are up to date
- Execute training and education programs for operators, support the T&L organization in defining and maintaining qualification criteria, deliver instructor-led training, and promote Quality and HSE culture on the shop floor

Compliance Activities

- Lead area walkdowns, Gemba, and environmental monitoring governance on the shopfloor to identify and address facility maintenance, housekeeping, process, or personnel issues. It also includes ensuring timely treatment of deviations, complaints, out-of-specification (OOS) results, and implementing effective corrective and preventive actions (CAPAs).
- Collaborate with MS&T experts for multi-product risk assessments and validation strategy definition. It also involves preparing, supporting, and following up on health authority and internal inspections, and collaborating with Regulatory Compliance QA for dossier submissions and revisions.
- Manage GMP documentation, master manufacturing documents, and validation, revalidation, and qualification activities. Periodic review of production unit equipment and consistent reporting of trending and evaluation reports required

Operational Excellence and Continuous Improvement

- Lead and participate in continuous improvement projects, provide support for the implementation of improvements, and actively develop production staff in the continuous improvement process
- Manage various projects, conduct risk analyses, draft and validate documents, collaborate on technology

transfers, and define technical needs to achieve strategic objectives

Quality and HSE

- Promote and improve the Quality and HSE culture in collaboration with Quality Assurance and the HSE Lead. This includes upgrading and checking the practical application of Quality and HSE systems on the shop floor and within the team
- Ensure overall inspection readiness and compliance with the principles and practices described in the "Novartis Manufacturing Manual" for the site.

Requirements

- Minimum 2 years experience in GMP manufacturing process support role
- University degree in Science in Pharmacy or Chemical Engineering, Pharmaceutical Technology
- Minimum 8 years experience in the field of expertise for lower Education levels
- Advanced English and proficient in site local language

Competencies

- Good scientific and technical (automation) understanding
- Team player with strong team spirit
- Good negotiator, Influencing and persuading
- Change management, adaptability, ability to work under pressure
- Good understanding or capacity to quickly understand production processes
- Quality and compliance skills
- Good understanding of regulatory requirements across multiple health authorities
- Good working knowledge/understanding of manufacturing execution systems (e.g. MES, SAP)
- Office software applications

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Division
Operations
Business Unit
Universal Hierarchy Node
Location
Malaysia
Site
Selangor
Company / Legal Entity

MY01 (FCRS = MY001) Novartis Corporation (Malaysia) Sdn. Bhd. (19710100054)
Functional Area
Technical Operations
Job Type
Full time
Employment Type
Regular
Shift Work
No
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