Process Expert / Manufacturing Science and Technology

Job ID
REQ-10015770
Jul 19, 2024
Turquía

Resumen

•Shift Lead II Der Shift Leader ist verantwortlich für die Verwaltung seines Teams, um die Fertigung nach Zeitplan in Übereinstimmung mit den HSE- und GMP-Regeln durchzuführen. Prozessexperte •Bereitstellung technischer und wissenschaftlicher Expertenunterstützung an vorderster Front für alle prozessspezifischen Fragen, um die terminliche Durchführung von Prozessen sicherzustellen (Business Continuity); einhaltung von cGMPs, SOPs und anwendbaren Richtlinien und funktionalen Standards (z. B. HSE, NOSSCE) und eine kontinuierliche Verbesserung der Qualität und Produktivitätseffizienz zu ermöglichen. •Operational Scheduler Der Operational Scheduler erstellt und führt einen aktuellen Plan für die Aktivitäten im Zusammenhang mit der Fertigungseinheit. Der Operational Scheduler ist verantwortlich für die Entwicklung verschiedener Produktionsszenarien (Laufzeiterhöhung, Prozessänderungen, Hochlauf, Schichtmodellanpassung etc.) sowie die Verbesserung des Planungstools. Manufacturing Systems Expert MES Expert bietet technisches Fachwissen zur Unterstützung aller Fragen im Zusammenhang mit elektronischen Chargendatensätzen (eBRs). MES Expert unterstützt den MES-Einsatz, die Implementierung und kontinuierliche Verbesserung der Fertigungseinheiten und bietet routinemäßigen technischen Support in der Werkstatt. •Technischer Trainer •Liefert technische Schulungen und bewertete Lernergebnisse für den zugewiesenen Bereich. Kann auch Lerninterventionen entwerfen und entwickeln. Kann auch die Schulung Audit-Antwort für den Standort leiten.

About the Role

Location: Istanbul Kurtköy, Turkey #LI-Hybrid

Novartis is unable to offer relocation support for this role: please only apply if this location is accessible for you.

Key Responsibilities:

- Using structured RCA (Root Cause Analysis) methodologies such as impact assessment, Fish bone diagram, 5 whys, Timeline & process mapping for investigation of deviations
- Handling Investigations and Deviations related to Process (Upstream / Downstream), Product & Equipment
- Understanding of core manufacturing unit operations such as sampling, monitoring, and continuous process support
- Handling procedural requirements for HA audits

- Responsible for offering technical and scientific expertise to address process-specific matters, ensuring compliance with cGMPs, SOPs (Standard Operating Procedures), and relevant guidelines and functional standards (such as HSE (Health, Safety and Environment) and NOSSCE)
- Handling internal and health authority audits and inspections
- Ensuring overall inspection readiness for area of responsibility -Reporting of technical complaints / adverse events / special case scenarios related to Novartis products within 24 hours of receipt - Distribution of marketing samples (where applicable)

Essential Requirements:

- Bachelor's degree in pharmacy, Pharmaceutical Technology, Chemical Engineering, Biomedical engineering, Biotechnology, Chemistry, or equivalent science streams. Master´s degree is a plus
- Min 5 years of experience in MS&T, Quality Assurance, Regulatory or in the manufacturing of pharmaceutical drug substance or drug products in Sterile/Large Molecules platform/facility
- Minimum 2 years of experience with deviation management and investigation
- Knowledge of risk assessment and risk management programs
- Fluent English, German is a plus

Desirable Requirements:

- Good communication, presentation and interpersonal skills
- Basic knowledge of statistical analysis, results interpretation, and usage of statistical tools (Example: Minitab, Statistica etc.)

Benefits and Rewards:

Read our handbook to learn about all the ways we'll help you thrive personally and professionally: Novartis Life Handbook

Commitment to Diversity & Inclusion:

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

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

Join our Novartis Network: Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up: https://talentnetwork.novartis.com/network

División
Operations
Business Unit
Innovative Medicines

Ubicación
Turquía
Sitio
İstanbul Kurtköy
Company / Legal Entity
TR01 (FCRS = TR001) Novartis Sağlık, Gıda ve Tarım Ürünleri San. Ve Tic. A.Ş.
Functional Area
Technical Operations
Job Type
Full time
Employment Type
Regulär
Shift Work
No
Apply to Job
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