

# Process Expert / Manufacturing Science and Technology

Job ID

REQ-10015770

Juli 19, 2024

Türkei

## Zusammenfassung

### •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, Schichtmodell Anpassung 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>

**Benefits and Rewards:** Read our handbook to learn about all the ways we'll help you thrive personally and

professionally: <https://www.novartis.com/careers/benefits-rewards>

Abteilung

Operations

Business Unit

Innovative Medicines

Ort

Türkei

Website

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

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