# 🕑 NOVARTIS

## Senior Process Expert / Manufacturing Science and Technology

Job ID REQ-10015771 Jul 19, 2024 Türkiye

### 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 8 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 5 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: 1/3

Minitab, Statistica etc.)

Benefits and Rewards:

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

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.

#### **Role Requirements**

**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? <a href="https://www.novartis.com/about/strategy/people-and-culture">https://www.novartis.com/about/strategy/people-and-culture</a>

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**Benefits and Rewards:** Read our handbook to learn about all the ways we'll help you thrive personally and professionally: <u>https://www.novartis.com/careers/benefits-rewards</u>

Division Operations **Business Unit Innovative Medicines** Location Türkiye Site 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 Job ID

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