

Senior QA Expert ESO

Job ID
REQ-10067670

12月 02, 2025

Poland

摘要

#LI-Hybrid

Primary Location: Warsaw, Poland

Other Locations: Mumbai, India; Hyderabad, India

Relocation Support: This role is based in Warsaw, Poland. Novartis is unable to offer relocation support: please only apply if accessible.

Join Novartis in shaping the future of quality excellence!

As a Senior QA Expert ESO, you 'll ensure that all Novartis products manufactured by external suppliers meet international GMP standards and regulatory requirements. Acting as the Single Point of Contact, you 'll drive compliance, foster strong partnerships, and lead continuous improvement initiatives that make a real impact on patient safety and global quality standards.

About the Role

Key Responsibilities

- Act as Single Point of Contact for all quality-related activities at assigned external suppliers.
- Provide quality input and presence in technical meetings with external suppliers.
- Ensure supplier qualification and maintain valid Quality Agreements aligned with business needs.
- Monitor quality trends and drive continuous improvement through KPIs and performance assessments.
- Ensure site readiness for regulatory inspections and support during audits.
- Manage quality issues, including complaints, deviations, and out-of-specification results, ensuring timely resolution.
- Oversee change controls from initiation through implementation and closure.
- Support manufacturing process and analytical method transfers with robust QA oversight.

Essential Requirements

- Bachelor ' s degree or higher in Pharmacy, Biochemistry/Biotechnology, Chemistry, Microbiology, or a related science.
- Fluent in English, both spoken and written (minimum C1 level or equivalent certification).
- Minimum 8 years of experience in the pharmaceutical industry, including 5 years in sterile manufacturing.
- Expert knowledge of aseptic processes and biologics manufacturing; strong understanding of cGMP for EU and US markets.
- Advanced experience with FDA, EMA, and other Health Authorities; skilled in risk management and project management.
- Strong communication and negotiation skills; advanced decision-making abilities and basic leadership experience.

Commitment to Diversity & Inclusion:

We are committed to building an outstanding, inclusive work environment and diverse teams representative of the patients and communities we serve.

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>

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>

部門
Operations

Business Unit
Quality

地点
Poland

站点
Warsaw

Company / Legal Entity
PL03 (FCRS = PL003) Novartis Poland Sp. z o.o.

Alternative Location 1
Hyderabad (Office), India

Alternative Location 2
Mumbai (Head Office), India

Functional Area
Quality

Job Type

Full time

Employment Type
Temporary (Fixed Term)

Shift Work
No

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