

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>

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>

部门

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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