

## Development Quality Manager in Pharma

Job ID  
REQ-10060189

9月 05, 2025

Poland

### 摘要

Internal job title: Development Quality Assurance Manager  
Location: Warsaw (Poland) / Bucharest (Romania)

The Development Quality Assurance Manager is responsible for assuring quality oversight of activities undertaken in all Novartis entities in a country to ensure they are conducted in compliance with relevant Good Clinical Practice (GCP) and Good Pharmacovigilance Practice (GPvP) regulations and guidelines.

Operates in direct collaboration with local Development colleagues (Study and Site Operations, Patient Safety and Regulatory Affairs), Medical Affairs, Novartis Country Quality (NCQ) & Commercial teams for patient-facing projects, products and programs. Ensures implementation of the Novartis Quality Manual and Quality Management System in the country to achieve a high level of quality and compliance.

This position is part of Global Development Country Quality team and reports directly into Head, Clin&PV Region/Cluster Quality GDQ.

## About the Role

### Major accountabilities:

- Oversee implementation, maintenance, and monitoring of the local Quality System and Quality Plan to ensure compliance with Novartis global requirements and applicable local regulations.
- Ensure adequate training systems are in place for GCP, GPvP, and other relevant Development activities.
- Monitor local Quality System, processes, and Key Quality Indicators (KQIs) to proactively identify potential quality risks and collaborate with business partners to address them.
- Partner with local and global Development teams in the execution and follow-up of quality issues and audits related to clinical development and PV activities, ensuring robust corrective and preventive actions are implemented.
- Provide leadership and support for GCP and GPvP Health Authority (HA) inspections, ensuring timely submission of responses to local HA and completion of CAPAs.
- Execute QA activities required for the qualification and monitoring/governance of third party activities with a clinical/medical or PV component.

### Minimum Requirements:

- Degree in Life Sciences or related fields
- Solid experience in the pharmaceutical industry in a relevant field such as quality assurance, regulatory affairs, pharmacovigilance or a directly related area, ideally with several years of experience in clinical development.
- Excellent verbal and written communication skills, capable of delivering messages in a clear, concise, and convincing manner.
- Proven track record in leading projects and stakeholders-management
- Full professional proficiency in English and native proficiency in Polish or/and Romanian

### Benefits and Rewards:

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### Commitment to Diversity and Inclusion / EEO:

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部门  
Development

Business Unit  
Innovative Medicines

地点  
Poland

站点  
Warsaw

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

Alternative Location 1  
Bucuresti, Romania

Functional Area  
Quality

Job Type  
Full time

Employment Type  
Regular

Shift Work  
No

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