

# Global GMP Quality Auditor

Job ID
REQ-10061029

11月 04, 2025

Mexico

### 摘要

-Responsible for managing quality aspects within area of responsibility and to ensure that the operational business is in compliance with cGMP (Current Good Manufacturing Practices), the Quality Assurance Agreement, regulatory requirements and the Novartis Quality Manual and is conducted according to the relevant Standard Operating Procedures

## About the Role

### Major accountabilities:

 Oversight of all production and testing activities, ensures compliance with cGxP, incl. data integrity and eCompliance -Support exception investigations -Review and approval of production, QC, and AS and T records -MBR review -Support OpEx improvement projects Qualified Person - Executes batch release in compliance with registration -Reporting of technical complaints / adverse events / special case scenarios related to Novartis products

#### Key performance indicators:

- On-time and GMP-compliant release of dosage forms -No Complaints about inspections by authorities in your own area of responsibility without these being noticed and communicated beforehand.
- Successfully Support continuous improvement Projects -Executes batch release in compliance with registration

### Minimum Requirements:

#### Work Experience:

- · Critical Negotiations.
- Functional Breadth.
- Project Management.
- People Leadership.
- · Collaborating across boundaries.
- Operations Management and Execution.

#### Skills:

- · Continuous Learning.
- Dealing With Ambiguity.
- Employee Performance Evaluations.
- Gmp Procedures.
- People Management.
- Qa (Quality Assurance).
- Quality Control (Qc) Testing.
- Quality Standards.
- Self Awareness.
- Technological Expertise.
- Technological Intelligence.

#### Languages:

• English.

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部门
Operations

Business Unit
Innovative Medicines

地点
Mexico

站点
INSURGENTES

Company / Legal Entity
MX06 (FCRS = MX006) Novartis Farmac é utica S.A. de C.V.

Functional Area
Quality

Job Type Full time

Employment Type Regular

Shift Work No

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