

Audit and Compliance Specialist

Job ID

REQ-10078782

Jun 11, 2026

LOC_MX

About the Role

Major Accountabilities:

- Ensure all site activities comply with cGxP, regulatory requirements, company quality standards, and data integrity expectations.
- Plan, support, review, and approve key quality activities including PQR/APQR, validation, qualification, change controls, CAPAs, deviations, and follow-up actions.
- Implement and maintain Quality Systems, including documentation management, process quality assurance, KPI trending, and continuous improvement initiatives.
- Provide quality oversight for GxP computerized systems, including classification, qualification, supplier assessment, lifecycle management, risk mitigation, and review/approval of related documentation.
- Support audit and inspection readiness, including preparation, coordination, participation, follow-up, and communication with internal and external stakeholders.
- Manage supplier quality activities, including quality agreements, oversight, audits, and ensuring compliance with applicable Novartis and regulatory requirements.
- Act as a key point of contact for Health Authorities and internal compliance partners, ensuring aligned communication, certificate maintenance, applications, and regulatory submissions as required.
- Comply with HSE requirements, participate in risk assessments and audits, report potential risks, complete required training, and contribute to personal development while representing the company's values.

Obligatory requirements:

- Education: Degree in chemistry, biology, computer science, life sciences
- Minimum 3 years of overall automation/CSV experience, or a minimum of 3 years of Laboratory.
- Strong drive to learn, a commitment to accuracy and excellent communication skills.
- Solid quality experience in inspections and audits as essential to maintaining high standards and ensuring compliance.
- Excellent knowledge of Microsoft Office
- Fluent English, written and spoken. Spanish is desirable.

Why Novartis: Our purpose is to reimagine medicine to improve and extend people's lives and our vision is to become the most valued and trusted medicines company in the world. How can we achieve this? With our people. It is our associates that drive us each day to reach our ambitions. Be a part of this mission and join us! Learn more here:

<https://www.novartis.com/about/strategy/people-and-culture>

You'll receive: You can find everything you need to know about our benefits and rewards in the Novartis Life Handbook.

<https://www.novartis.com/careers/benefits-rewards>

Commitment to Diversity and Inclusion:

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

Join our Novartis Network: If this role is not suitable to your experience or career goals but you wish to stay connected to hear more about Novartis and our career opportunities, join the Novartis Network here:

<https://talentnetwork.novartis.com/network>.

Division
DIV_TO
Business Unit
Production / Manufacturing
Location
LOC_MX
Site
INSURGENTES
Company / Legal Entity
MX06 (FCRS = MX006) Novartis Farmacéutica S.A. de C.V.
Functional Area
FCT_QA
Job Type
Full time
Employment Type
Regular
Shift Work
No
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