NOVARTIS

Audit and Compliance Specialist

Job ID
REQ-10078782
Июн. 11, 2026
Мексика

Сводка

The Audit and Compliance Specialist is responsible for the compliance and Quality Assurance support of the GxP computerized systems including supplier quality assessment/management throughout their lifecycles in regards to the applicable regulations and requirements defined in the Novartis Quality Manual and procedures. eCompliance provides guidance on CSV related topics and related information.

Reviews and/or approves the qualification and operational deliverables of respective GxP computerized systems. Managing work in accordance with the law, internal regulations, good practices and business objectives.

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.

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: Learn about all the ways we'll help you thrive personally and professionally.
Read our handbook (PDF 30 MB)

Дивизион
Operations
Business Unit
Production / Manufacturing
Место
Мексика
Сайт
INSURGENTES
Company / Legal Entity
MX06 (FCRS = MX006) Novartis Farmacéutica S.A. de C.V.
Functional Area
Quality
Job Type

Full time
Employment Type
Regular
Shift Work
No

Accessibility and accommodation

Novartis is committed to work with and provide reasonable accommodation to individuals with disabilities. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the recruitment process, or in order to perform the essential functions of a position, please send an e-mail to tas.mexico@novartis.com and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

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