Laboratory Auditor (GLP/GCLP)

Job ID
REQ-10088824
Окт. 14, 2026
Мексика

Сводка

Conduct and support GLP/GCLP audits, including integrations and non-GxP assessments, following the Novartis Quality System and current regulations. Ensure compliance with applicable standards and guidance documents. Review and approve corrective action plans for audit observations.
Ensure alignment with strategic direction of the company and assist in driving implementation of the applicable actions. Provide consultation to Novartis business units through risk-based assessments. Act as a subject matter expert for assigned areas of responsibility.

#LI-Hybrid
Location: Insurgentes, Mexico City

About the Role

Major accountabilities:

- Support the strategic development of an effective global risk-based audit strategy and program; collect, collate, and incorporate input into audit strategy and plan.
- Lead, plan, conduct, document and follow-up of global quality regulatory compliance audits of GLP/GCLP according to the requirements specified in the respective Novartis Quality Module. Assess the adequacy of responses (CAPA plans) to audit findings.
- Conduct assessments for companies and their vendors during BD&L integration activities including non-GxP assessments, which include, but not limited to data reviews, IT system evaluations.
- Provide technical guidance, leadership, mentoring and training of other auditors on audit related activities.
- Ensure appropriate escalation to responsible management in case of critical findings and support immediate follow-up measures accordingly.
- Identify and communicate quality and regulatory compliance issues to Quality Management and recommend remediation.
- Liaise as needed with the third-party management team.
- Proactively research local and global initiatives, trends and events that impact maintenance of compliance. Maintain current knowledge of regulations, standards and guidance documents.

Key performance indicators:

- Complete audits/assessments promptly and accurately.
- Ensure findings and reports meet timelines, procedures, and Key Quality Indicators (KQIs).
- Analyze audit metrics and non-compliance causes effectively.
- Escalate issues through proper channels promptly.
- Communicate and support business partners thoroughly and accurately.

Minimum Requirements:

Work Experience:

- 7+ years of GLP/GCP/Pharmaceutical Industry/Health Authority experience or equivalent.
- 3+ years of GxP auditing experience. GCP/PV/GLP auditing experience preferred.
- International travel expectation 25%

- undefined

Skills:

- Ability to independently manage and objectively evaluate complex compliance issues with minimal supervision.
- Experience with Health Authority inspections
- Excellent verbal and written communication, organizational and interpersonal skills.
- Knowledge of applicable GxP regulations, guidelines, policies, and procedures.
- Good knowledge of computer systems validation and 21CFR Part 11 requirements.
- Leadership and facilitation skills
- Demonstrated ability to simplify processes including application of AI, Copilot, etc.

Languages:

- English.

Additional languages including German and French considered a plus

Commitment to Diversity & Inclusion:

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

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.

Novartis tiene el compromiso de trabajar y proporcionar adaptaciones razonables para personas con discapacidad. Si, debido a una condición médica o discapacidad, necesita una adaptación razonable para cualquier parte del proceso de contratación, o para desempeñar las funciones esenciales de un puesto, envíe un correo electrónico a tas.mexico@novartis.com y permítanos conocer la naturaleza de su solicitud y su información de contacto. Incluya el número de posición en su mensaje.

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

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

Дивизион
Biomedical Research
Business Unit
Quality
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

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