APPS Specialist

Job ID
REQ-10050407

5月 02, 2025

Mexico

摘要

-Supports the follow up of local - regional processes, procedures and activities related to stability studies life cycle management, required for drug product control, preserving compliance of local, regional and global quality standards as delegated to QOP, and any data analysis required such as trend reports.

About the Role

Major accountabilities:

- Assure stability studies implementation, fulfilling local and international guidelines and standards (such as NOM-073, RE n ° 01/2005).
- Safeguard the execution of activities related to the development of protocols and stability reports, as well as trend analysis (implementation and maintenance of statistical analysis), sample calculation, sample entry to stability chambers, and management of analytical results

of samples corresponding to stability studies, according to study requirements and the corresponding climatic zone.
- Guarantee according to study requirements, internal or third parties physicochemical and microbiological analyses.
- Ensure timely and proper execution of foreign stability programs, as well as request the necessary technical information for implementing the use of foreign stability studies.
- Assist and support internal and external audits. Establish and verify timely execution of all CAPAs derived from these audits. Collaborate in appropriate resolution of all deficiencies detected during health, internal, corporate and security authorities ' audits.
- Guarantee compliance of quality system procedures, such as change control, results out of specification, out of trend and deviations detected in results of stability studies and/or related elements.
- Prepare and update standard operating procedures and work instructions that guarantee reproducible processes and fulfilment of local, regional and global corporate and health standards.
- Collaborate in the compliance of local and global performance indicators and implement the corresponding actions and/or remediation plans if necessary.
- Collaborate in optimization projects as required in the functional area.
- Set and provide input on priorities for owned activities.
- Responsible for data compilation and preparation of dashboard/data bases on regular basis to track and report deliverables.
- Regularly communicate with partners to collect feedback on supported processes.
- Report and record Issues, Deviations, Quality Events emerging from process delivered, and communicate progress as appropriate in collaboration with team leader.
- Ensure efficient, timely and clear communication to all involved partners (local and global functions) as required for follow-up on activities under scope.
- Build and maintain high expertise and continuously acquire process knowledge.
- Support and participate in the implementation and modification of services.

Key performance indicators:

- Processes under scope KPIs and KQIs.
- High customer satisfaction/responsiveness (no customer complaints).
- Adherence to projects timelines and proactive management of upcoming issues.
- Generation / delivery of reports related to owned activities.
- No issues due to non-observance of cGMP, SOPs and no critical deviations/findings.

Minimum Requirements:
Work Experience:

- Bachelor's degree in a related career in pharmaceutical, chemical or biological area, with a professional license.
- At least 1 year in the Pharmaceutical Industry, experience in key areas such as Quality Assurance, Quality Control, Stability or Analytical Services.

Skills:

- Continuous Learning.
- Dealing With Ambiguity.
- GMP Procedures.
- QA (Quality Assurance).
- Quality Control (Qc) Testing.
- Quality Standards.
- Self Awareness.
- Technological Expertise.
- Technological Intelligence.

Languages :

- English.

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

Join our Novartis Network: Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up: https://talentnetwork.novartis.com/network

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

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

Apply to Job

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

Job ID
REQ-10050407

APPS Specialist

Apply to Job

Source URL:
https://www.novartis.com.cn/careers/career-search/job/details/req-10050407-apps-specialist

List of links present in page

1. https://www.novartis.com/about/strategy/people-and-culture
2. https://talentnetwork.novartis.com/network
3. https://www.novartis.com/careers/benefits-rewards
4. https://novartis.wd3.myworkdayjobs.com/en-US/NovartisCareers/job/INSURGENTES/APPS-SpecialistREQ-10050407-1
5. mailto:tas.mexico@novartis.com
6. https://novartis.wd3.myworkdayjobs.com/en-US/NovartisCareers/job/INSURGENTES/APPS-SpecialistREQ-10050407-1