Change Control Specialist - Quality Operations

Job ID
REQ-10050405

5月 02, 2025

Mexico

摘要

Responsible for the coordination of the Change Control activities, assuring that the process adheres to the Novartis QM directives, Global SOPs, Health Authorities requirements. Manages and follows assigned Change Control projects from initiation (when applicable), until completion, to ensure timely supply to the markets in compliance with regulatory and cGMP requirements

About the Role

Major accountabilities:

- Coordinate Change Control activities for Americas region.
- Request input from local functions and ensure that specific information is available in Change Controls and in relevant databases.
- Actively participate in the decision-making process whether a change has impact to Country Organizations or not.

- Generate and analyze predefined and ad-hoc reports in the electronic Change Control system to ensure appropriate execution of services deliverables.
- Drive and coordinate evaluation, execution, authorization, and implementation phases of change requests, considering the most effective implementation strategy, cGMP ' s, regulatory requirements, Corporate Quality Manual, Novartis polices and cost effectiveness.
- Facilitate meetings with the experts and stakeholders of the change request to determine & agree required activities and timelines.
- Communicate CR Plan progress, delays and perform escalations as appropriate, in collaboration with project leader.
- Set priorities for change requests.
- Report changes emerged from the divisions which affects other sites, other BU or authorized third parties for the corresponding impact assessment.
- Initiating Changes by Country Organization that are Managed by NTO/ Global Functions
- Managing country assessments and local implementations in changes from NTO/Global Functions
- Super user in electronic Change Control platform
- Set and provide input on priorities for owned activities.
- Demonstrate customer-oriented service mindset in handling and executing deliverables.
- Responsible for data compilation and preparation of dashboard on a regular basis to track and report deliverables.
- Regularly communicate with customers and partners to collect feedback on support services.
- Responsible for writing and updating SOP ' s applicable to owned activities.
- Follow-up on the actions determined by audits, Self-Inspection, Quality Manual, etc.
- Report and record Issues, Deviations, Quality Events emerging from Service delivered.
- Ensure efficient, timely and clear communication to all involved partners (local and global functions) as required for flawless follow-up on activities under scope. Communicate progress and deviations as appropriate in collaboration with team leader.
- Build and maintain high expertise and continuously acquire process knowledge.
- Support and participation in the implementation and modification of the support provided.

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:

- Professional related to Chemical-Biological areas: IF, IQ, IQI, IBT, IB, QFI, QFB, QBP, LF or Project Management with Pharma experience.

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 Farmacéutica 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-10050405

Change Control Specialist - Quality Operations

Apply to Job

Source URL:
https://www.novartis.com.cn/careers/career-search/job/details/req-10050405-change-control-specialist-quality-operations

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/Change-Control-Specialist---Quality-OperationsREQ-10050405-1
5. mailto:tas.mexico@novartis.com
6. https://novartis.wd3.myworkdayjobs.com/en-US/NovartisCareers/job/INSURGENTES/Change-Control-Specialist---Quality-OperationsREQ-10050405-1