QA Analyst ACC

Job ID
REQ-10030331
nov 20, 2024
Chili

Résumé

Job Objectives

1. Ensure and support the implementation, control and maintenance of the Quality Management System in Novartis, in line with current regulatory requirements or national, international and corporate guidelines, ensuring regulatory compliance and adherence to registration conditions, as well as ensuring the quality and business continuity of the products marketed in the region ACC Country Organization (CO) - comprised of the IM businesses in Chile, Central America and Caribbean (CAC), Ecuador, Peru, Paraguay, Uruguay, Venezuela and Bolivia.
2. Through local, international, and corporate regulatory compliance, prevent quality problems that may lead to product shortages or recalls, as well as delays in product approvals or events that have a negative impact on the financial results or reputation of the company.
3. Serve as a business partner from the quality function that provides support to areas with GMP activity, to ensure that business initiatives, processes and projects are designed, evaluated and executed with local regulatory compliance and global corporate standards.

About the Role

1. Support NCQ Head on Quality governance and planning process at CO ACC through the implementation of the Annual Quality Plan, Quality Management Review Board, Key Quality Indicators (KQI's), Annual Quality Management Review and Quality Risk Assessment by adequately monitoring and reporting, proactively ensuring that actions are taken to mitigate potential risks detected.

2. Support proper management of Quality Exceptions (deviations, quality events, CAPAs, actions, complaints, product tampering/counterfeiting and commitments to health authorities) of ACC, adhering to corporate escalation processes and ensuring that root cause analysis of related investigation processes allows for recurrence prevention, timely decision making and minimization of patient impact due to product quality issues.

3. Maintain knowledge of local and international regulatory requirements (e.g., FDA and EMA), as well as industry trends to ensure adequate support for Quality and regulatory compliance issues for all services provided at ACC.

4. Support that the quality management systems of all ACC GMP service providers are qualified, with their QAAs in place, implementing evaluation and approval processes for these providers prior to their use by Novartis. Ensure and/or coordinate follow-up audits of these GMP service providers, whether scheduled or event driven.

5. Support that establishments with sanitary authorization and notice of operation in ACC remain current and in compliance (e.g., finished product warehouses, legal representative offices for Novartis) with local and international standards.

6. Support that the handling and market release of all products registered in ACC is performed according to Novartis specifications and standards of quality, safety, and efficacy, in compliance with the conditions of registration and/or applicable local regulations. The release shall be done efficiently and in close collaboration with the needs of the business and patients, avoiding lack of product in the market.

7. Support that the CO ACC organization is ready to receive regulatory and corporate audits, periodically executing self-inspection exercises as a preparation and monitoring mechanism for compliance and continuous improvement. Ensure communication with local Health authorities is adequately shared within the organization and commitments are tracked and closed in time.

9. Contribute to the development of a Quality Culture at ACC in line with global initiatives, disseminating quality management principles with related areas in the organization (SC, RA, REFS, Purchasing, Marketing, BD&L/Strategic Alliances), fostering close collaboration as required on quality issues and business initiatives.

10. Contribute to local and regional projects as well as participate in global projects of continuous improvement.

11. Ensure that training plan is accomplished following Novartis guidelines and is being followed up, documented, and periodically verified.

Key performance indicators

1. Zero critical findings in internal or external audits.

2. Zero stock outs generated by events in the area in charge.

3. Timely launch of new products.

4. Compliance with the KPI's established by the global NCQ function.

5. Adherence to the annual expenditure budget.

6. Fulfillment of the objectives defined for strategic projects.

7. Positive survey results from Glint, regarding your management as a leader.

Background

Education: Bachelor´s degree in pharmaceutical sciences.

Language: Fluent English and Spanish

Experience

Knowledge of quality and compliance systems, good manufacturing, documentation, laboratory, good storage and distribution practices.

Preferred knowledge of the comprehensive handling of controlled products, local regulatory framework of the countries that conform ACC and the applicable international regulation such as CFR 21, ICH.

Knowledge of manufacturing and packaging processes of medicines, as well as analytical processes; storage

and distribution process.

Minimum 1 year experience in areas of Regulatory and Quality Assurance in the Pharmaceutical Industry.

Competencies

1.Quality decision making

2.Capacity to anticipate and manage risks appropriately

3.Demonstrate passion for the 3C's (Customers, Consumers and Competence)

4.Effective communication

5.Organizational and planning capacity

6.Leadership

7.Conflict management

8.Exercise good judgment and drive change

9.Promote continuous improvement and creative thinking

10.Energize the team

11.Establish clear direction and align the Team

Specific competencies

1.Knowledge of manufacturing and packaging processes, analytical processes, and storage and distribution processes.

2.Knowledge for the comprehensive management of controlled products.

3.Knowledge and management of SAP in modules related to product release.

4.Knowledge in Good Manufacturing Practices, Documentation, Storage and Distribution.

5.Desirable knowledge in computer system validation, analytical methods, stability studies, systems and equipment qualification.

6.Knowledge and application of quality systems and local regulation.

7.Office parcel management (Excel, PowerPoint, Visio, Word, MS Project, etc.)

8.Project management and change management.

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

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