Quality System Owner Batch Release Management - Team Lead

Job ID
REQ-10045792

3月 31, 2025

Spain

摘要

The Quality System Owner Batch Release Management Team Lead manages, drives and maintains initiatives and strategy for Batch Release Management Quality System across Novartis, ensuring alignment and collaboration with all functions involved in batch release activities.
Maintains knowledge with current industry trends, Health Authority expectations and influences standards accordingly to enable them to be incorporated into business processes and maintain the compliance of the Product Release and APQR Quality System.
Manages Quality Assurance activities and Projects related to batch release management quality system to ensure that all aspects of the operational business comply with cGMP legal and regulatory requirements and the Novartis Quality Manual and Policies.

About the Role

Deadline for applications: **14th of April 2025.**

Major accountabilities:

- Act as Quality System Owner for Product Release (including annual product quality review process), ensuring the objectives and strategy for batch management meet the expectations of Novartis and external regulatory bodies. Drive Harmonization and Standardization for batch management across Novartis.
- As QSO (Quality System Owner) for Batch Release Management, accountable for the development and implementation of an effective and efficient end-to-end Quality System. Drives simplification and harmonization through cross-functional collaboration. Manage and perform review of relevant Quality Manual documents for batch management and APQR, ensuring alignment with the approved quality system strategy and ensures GxP procedures & processes for the quality system are up to date, robust, aligned, and fit for purpose.
- Drive and support projects associated with and impacting Batch Management, to ensure the final process, tool and/or system is fit for purpose and provides an effective and efficient means to perform batch release within the specified function and Novartis as a whole. Ensure issues are resolved and in compliance with regulatory requirements and Novartis expectations. Ensure that operationally, proposals can be implemented within MSO Platforms, NCQ and other functions as necessary, to support other areas such as QA Agreements, APQRs, Artwork process, Retesting Centers, Quality control activities, Change control, etc., as well as batch release.
- Ensure systems to support Batch Management, such as SAP/ERP, operate as required and provide the necessary level of control needed for compliance purposes and meet the needs of the business, incorporating continuous improvement, utilizing new digital and data technologies where identified.
- Manage and organize the Qualified Person Forum and the Joint Batch Release Forum for Novartis Technical Operations, Technical Research and Development and Novartis Country Quality Qualified Person, to allow sharing of best practice, review of new guidelines, as well as discuss and propose solution of issues/challenges faced by the QPs.
- Provide QA support to the owner of the Safety Label Change process, providing guidance and input on the process, improvements and its performance.
- Establish strong partnership with key stakeholders. Collaborate with cross-functional teams to identify areas for improvement and recommend actionable solutions and support cross functional teams by providing provide global insight and guidance for APQR and Batch Release process.
- Attend appropriate QMS Leadership Team meetings and governance boards to ensure alignment and gaining of synergies across the different QMS activities.
- Maintain current knowledge of local and international regulatory and legislative requirements and trends and of Novartis business processes.

Minimum Requirements:

- Education: Degree in Pharmacy, Chemistry, Biology, or related subject; additional knowledge in Quality Assurance and Compliance
- At least 5 years ' experience in the pharmaceutical industry, e.g. in Production/Technical Operations and/or Quality Assurance. A minimum at least 2 years in Quality Assurance
- English fluent in speaking and writing, second language desirable.
- Strong Quality Assurance and QMS understanding Project management and analytical skills.
- Excellent interpersonal skills, including leadership, organizational, analytical, intercultural communication, and negotiation. Team player.

- Experience in an international matrix organization Thorough knowledge of cGMP requirements:
- Strong understanding of regulatory requirements for commercial biological and pharmaceutical products Strong understanding of risk assessment and risk management fundamentals/tools.

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

You will receive: Competitive salary, Annual bonus, Pension scheme, Share scheme, Health insurance, 27 days annual leave, Flexible working arrangements, subsidized dining facilities, Employee recognition scheme, learning and development opportunities.

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.

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
Corporate

地点
Spain

站点
Barcelona Gran V í a

Company / Legal Entity
ES06 (FCRS = ES006) Novartis Farmac é utica, S.A.

Functional Area
Quality

Job Type
Full time

Employment Type
Regular

Shift Work
No

Apply to Job

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

Job ID
REQ-10045792

Quality System Owner Batch Release Management - Team Lead

Apply to Job

Source URL:
https://www.novartis.com.cn/careers/career-search/job/details/req-10045792-quality-system-owner-batch-release-management-team-lead

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://www.novartis.com/about/strategy/people-and-culture
5. https://talentnetwork.novartis.com/network

6. https://www.novartis.com/careers/benefits-rewards
7. https://novartis.wd3.myworkdayjobs.com/en-US/NovartisCareers/job/Barcelona-Gran-Va/Quality-System-Owner-Batch-Release-Management---Team-LeadREQ-10045792-1
8. https://novartis.wd3.myworkdayjobs.com/en-US/NovartisCareers/job/Barcelona-Gran-Va/Quality-System-Owner-Batch-Release-Management---Team-LeadREQ-10045792-1