Regulatory CMC facilitator (m/f/d), Menge š

Job ID
REQ-10037816

1月 24, 2025

Slovenia

摘要

Interested in managing and facilitating regulatory CMC related launch and post-approval activities of innovative medicines? Willing to contribute timely market supply while complying with regulatory obligations?

About the Role

Major accountabilities:

- Act as single point of contact and advisor for worldwide regulatory intelligence information on the site. Maintain a close collaboration with Global Reg CMC in order to keep track with new regulatory requirements, Global Reg CMC strategies and the knowledge of the global product dossiers (CTD module 3).
- Perform the product independent pre-evaluation of new change requests to assign/confirm category I or category II classification. Consider current regulatory requirements and trends in

order to ensure accuracy and completeness of regulatory relevant information in the change requests while including potential regulatory hurdles. Follow up with Reg CMC for product specific regulatory topics after having consolidated all information available at the site.
- Support the site in generation of effective change control strategies particularly when changes affect a wide range of products or other sites/divisions.
- Support the variation documentation preparation by facilitating timely provision of good quality source documentation and accurate comments from technical experts to Global Reg CMC while ensuring regulatory compliance.
- Facilitate the timely writing of high-quality CMC modules on site in line with agreed CMC regulatory strategies, assuring technical congruency, regulatory compliance and adherence to best practices (e.g. LEAN).
- Support the preparation of CMC responses to health authority questions for site specific products.
- Maintain overview on commitments impacting the site. Train and develop the site ' s personnel on regulatory specific aspects of change management by sharing lessons learned and regulatory intelligence information with the goal of improving their skills and capabilities for handling change requests and keeping the highest level of compliance.

Minimum Requirements:

- Degree in Science (e.g. Chemistry, Pharmacy, Biochemistry, Biotechnology, Biology) or equivalent.
- Fluent English (oral & written).
- 2 years or more experience in Regulatory CMC and/ or working on a manufacturing site (e.g. QA, QC or production) or laboratory or equivalent experience from external company or other line function preferable.
- Working Knowledge of local and global regulations and submission and approval processes for New Chemical Entities (NCE) and product life cycle management.
- Excellence in negotiation and communication skills as well as capability to influence others in a matrix organization with the necessary strategic thinking.
- Excellent organizational skills. Proactive and action-oriented attitude in driving projects.
- Computer literacy in MS-project, Power Point, document management systems, databases and ability to quickly learn new software, tracking tools and associated processes.

We are offering a **permanent employment contract**, including a 6-month probation period. Submit your application with the CV in English language.

You ' ll receive:

Competitive salary, Annual bonus, Flexible working schedule, tailored to your needs, possibility to work from home, Pension scheme, Employee Recognition Scheme, Expanded program for the promotion of health in the field of physical, mental and social well-being (Wellbeing), employment at Top SI Employer, Unlimited 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

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部门
Operations

Business Unit
Innovative Medicines

地点
Slovenia

站点
Menge š

Company / Legal Entity
SI19 (FCRS = SI019) Novartis farmacevtska proizvodnja d.o.o.

Functional Area
Quality

Job Type
Full time

Employment Type
Regular

Shift Work
No

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Accessibility and accommodation

Novartis is committed to working with and providing 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 diversity.inclusionslo@novartis.com and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

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