Regulatory Affairs CMC Manager

Job ID
REQ-10011559
Sep 02, 2024
Austria

Summary

Our Development Team is guided by our purpose: to reimagine medicine to improve and extend people's lives.

To do this, we are optimizing and strengthening our processes and ways of working. We are investing in new technologies and building specific therapeutic area and platform depth and capabilities – all to bring our medicines to patients even faster.

We are seeking key talent, like you, to join us and help give people with disease and their families a brighter future to look forward to.

Apply today and welcome to where we thrive together!

As manager, you provide strategic and operational global CMC regulatory direction and documentation for our products covering development and post-approval activities. You bring regulatory knowledge regarding drug development, manufacturing, and analytical testing, as well as a collaborative and patient-focused mindset.

About the Role

Major accountabilities:

- Formulate and lead global CMC regulatory strategy with a focus on innovation, balancing business benefit with regulatory compliance for Biologics and Small Molecules projects/ products.
- Lead and implement global CMC submission activities (planning, authoring, reviewing, coordination, submission) for assigned projects/products.
- Identify the required documentation and any content, quality and/or timelines issues for global submissions and negotiate the delivery of approved technical source documents in accordance with project timelines.
- Author and/or review high-quality CMC documentation for HA submission, applying agreed CMC global regulatory strategies, current regulatory trends and guidelines. Ensure technical congruency and regulatory compliance, meeting agreed upon timelines and e-publishing requirements.
- Proactively communicate CMC regulatory strategies, risks and key issues throughout the life cycle in a timely manner to project teams and other stakeholders. Represent department in cross-functional project teams.

- Prepare and communicate CMC risk management assessments and lessons learned on major submissions.
- Initiate and lead Health Authority interactions and negotiations.

Minimum Requirements:

- Education Minimum: Science degree (e.g. Chemistry, Pharmacy, Biochemistry, Molecular Biology, Biotechnology, Biology) or equivalent; advanced degree desired
- Ideally, at least 2 years' experience in regulatory CMC experience and/or pharmaceutical industry experience; working knowledge in regulatory submissions desirable.
- Demonstrated working knowledge of chemistry/biotechnology, analytics or pharmaceutical technology. Knowledge/experience of regulations, guidelines and product life cycle maintenance desirable.
- Ability to critically evaluate data from a broad range of scientific disciplines.
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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

Commitment to Diversity & Inclusion:

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

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

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Division
Development
Business Unit
Innovative Medicines
Location
Austria
Site

Schaftenau
Company / Legal Entity
AT33 (FCRS = AT033) Novartis Pharmaceutical Manufacturing GmbH
Functional Area
Research & Development
Job Type
Full time
Employment Type
Regular
Shift Work
No
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