Sr Regulatory Affairs Coordinator

Job ID
REQ-10019496
Ago 19, 2024
Messico

Sommario

Support and facilitate on-site regulatory CMC related launch and post-approval activities (post-approval changes, transfers, remediation, divestment, pruning and due diligence) of the site specific (global and local) products to ensure timely supply to the markets in compliance with current regulatory obligations and requirements. Champion regulatory compliance and consistency through representation in initiatives and experience sharing within and outside the site.

About the Role

Responsibilities:

- Regulatory transmission:
  - Act as single point of contact for worldwide regulatory intelligence information on the site.
  - Maintain a partnership with RA CMC members / management and RA to keep track of new regulatory requirements, strategies and the knowledge of the global product dossiers (CTD module 3).
  - Collaborate on implementation of new regulatory requirements and provide guidance on regulatory and change control related aspects. Participate in the CMC facilitator network sharing lessons learned, providing expertise to facilitators from other sites and raising and resolving issues.
- Change control:
  - Support the site in generation of effective change control strategies from a Regulatory Affairs CMC perspective.
  - Verify and monitor regulatory relevant changes - includes performing regulatory pre-evaluation of changes.
  - Provide regulatory strategic guidance as member of local change control board.
  - Consider current regulatory requirements and trends to ensure accuracy and completeness of regulatory relevant information in the change requests while including potential regulatory hurdles.
- Submission support:
  - Support the CMC documentation preparation by facilitating timely provision of good quality source documentation, involving co-authoring as applicable, and accurate comments from technical experts to RA CMC while ensuring regulatory compliance, quality oversight and adherence to best practices.
  - Monitor project scope, timing and progress of submission-related activities e.g. transfers, ensuring activities completed without delays.
  - Address and escalate issues adequately and in time.
- Health Authority Responses:
  - Provide guidance and support for the preparation of CMC responses to Health Authority (HA)

questions for site specific products, balancing internal and external customer focus considering Novartis global interests.
    - Ensure overview and timely follow-up to commitments impacting the site.
- Declarations:
    - Maintain oversight and ensure consistency; contribute to the establishment of standards; align requirements with RA CMC and RA, provide guidance to implementation of requirements into declarations; ensure alignment on content among all sites; ensure compliance to quality and regulatory standards. Coordinate or prepare declarations if needed.
- Local products:
    - In addition, for local products and products crossing Novartis legacy divisions, maintain close contact with local RA to follow regional regulatory trends and requirements, cooperating to formulate the regulatory strategy based on information at the site.
    - Support the preparation of submission documentation and HA responses written for local products, reviewing for content, format, completeness, consistency and adherence to best practice, and ensure regulatory compliance incl. via maintaining an archive of currently filed documentation for local products.
    - Support processing of changes related to supply to other divisions/external partners.

Requirements

- Degree in Science (e.g., Chemistry, Pharmacy, Biochemistry, Biotechnology, Biology) with 6+ years of experience in pharmaceutical manufacturing with a focus on QA or regulatory affairs.
- Project management experience
- Fluent English (oral & written)
- Proven excellence in successfully collaborating with interdisciplinary teams while simultaneously planning, coordinating, and leading activities on multiple projects.
- Excellence in negotiation and communication skills as well as capability to influence others in a matrix organization.
- Knowledge experience of local and global regulations, submissions, and approval processes for new registrations and product life cycle management and proven practical knowledge of and ability to deal with complex CMC regulatory issues and requirements.
- Computer literacy in Microsoft Office applications, document management systems, databases, and ability to quickly learn new software, tracking tools and associated processes.
- Proactive and action-oriented attitude and proven success in driving projects.

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Business Unit
Innovative Medicines
Posizione
Messico
Sito
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
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Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

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