# Regulatory Affairs Leader

Job ID
REQ-10053867

6月 05, 2025

Mexico

## 摘要

Garantiza un sistema de documentaci ó n controlado, retenci ó n de registros y servicios de informaci ó n, incluidos los procesos de retenci ó n de registros electr ó nicos de acuerdo con los requisitos reglamentarios. Asegura el cumplimiento de los requisitos de las agencias reguladoras. Mantiene el sistema de cambio de documentaci ó n t é cnica y no t é cnica. Asegura que existen procedimientos para clasificar y mantener registros. Interpreta y hace cumplir todos los requisitos de formato, est á ndares, pol í ticas y procedimientos operativos de la documentaci ó n. Puede identificar los componentes de presentaci ó n, comunicar las normas de documentaci ó n y coordinar el montaje de los expedientes reglamentarios. Puede analizar y evaluar datos, extraer informaci ó n pertinente, preparar res ú menes de informaci ó n y res ú menes ejecutivos del material buscado. Puede mantener un amplio conocimiento de la informaci ó n del producto y contactos continuos con clientes locales, regionales y divisionales.

## About the Role

**Key Responsibilities**

- Lead and manage mid- to small-scale global regulatory submission projects, ensuring timely and compliant delivery
- Provide strategic input and regulatory intelligence to support global product development, registration, and lifecycle management
- Collaborate with cross-functional teams to implement and optimize global systems, tools, and processes for regulatory operations
- Ensure documentation complies with internal standards and external regulatory requirements, including formatting and retention policies
- Coordinate the preparation, review, and assembly of high-quality regulatory dossiers and submission components
- Analyze and interpret regulatory data, preparing executive summaries and abstracts to support decision-making
- Build and maintain strong relationships with internal stakeholders and external partners to align regulatory strategies

**Essential Requirements**

- Bachelor ' s degree in life sciences, pharmacy, or a related scientific discipline
- Minimum 3 years of experience in regulatory affairs or related pharmaceutical industry role
- Proven ability to manage regulatory submissions and documentation in compliance with global standards
- Strong understanding of regulatory guidelines and documentation systems
- Experience working in cross-functional and multicultural teams
- Excellent written and verbal communication skills in English
- Strong analytical skills with the ability to interpret complex data and summarize key insights
- Proficiency in documentation tools and electronic records management systems

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部门
Development

Business Unit
Innovative Medicines

地点
Mexico

站点
INSURGENTES

Company / Legal Entity
MX06 (FCRS = MX006) Novartis Farmac é utica S.A. de C.V.

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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