Reg Affairs Assoc. Dir._Denmark_Testing

Job ID
REQ-10021714
Sep 24, 2024
Dänemark

Summary

-Ensures a controlled documentation system, record retention, and information services including electronic records retention processes in accordance with regulatory requirements. Ensures compliance to the requirements from regulatory agencies. Maintains the technical and non-technical documentation change system. Assures procedures are in place to classify and maintain records. Interprets and enforces all documentation formatting, standards, policies, and operating procedure requirements. May identify submission components, communicate documentation standards and coordinate assembly of regulatory dossiers. May analyze and evaluate data, extract pertinent information, prepare information abstracts and executive summaries of material searched. May maintain extensive knowledge of product information and continuous contacts with local, regional, and divisional customers. -Develop and provide submission and technical related regulatory strategy, intelligence and knowledge required to develop, register, and maintain global products. Develop strategic and technical input/support to drive implementation of global systems, tools and processes to support global development projects and/or marketed products.

About the Role

Major accountabilities:

- Provide a robust framework to oversee the management, compilation and timely dispatch of high quality, regulatory compliant global HA submissions.
- Provide advise to project teams on technical submission requirements.
- Stay on the pulse of evolving submission related global Health Authority requirements, ensuring NVS is influencing and shaping policy in this area and building strategies to proactively prepare the organization for the future.
- Continually develop and implement enhanced compliance /process efficiencies to global submission preparation standards, strategies and related procedures/tools.
- Ensure global cross-functional business/IT/external partners adopt and continually adhere to the established submission/document standards, policies and operating procedures.
- Oversee the management and support of all Regulatory Systems and tools, keeping them updated, compliant and validated.
- Own and ensure a controlled documentation system/record retention, and information services including electronic records retention processes in accordance with regulatory requirements.
- Ensures compliance to the requirements/guidances from regulatory agencies.
- Assures adherence to procedures to classify and maintain records.
- May analyze and evaluate data, extract pertinent information, prepare abstracts and executive summaries of material searched.
- May maintain extensive knowledge of product information and continuous contacts with local, regional,

and divisional customers.
- May execute people management role, with responsibility for a specific function/technical area.
- Establishes operational objectives and work plans, and delegates assignments to subordinates.
- Senior management reviews objectives to determine success of operation.
- Establishes and assures adherence to budgets, schedules, work plans, and performance requirements.
- Contributes to and often leads the development of departmental goals and objectives.
- Reporting of technical complaints / adverse events / special case scenarios related to Novartis products within 24 hours of receipt -Distribution of marketing samples (where applicable)

Key performance indicators:

- Adherence to Novartis policy and guidelines -Project and stakeholder feedback

Minimum Requirements:
Work Experience:

- Strategy Development.
- Major Change.
- People Challenges.
- Managing Crises.
- Collaborating across boundaries.
- Operations Management and Execution.
- Project Management.

Skills:

- Data Analysis.
- Documentation Management.
- Lifesciences.
- Proactivity.
- Process Improvement.
- Project Management.
- Regulatory Compliance.

Languages :

- English.

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Functional Area
Research & Development
Job Type
Full time
Employment Type
Regular
Shift Work
No
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