RA Structured Data Submission Manager

Job ID
REQ-10058056

7月 17, 2025

India

摘要

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.

About the Role

Key Responsibilities

- Structured Data Submissions (SDS): Independently perform timely SDS (e.g. xEVMPD, IDMP) via RIM system, ensuring data quality and exchange with EMA including analysis and tracking of 3rd acknowledgements. Ensure Data Quality Management and timely delivery of requests for new/changes of code lists/terms including external reference data (e.g. SPOR).
- Provide guidance and support to cross-functional teams related to planning, submission compilation and dispatch of worldwide compliant SDS, as well as submission filing strategy, eCTD document lifecycle management and workflows, in alignment with FHIR (Fast Healthcare Interoperability Resources). Assess SDS resources and support needs and develop/implement solutions to create efficiencies. Effectively troubleshoot technical/quality issues relating to compilation, validation and dispatch of global submission outputs.
- Coding of Clinical Particulars: Perform coding of the Clinical Particulars attributes in Novartis Regulatory Information Management (RIM) system: Therapeutic Indications and Co-morbidity using the MedDRA dictionary, Intended effect using a controlled vocabulary, as required to ensure compliance with xEVMPD / IDMP requirements.
- Review and maintain MedDRA code values used in EU registrations upon MedDRA version updates by performing gap analysis of changes, and update existing values accordingly in RIM system. Review and update coding values as needed upon queries from the European Medicines Agency (EMA), for instance receipt of 3rd acknowledgment.
- Interactions: Liaise with GDD colleagues regarding new regulatory requirements and related business processes, to ensure proper knowledge transfer to IT business partners for system enhancement requests.
- Manage interactions and collaboration with RA Country Organisations (CO), Global RA and non-RA functions on regulatory and compliance maintenance activities for Authorised and Investigational medicinal products.
- Optimally support QPPV and PV-related processes (incl. fees), provide support for internal /external audits /inspections. Facilitate and/or participate in meetings with internal and external stakeholders (including acquisitions, partnerships and divestiture efforts). Participate as key business contributor in Technology initiatives including, but not limited to, systems upgrades, validation, implementation activities and functionality enhancements, including external service providers.
- General & Training: Support user training of RA end users, as required, Coach / mentor new team members. Support PQ testing and Application verification activities, as required. Support preparation of administrative procedures and Working Instructions to support system implementations. Develop, implement, and support innovative regulatory strategies and life-cycle management of RA systems, including process productivity and efficiency improvement and propose potential solutions. Identify and investigate operational needs, problems, and opportunities, contribute to the implementation of improvements within area of responsibility.

Minimum requirements

- BS in Life Sciences (Medicines/Pharmacy) or a relevant discipline with at least 7 years of professional work experience. Master ' s degree preferred (M.Pharma or MD).
- 4-6 years of relevant experience in structured data submissions (e.g. xEVMPD) and use of RIM systems, including familiarity with submission publishing activities.
- 3-5 years in Clinical coding (e.g. MedDRA, SNOMED), Labelling, Regulatory Affairs or Regulatory submission related experience. WITH SDS experience as 1st bullet, Proficient knowledge of EMAs databases (e.g. SPOR).
- Knowledge and experience with eCTD, xEVMPD, IDMP, Publishing Standards and applicable related tools is desirable.

- Experienced in using RA systems of data (RIMS, DMS, Change Control databases), systems ' data model and vocabularies. Familiar with the drug development and registration process.
- Solid project management, organizational and time management skills to manage multiple ongoing projects simultaneously.
- Familiar with global Health Authority regulations/guidelines e.g., FDA regulations, ICH and EMA guidelines/directives.
- Proficiency with computer programs/systems (MS office, etc.) with demonstrated ability to learn new systems quickly. Strong analytical skills and problem-solving skills. Ability to coordinate and work effectively with cross-functional teams

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  Our purpose is to reimagine medicine to improve and extend people ' s lives and our vision is to become the most valued and trusted medicines company in the world. How can we achieve this? With our people. It is our associates that drive us each day to reach our ambitions. Be a part of this mission and join us! Learn more here:
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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

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部门
Development

Business Unit
Universal Hierarchy Node

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India

站点
Hyderabad (Office)

Company / Legal Entity
IN10 (FCRS = IN010) Novartis Healthcare Private Limited

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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