Regulatory Records Associate

Job ID
REQ-10006673
Juli 29, 2024
Vereinigtes Königreich

Summary

1,800+ associates. 86 countries. One Regulatory Affairs. At Novartis your voice, experience, and quality mindset can truly make a difference in Regulatory Affairs (RA). Novartis has a unique and promising portfolio with 70 projects as potential NMEs in development, 65 projects in Phase 3 or already undergoing registration, and 100 Phase 1/2 projects.

An individual contributor position in Regulatory Affairs Operations responsible for supporting the implementation of Regulatory Records Management (categorizing and classifying information) related to Novartis product portfolios and Mergers, Acquisitions and Divestment (MA&D) activities in a global setting.

Primarily this role will:

- Ensure proper handling, index, scan (in case of paper) , archival and retention of regulatory relevant electronic and paper records.
- Ensure compliance to the requirements from regulatory agencies as well as internal Novartis standards that uphold these HA standards.
- Collaborate with various line functions and assist in collecting data and metrics, help generate reports to support M&A related audits or internal queries to serve business needs.

Please note this role will require ad hoc on site support to manage the specific requirements of this role - more information will be provided at the interview stage.

Visa sponsorship or relocation is not on offer for this role.

About the Role

Major accountabilities:

- Under the supervision of Head, RA Ops Mergers and Acquisitions, support assigned tasks related to the areas of archiving, retention, and timely disposition of impacted Regulatory Records.
- Receives, tracks, and responds to inquiries and requests for retrieval of stored RA records in a timely manner.
- Responsible for receiving, classifying scanning, indexing, and archival of regulatory relevant records in support of MA&D activities.
- Ensure timely generation of reports; assist Operational team in developing and maintaining meaningful KPI’s/metrics related to physical and electronic record transfers.
- Participate in the development and review of line function related records management processes and

procedures.
- Provide audit support related to RA records managed by RA Operations , including support for MA &D related needs.
- Support, as per guidance from RA Ops M&A team, the litigation team on document discovery requests (due diligence); assist in legal hold implementation as per Legal Department needs
- Collaborates with RA Operational team in development, implementation, communication, training and enforcement of Regulatory Records Management best practices.
- Proactively identify opportunities for operational process or system related improvements relevant to both paper and electronic records management.

Key performance indicators:

- Flexible, proactive, with demonstrated attention to detail and accountability for deliverables as well as proven ability to work in a fast-paced team / matrix environment or independently as needed.
- Results driven, action oriented, highly motivated, self-starter and forward thinker.
- Ability to effectively collaborate with internal/external partners, stakeholders, peers and colleagues in a multi-cultural, global environment.
- Strong organizational and time management skills to help plan activities and manages tasks and timelines with efficiency while navigating competing and complex priorities.
- Demonstrated skills to understand complex discussions, has a positive attitude and follow directions to help develop/implement innovative solutions.
- Able to effectively adjust to constant change and related challenges, is decisive and composed under pressure.
- Adherence to Novartis policy and guidelines -Project & stakeholder feedback

Minimum Requirements:
Education:

- BS or MS degree with 3+ years of Regulatory and/or Archives/Records management experience within Pharmaceutical industry.

Work Experience and Skills:

- 3+ years' experience in Pharma (preferably in the area of Regulatory Records
- Management) is preferred.
- Familiar with drug development process, worldwide regulatory practices, electronic submission guidelines and requirements as well as records/document management processes
- Hands-on experience with regulatory records or document management systems and related software/tools preferred
- Working knowledge of regulatory affairs.
- Project management and time management skills to manage multiple ongoing projects simultaneously.
- Proficiency with computer programs/systems (MS office, etc.) with demonstrated ability to learn new systems quickly.
- Works independently and with minimal supervision.
- Good analytical and problem-solving skills.
- Ability to coordinate and work effectively with cross-functional teams.

Languages :

- English.

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

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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.

Division
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Business Unit
Innovative Medicines
Standort
Vereinigtes Königreich
Site
London (The Westworks)
Company / Legal Entity
GB16 (FCRS = GB016) Novartis Pharmaceuticals UK Ltd.
Functional Area
Research & Development
Job Type
Full time
Employment Type
Regular
Shift Work
No
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