Regulatory Affairs Process Director

Job ID
REQ-10044487
Απρ 07, 2025
India

Περίληψη

Accountable for the strategy, development and implementation - including adequate training to staff, efficiency, gap assessment and continuous improvement and overall performance - of assigned regulatory processes in the respective process area(s), in alignment with other functions as applicable, to ensure organizational readiness and compatibility with associated systems and technology and compliant with global regulatory requirements and Novartis standards.

About the Role

Key Responsibilities:

- Under the supervision of the Process Transformation Lead, contribute to E2E regulatory processes transformation roadmap and implementation strategy for assigned processes and/or process area, further enabling increasing efficiency, reducing complexity and securing high quality or regulatory deliverables.
- Act as a core member of the RA Process Review Committee (or equivalent) to secure meaningful content, timely and impactful review, finalization, implementation and assignment of new or revised process documents to relevant roles within RA.
- For assigned processes and/or process area(s):
- o Lead Impact assessment, business process design, ownership, continuous improvement (including technology and automation needs to improve process performance). This includes developing, authoring/writing (as applicable) and maintaining procedural documents, establishing KPI and working with Training & Capability team members to provide associated functional.
- o In partnership with International / Regions and Policy, monitor and review emerging regulations and regulatory guidelines and analyze impact on Novartis regulatory processes, and ensure outcome of the assessment is actioned (e.g. need to adapt a process).
- o Lead process changes in case of identified compliance issues (resulting from audit/inspection, QI, KPI trending)
- o Contribute to inspections and internal audits as Point of Contact for respective processes.
- o Provide direct input and expertise in the areas of process design, risk management, governance, organizational design and compliance, self-author/write or provide guidance to author(s) on the content of a procedural document
- o Ensure high level of connectivity, alignment, transparency and collaboration with Subject Matter Experts (SME) across RA and with other Development and Corporate functions and departments, as required.
- o In partnership with the Systems team, incorporate technology portfolio deliverables into integrated transformation roadmap as well as any other non-drug development projects that impact the broader transformation.

- o Contribute to the development of the learning & training strategy for enhancing regulatory capability building, functional learning and learning technology.
- Participate in or lead select cross-functional process related projects as applicable and on-need basis to support the overall roll-out of the RA organization.
- Monitor regulatory changes for processes in scope: Keep up-to-date with changes in regulations, industry trends, and evolving compliance standards. Partner with Capability / Learning Manager (as applicable) to disseminate relevant information and/or provide guidance on adapting to new requirements to relevant stakeholders.
- When designated, may represent RA at enterprise process community(ies) at and/or process/training governance boards
- Acts as deputy to Process Transformation Lead

Essential Requirements:

- Life Science Degree or other University degree with equivalent experience
- Significant regulatory and drug development experience
- Extensive knowledge on E2E process, supporting system, regulations and business change(s).
- Strong working knowledge of Quality Management System (QMS), SOPs and compliance
- Technology-savvy – ability to leverage and foster use of systems, technology and automation (including digital assistants and AI tools) to derive efficiency; embrace the mindset shift towards enhanced use of technology in daily work
- Ability to anticipate the impact of any change(s) from external and internal sources to the E2E process(es), supporting systems as applicable and to training
- Strong organizational awareness, including experience working cross-functionally
- Ability to lead teams in a matrix environment
- Superior negotiation, influencing and communication skills
- Desirable Requirements:
- Ability to define and interpreting metrics
- Strategic thinking; process simplification and optimization
- Strong process authoring/writing capabilities

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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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Accessibility and accommodation

Novartis is committed to working with and providing reasonable accommodation to individuals with disabilities. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the recruitment process, or in order to perform the essential functions of a position, please send an e-mail to diversityandincl.india@novartis.com and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

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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