Senior Global Process Owner, PRS

Job ID
REQ-10060303

9月 11, 2025

Ireland

摘要

Locations: Dublin, Ireland; Barcelona, Spain or Westworks, London, UK
Full time, Hybrid, #LI-Hybrid

The Senior Global Process Owner (Sr. GPO) is accountable for designing and managing an end-to-end business process that is compliant with regulatory requirements and is fulfilling business needs across the end-to-end trial process in Development.

The Sr GPO will be responsible for overall governance and oversight of a process by setting appropriate strategy, coordinating process mapping activities, overseeing the development the various procedural documents related to a process, ensuring efficiency and effectiveness of the process and managing risks. In addition, the Sr GPO would also be responsible to monitor process performance via KPIs/KQIs aligned with regulatory and organizational strategies.

About the Role

The role acts as a single point of ownership that drives process health and continuous improvement for sustained process maturity. The role drives adoption by working collaboratively with Global Line Functions, within a complex matrix, ensuring that processes meet both high design standards, regulatory compliance, and high levels of practicality. Promotes simplification and process automation.

The specific domain for this role is study feasibility and start up, and regulatory green light (in particular, demonstrated expertise in FDA 21 CFR and EU CTR); hands-on experience with CTIS highly desired.

Accountable for the end-to-end delivery, maintenance and improvement of the designated process(es).

- Act as point of contact for the Quality System Owner (QSO) for any process related queries or tasks, as well as for the Line Function Representative.
- Play a leading role in the designing and management of streamlined processes within functional and cross-functional settings.
- Coordinates process mapping activities executed by Business Process Excellence Experts
- Ensure oversight of the controlled documents e.g., Standard Operating Procedures (SOPs) and Working Practices (WPs) of the designated process.
- Act as point of contact for the author (Lead SMEs) of controlled documents to ensure consistent document lifecycle management within a process.
- Provide guidance to authoring teams on the content of a procedural document with respect to the process.
- Ensure coherence between the various activities surrounding a defined process and its controlled documents through robust checks and controls so that they are compliant with regulatory requirements
- Drive harmonization and simplification of process across different controlled documents within the process
- Support QSO in monitoring and analyzing the impact regulatory changes related to the owned procedures (including digitization of the QMS).
- Monitor and analyze the impact of other procedural (SOP/WP/User Manuals/WPs, etc.) changes on own procedures
- Lead cross-functional process improvement & change management activities to optimize and help bring consistency in way of working and to strengthen overall operations.
- Ensure new and transformed business processes and activities are aligned and can be delivered globally and functionally by the responsible parties e.g., Global Line Functions
- Input into training strategy of the process, through close collaboration with Training Lead(s) Design, develop and maintain metrics in collaboration with Global Line Functions, Compliance & Quality, when relevant Monitor Key Performance Indicators (KPI) and Key Quality Indicators (KQI), when relevant and assess deviation trends SPOC for audits and inspections as relevant and based on scope of audit/inspection (e.g., if the scope is on an entire process). Responsible for oversight and management of risks related to the designated process.
- Participate in Annual QS review under the direction of the QSO. Conduct root cause analyses and/or failure mode effect analyses (FMEA) as applicable and develop CAPA in alignment with Author (Lead SME), as required Develop CAPAs and measure CAPA effectiveness for deviations/quality incidents, audit and inspection findings pertaining to the owned process.

Education (minimum/desirable):

Minimum: University degree in Life Science, quantitative science or business. Desirable qualifications in shared services, outsourcing, global sourcing. project management/Coaching, 6-Sigma, Lean education/training, Master of Business Administration or equivalent

Languages:

- Proficiency in English (read/ write/ speak)

Relevant Experiences

- Extensive knowledge of end-to-end processes within clinical development, including supporting systems, regulations, and awareness of business changes.
- Study Start-up, feasibility and clinical trial application (CTA) experience (min 1-2 years) required; hands-on CTIS experience highly desirable
- Demonstrated EU CTR and FDA 21 CFR knowledge required
- Ability to anticipate and assess the impact of external and internal changes on the end-to-end process, supporting systems (and vice-versa), and associated training requirements.
- Experience in defining metrics to effectively monitor and improve processes.
- Strategic thinker with the ability to contribute to long-term process improvements and operational planning.
- Experience with process simplification and optimization, including improvements to quality documentation.
- Demonstrated ability to collaborate effectively across functions, supporting performance improvements within the end-to-end clinical development value chain.

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部门
Development

Business Unit
Innovative Medicines

地点
Ireland

站点
Dublin (NOCC)

Company / Legal Entity
IE02 (FCRS = IE002) Novartis Ireland Ltd

Alternative Location 1
Barcelona Gran V í a, Spain

Alternative Location 2
London (The Westworks), United Kingdom

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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