NOVARTIS

Senior Manager Inspection & Audit Readiness

Job ID
REQ-10047751
Απρ 16, 2025
United Kingdom

Περίληψη

Responsible for management and coordination of global GVP/GCP inspection & audit participation, conduct of global PS&PV self-assessments and contribute to review of draft, new and changed pharmacovigilance/device vigilance regulatory requirements

About the Role

Major accountabilities:

- Responsible to provide coordination of central pharmacovigilance subject matter expert input and preparation for GVP or GCP inspections, EMA or national
- Establishment and maintenance of communication channels (SharePoint, Teams) etc for the inspection preparation
- Providing guidance to SME on expectations and content delivery
- Review of requests by inspectors and ensuring timely provision
- Maintenance of SME list
- Inspection observation impact assessment for vigilance partners
- Routine upcoming inspection notification to pharmacovigilance community in Novartis
- Responsible for the coordination and management of audits and audit readiness in the central sites, including response development
- Management of 1QEM for assigned audits
- Audit observation impact assessment for vigilance partners
- Collation of insights across audits to provide lessons learned and support self-assessment target identification
- Support mentoring for effective audit and inspection readiness in the global ESPs supporting pharmacovigilance activities.
- Support global PS&PV self–assessment facilitation and management Deputise for Global Head, I&AR in the review of draft, new or revised pharmacovigilance/ device vigilance regulatory initiatives, requirements and guidelines. When required, conduct an impact assessment for changes in requirements impacting audits and inspections.

Minimum Requirements:

- Life science Degree
- Good knowledge /Fluency in English . Knowledge of other language desirable.
- Experience mainly in a Clinical Safety Department & closely related areas eg Clinical Development.
- Must have knowledge of global regulations for Pharmacovigilance/ Device vigilance
- Global vision of Pharmacovigilance/device vigilance process inter-relationships

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Benefits and Rewards: Read our handbook to learn about all the ways we'll help you thrive personally and professionally: https://www.novartis.com/careers/benefits-rewards

Τομέας
Development
Business Unit
Universal Hierarchy Node
Τοποθεσία
United Kingdom
Τοποθεσία
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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