

Pharmacovigilance & Regulatory Quality Assurance (PVRQA) Lead / PV Auditor

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Company: CSL

Location: United Kingdom

Category: business-and-financial-operations

Responsibilities:

The Pharmacovigilance & Regulatory Quality Assurance (PVRQA) Lead / PV Auditor is responsible for leading and coordinating the Global PVRQA activities in the respective region (Americas, Asia-Pacific (APAC), European Economic Area (EEA), ECI) under the general direction of the PVRQA Regional Head, to ensure that CSL's (CSL Behring / CSL Seqirus / CSL Vifor) entire Pharmacovigilance (PV) System is in compliance with applicable pharmacovigilance regulations and requirements, GVP, ICH GCP guidelines, respective GxP guidelines, international standards, relevant regulatory requirements and company policies.

Under guidance of the PVRQA Regional Head, this position is responsible for the ongoing operational support of existing PV Quality processes and systems across multiple departments like Global Clinical Safety & Pharmacovigilance (GCSP), Global Regulatory Affairs (GRA), Global Medical Affairs (GMA), Affiliates, Commercial Operations as well as other related interface departments in the region. The primary business processes include but are not limited to: Deviation and CAPA Management, Inspection Preparation and Management, Change Management, Continuous Improvement, Compliance, Governance and Reporting, 3rd Party Qualification and Management, Regulatory Intelligence, PV IT Systems and Procedural Quality Assurance. The position is also responsible for driving the planning, maintenance, and implementation of the Global PVRQA risk-based Audit Program in the respective region under the guidance of the PVRQA Regional Head. This position will liaise and interface with local, regional, and global customers within

GCSP, GRA, GMA, Affiliates Commercial Operations, as well as with other respective local / global interface functions to provide support related to PV Quality and processes including provision of PV Quality training for the region to support continuous improvement.

Qualifications:

- Graduate degree in Scientific Discipline/ Life Sciences or related disciplines, or alternatively a bachelor's degree and significant work experience
- Minimum of 5 years of pharmaceutical industry or research/management experience, minimum 4 years' experience in Pharmacovigilance Quality Assurance or other GxP Quality Assurance experience
- Good communication skills including verbal, oral and active listening
- Exceptional critical thinking and analytical skills
- Strong problem-solving capabilities
- Adaptability and resilience in fast-paced environments

We are looking forward to receiving your online application. Applications must include a motivation letter and CV, as well as letters of references and copies of relevant transcripts and/or diplomas in the original language. Please include all these in one document together with the CV.

Our Benefits

We encourage you to make your well-being a priority. It's important and so are you.

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