Insuvia is an outsourcing and consultancy services provider for the pharmaceutical industry. We help pharmaceutical & biotech companies make safe and effective healthcare products available worldwide by providing superior quality pharmacovigilance and regulatory affairs services. Currently, we are looking for a Quality Assurance Specialist to join our team in Lithuania.

QUALITY ASSURANCE SPECIALIST IN LITHUANIA

Main Tasks and Responsibilities

- Promote quality achievement and performance improvement throughout the organization.
- Develop and maintain a Quality Management System (QMS) at Insuvia in compliance with Good Pharmacovigilance Practice (GVP) and Good Clinical Practice (GCP) guidelines, regulatory requirements, ISO 9001 and industry standards.
- Create, review, and maintain QMS documents, such as the Quality Manual, Policies, Standard Operating Procedure (SOPs), Working Instructions, etc.
- Plan and execute internal audits and audits of Insuvia suppliers.
- Manage external audits and regulatory inspections including planning, hosting, report preparation, and release, responses to audit findings, follow up on audit responses.
- Write, review and track Deviation Reports, Corrective & Preventive Actions (CAPA), Change Controls.
- Coordinate in root cause analysis, impact assessment, corrective planning, follow up and trend analysis.
- Oversee the implementation of corrective and preventive actions plans (CAPA), review evidence to ensure that activities in CAPA have been implemented, evaluate CAPA effectiveness.
- Review of training requirements of staff, create and maintain internal training matrices, annual training plans and follow-up on planned training to be completed on time.
- Coordinate, supervise, prepare and deliver required training for staff (staff onboarding, QMS training, SOP training, training on tools used within the company, training on regulatory requirements, etc.).
- Implement and maintain company's electronic Learning Management System.
- Oversee Standard Operating Procedure (SOP) training compliance.
- Maintain and control the quality of staff training files and records (CVs, training plans and records, SOP training records, certificates, etc.).
- Gather customer satisfaction data and implement improvement activities.
- Select suppliers that comply with required standards, including supplier evaluation.
- Maintain QA trackers, folders and documentation, ensuring they are up-to-date and organized to ensure inspection ready.

Insuvia, UAB
Jonavos g. 30,
Kaunas, Lithuania

+370 37 247902
info@insuvia.com
www.insuvia.com

Experience required skills and competencies

- Life science (Pharmacy, Medicine, Public Health, or similar) and/or Quality Management education;
- Fluent command of English (written and oral);
- Strong attention to details with a quality-focused attitude;
- Advanced knowledge of MS Office (Word, PowerPoint, Excel);
- Excellent organizational, time management, and communication skills;
- Self-motivation, ability to assume responsibility and work autonomously in a professional manner.

What we offer:

- Interesting, dynamic and diverse work in a young and rapidly growing company;
- Broad opportunities for self-expression and professional growth;
- Professional training and development;
- Contributing to challenging tasks and achieving ambitious targets;
- Office in the old town of Kaunas, flexible working hours and partial home-office possibility.

Please send your CV and short intro letter to career@insuvia.com

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