United Kingdom Jobs Expertini®

Regulatory Manager / Senior Regulatory Manager

Apply Now

Company: Precision Medicine Group

Location: United Kingdom

Category: other-general

Precision for Medicine (CRO) are recruiting a Regulatory Manager to join our team, candidates can be based in the following countries: UK, Spain, Hungary, Slovakia, Serbia, Romania or Poland.

The Regulatory Manager (RM) provides regulatory strategy and development guidance for optimal conduct of clinical trials, regulatory agency meetings, orphan designations, paediatric planning, and accelerated procedures, ensuring timely preparation of well organized, quality regulatory submissions in compliance with applicable regulations. The RM coordinates and prepares regulatory documents for submission to Regulatory Authorities and/or Ethics Committees, as applicable. The RM maintains a current knowledge of regulations and guidance documents, providing analysis to project teams, as well as supporting and enhancing Precision for Medicines corporate Regulatory function.

Essential functions of the job include but are not limited to:

Provides regulatory guidance throughout the clinical development life cycle

Compile, coordinate and review applications to Regulatory Authorities including, but not limited to, CTA/IND, annual reports, routine amendments, scientific advice/regulatory authority meetings, orphan designations, paediatric planning, and marketing applications. Also provides strategic regulatory input as required

Develops and/or reviews documents intended for submission to the Regulatory Authorities and/or Ethics Committees to assure compliance with regulatory standards

Serve as representative of Global Regulatory Affairs at project team meetings with both external

and internal customers

Works within a project team, and where necessary, leads project for the region or globally

Oversee and coordinate Regulatory Affairs Specialists to achieve submission targets for contracted programs

Maintenance of project plans, project trackers and regulatory intelligence tools as it pertains to assigned responsibilities and to keep Regulatory Leadership updated.

Assist in development of Regulatory Affairs Specialists and other operational area staff, as required

Provide input, as required, into regulatory strategy and timeline development for new study opportunities Assists in establishing company standards to ensure the highest quality of submitted information

Participates in maintaining and executing on the corporate quality initiatives across business units within clinical solutions.

Keeps abreast and continually expand knowledge of laws, regulations and guidelines governing drug development and approval

Provides ICH GCP guidance, advice and training to internal and external clients

Serve as representative of Global Regulatory Affairs at business development meetings

Qualifications:
Minimum Required:
Bachelors degree, or equivalent experience, ideally in a scientific or healthcare discipline

5 years Regulatory experience required for the Manager level and 7 years Regulatory experience required for the Senior Manager Regulatory level

Computer literacy (MS Office/ Office 365)

Fluent in English

Preferred:
Graduate, postgraduate

Possesses basic understanding of financial management

Other Required:
Candidates must have regulatory affairs experience working for a Clinical Research Organisation and have experience leading Clinical Submissions
Informed knowledge of all aspects of the drug development process inclusive of regulatory milestones and specialized knowledge of regulatory activities for at least one major region (EU, US) including but not limited to submissions to Regulatory Authorities, including INDs/CTAs and amendments, Scientific Advice Procedures, and post-approval submissions.
Ability to understand clinical and pre-clinical study results, to help in its interpretation for regulatory positions and strategy

Knowledgeable of clinical trials methodology, including a working knowledge of protocols and indications being studied

Knowledge and expertise with relevant regulations and guidance supporting pharmaceutical development

Availability for domestic and international travel including overnight stays

Competencies
Strong interpersonal skills and a proven ability to contribute to a team environment involving balancing the demands stemming from multifaceted research activities

Demonstrates an acceptable degree of professionalism, as evidenced by punctuality, ability to deliver on commitments, an understanding of the service culture and positive interactions with customers and teammates

Ability to manage multiple and varied tasks in a fast-moving environment, good record-keeping skills

Exhibits high self-motivation, and is able to work and plan independently as well as in a team environment

Motivates other members of the project team to meet timelines and project goals

Flexible attitude with respect to work assignments, and new learning

Resolves project related problems and prioritize workload to meet deadlines with little support from management

Focuses on continuous improvement, including the ability to make proactive assessments on how to make processes more efficient and people more effective

Collects data of consistently high standard

Communicates effectively in the English language both verbally and in written form

Conducts formal presentations to a wide variety of audiences including colleagues, investigative staff, and clients with a high level of proficiency

#LI-NC1 #LI-Remote

Apply Now

Cross References and Citations:

1. **Regulatory Manager / Senior Regulatory Manager Jobs United Kingdom ↗**
2. **Regulatory Manager / Senior Regulatory Manager Jobs United Kingdom ↗**
3. **Regulatory Manager / Senior Regulatory Manager Jobs United Kingdom ↗**
4. **Regulatory Manager / Senior Regulatory Manager Jobs United Kingdom ↗**
5. **Regulatory Manager / Senior Regulatory Manager Jobs United Kingdom ↗**
6. **Regulatory Manager / Senior Regulatory Manager search United Kingdom ↗**
7. **Regulatory Manager / Senior Regulatory Manager job finder United Kingdom ↗**

1. **Regulatory Manager / Senior Regulatory Manager jobs↗**
2. **Regulatory Manager / Senior Regulatory Manager jobs↗**
3. **Regulatory Manager / Senior Regulatory Manager jobs↗**

Source:https://uk.expertini.com/jobs/job/regulatory-manager-senior-regulatory-manager-united-kingdom-precision-medicine-g-6881cee1b3/