Turkey Jobs Expertini®

Regulatory Manager, Clinical Trials Regulatory Management- Home-based, Europe

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Company: IQVIA

Location: İstanbul

Category: other-general

Prepares and/or reviews regulatory documents to support clinical trial submissions. Independently provides regulatory support for complex projects and programs

RESPONSIBILITIES

Acts as a Clinical Trial Regulatory Manager (CTRM) on complex clinical trial projects or programs and may act as a Regulatory Oversight for a key customer

Ability to administratively and technically/scientifically review core scientific documentation and feedback gap analysis to customers.

Ability to write scientific documents e.g. Investigational Medicinal Product Dossier, clinical trial justifications

May strategically plan and perform European centralized submissions and facilitate global country submissions on complex studies or programs

May provide support on key regulatory business development opportunities and complete Data Informed Protocol Assessments (DIPAs)

Understands the Scope of Work, deliverables and budget for any given project and ensure timelines are met.

Ensures accurate completion, maintenance and adherence to internal systems, databases, tracking tools and project plans in line with agreed SOPs (customer and/or IQVIA).

Deliver regulatory training/presentations as required, internally or externally

May mentor junior colleagues and engage in department knowledge sharing

May perform additional tasks as deemed appropriate by Line Manager

REQUIRED KNOWLEDGE, SKILLS AND ABILITIES

Good understanding of the regulations, directives and guidance supporting clinical Research and Development

Demonstrates comprehensive regulatory/technical expertise

Good negotiating skills and the ability to identify and resolve issues, using flexible adaptable approach

Strong ownership and oversight skills

Demonstrated skills in chairing meetings and working on initiatives

Ability to work on several projects, retaining quality and timelines and can prioritize workload

Ability to propose revisions to SOPs or suggest process improvements for consideration

Strong mentoring skills, helping junior colleagues and setting a positive example

Innovative and solutions-driven

Strong skills in establishing and maintaining effective working relationships with co-workers, managers and clients

Strong software and computer skills, including MS Office applications

MINIMUM REQUIRED EDUCATION AND EXPERIENCE

Degree in life science-related discipline or professional equivalent plus at least 5 years relevant experience* or high school diploma plus at least 9+ years' experience* (*or combination of education, training and experience)

PHYSICAL REQUIREMENTS

Extensive use of telephone and face-to-face communication requiring accurate perception of speech

Extensive use of keyboard requiring repetitive motion of fingers

Regular sitting for extended periods of time

Travel might be required

IQVIA is a leading global provider of advanced analytics, technology solutions and clinical research services to the life sciences industry. We believe in pushing the boundaries of human science and data science to make the biggest impact possible – to help our customers create a healthier world. Learn more at

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