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Senior Reg Affairs Specialist - Global Clinical Trial Applications

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Company: Thermo Fisher Scientific

Location: Turkey

Category: other-general

At Thermo Fisher Scientific, you'll discover meaningful work that makes a positive impact on a global scale. Join our colleagues in bringing our Mission to life - enabling our customers to make the world healthier, cleaner and safer. We provide our teams with the resources needed to achieve individual career goals while taking science a step beyond through research, development and delivery of life-changing therapies. With clinical trials conducted in 100+ countries and ongoing development of novel frameworks for clinical research through our PPD clinical research portfolio, our work spans laboratory, digital and decentralized clinical trial services. Your determination to deliver quality and accuracy will improve health outcomes that people and communities depend on – now and in the future.

We are currently seeking a Senior Regulatory Affairs Specialist to join our global Regulatory Affairs department – **Regulatory Science** team. This is a fantastic opportunity to further develop your regulatory career and expertise in a global clinical trial setting.

In this role you will be a pivotal team member with regulatory affairs responsibilities, leading discussions, and coordinating regulatory strategies globally on assigned (Phase 1 to 4) clinical trials, studies and projects.

You will be part of a global team providing innovative solutions and global regulatory expertise, being client interfacing to provide strategic regulatory intelligence and guidance.

You will feel confident providing regulatory advice and carry out projects in the provision of regulatory affairs services whilst acting as liaison with internal and external clients.

You will act as a representative of the regulatory department with other departments,

supporting business development, working on initiatives, and contributing to quality improvement. You will also arrange, lead, and report on client and regulatory agency meetings.

The following skills are required to be successful in this position:

preparation and assembly of global regulatory submissions

interacting with sponsors,

review and assess clinical trial regulatory documents,

review and assess scientific literature.

manages project teams and preparation

participate in launch meetings, review meetings and project team meetings.

Optional skills:

Experience with bid defense meetings

Education and experience:

Bachelor's degree or advanced degree preferred, or equivalent and relevant formal academic / vocational qualification

Previous experience that provides the knowledge, skills, and abilities to perform the job

Knowledge of the global clinical trials landscape

Knowledge, Skills and Abilities:

Excellent command of the English language (written and oral) as well as local language where applicable

Excellent attention to detail and quality as well as excellent editorial/proofreading skills

Exceptional interpersonal skills to work effectively in a team environment and act as a liaison with other departments

Advanced computer skills including the use of Microsoft Word, Excel, Power Point; capable of learning new technologies

Strong organizational, time management, and planning skills to create and follow timelines,

conduct long-range planning, adapt to changing priorities and handle multiple projects

Capable of working independently and exercising independent judgment to assess sponsor regulatory needs and work with project team members to producing compliant deliverables

Excellent understanding of global/regional/national country requirements/regulatory affairs procedures for clinical trial authorization; expert knowledge of ICH and other global regulatory guidelines

Excellent analytical, investigative and problem-solving skills

What we offer:

As well as being rewarded a competitive salary, we have an extensive benefits package based around the health and well-being of our employees. We have a flexible working culture, where PPD Clinical Research Services truly value a work-life balance. We've grown sustainably year on year but continue to offer a collaborative environment, with teams of colleagues eager to share expertise and have fun together. We are
a global organisation but with a local feel.
Our Mission is to enable our customers to make the world healthier, cleaner and safer. Watch as our colleagues explain 5 reasons to work with us. As one team of 100,000+ colleagues, we share a common set of values - Integrity, Intensity, Innovation and Involvement - working together to accelerate research, solve complex scientific challenges, drive technological innovation and support patients in need. #StartYourStory with PPD, part of Thermo Fisher Scientific, where diverse experiences, backgrounds and perspectives are valued.

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