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Country Approval Specialist

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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.

Our global Clinical Operations colleagues within our PPD clinical research services provide end-to-end support for clinical trials from study start up to monitoring through to study close out, across commercial and government contracts. Together, we help clients define and develop clinical programs, minimize delays, and execute high-quality, cost-efficient clinical studies.

Position Overview:

As a , you will participate in the management and preparation, review and coordination of Country Submissions in line with global submission strategy in order to activate investigative sites. You have a strong attention to detail, taking ownership of the accuracy of these documents while holding yourself and others accountable. You

Essential Functions:

Prepares, reviews and coordinates, under guidance, local regulatory submissions (MoH, EC, additional special national local applications if applicable, gene therapy approvals, viral safety dossiers, import license) in alignment with global submission strategy.

Provides, under guidance local regulatory strategy advice (MoH &/or EC) to internal clients.

Provides project specific local SIA services and coordination of these projects.

May have contact with investigators for submission related activities.

Key-contact at country level for either Ethical or Regulatory submission-related activities.

Coordinates, under guidance, with internal functional departments to ensure various site start-up activities are aligned with submissions activities and mutually agreed upon timelines; ensures alignment of submission process for sites and study are aligned to the critical path for site activation.

Achieves PPD’s target cycle times for site.

May work with the start-up CRA(s) to prepare the regulatory compliance review packages, as applicable.

May develop country specific Patient Information Sheet/Informed Consent form documents.

May assist with grant budgets(s) and payment schedules negotiations with sites.

Supports the coordination of feasibility activities, as required, in accordance with agreed timelines.

Enters and maintains trial status information relating to SIA activities onto PPD tracking databases in an accurate and timely manner.

Ensures the local country study files and filing processes are prepared, set up and maintained as per PPD WPDs or applicable client SOPs.

Maintains knowledge of and understand PPD SOPs, Client SOPs/directives, and current regulatory guidelines as applicable to services provided.

Keys to Success:

Education and Experience:

Bachelor's degree or equivalent and relevant formal academic/vocational qualification.

Previous experience that provides the knowledge, skills, and abilities to perform the job (comparable to 2+years).

In some cases an equivalency, consisting of a combination of appropriate education, training and/or directly related experience, will be considered sufficient for an individual to meet the requirements of the role.

Knowledge, Skills, Abilities:

Effective oral and written communication skills.

Excellent interpersonal skills.

Strong attention to detail and quality of documentation.

Good negotiation skills.

Good computer skills and the ability to learn appropriate software.

Good English language and grammar skills.

Basic medical/therapeutic area and medical terminology knowledge.

Ability to work in a team environment or independently, under direction, as required.

Basic organizational and planning skills.

Basic knowledge of all applicable regional/national country regulatory guidelines and EC regulations.

Why Join Us:

We hire the best, develop ourselves and each other, and recognize the power of being one team. We understand that you will want to grow both professionally and personally throughout your career, and therefore you will benefit from an , ensuring you reach your potential.

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 , 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 organization 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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