Job Description
Country Approval Specialist - Brussels

Description
Summarized Purpose:
Participates in the management and preparation, review and coordination of Country Submissions in line with global submission strategy.

Essential Functions:

- Prepares, reviews and coordinates, under guidance, local regulatory submissions (MoH, EC, additional special national local applications if applicable, e.g. 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.

Qualifications
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 0 to 2 years') or equivalent combination of education, training, & experience.

Knowledge, Skills and 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, Dutch and French 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

Please contact **guillaume.istasse@ppdi.com**