Manager, Regulatory Affairs

PAREXEL - Home-Based Any Region

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About this job

Job description

The Manager of Regulatory Affairs is responsible in assisting the team with identification and review of regulatory issues likely to impact Liquent's customer's standards, processes, and solutions, related to management of regulatory information.

MAJOR ACCOUNTABILITIES include the following. Other duties may be assigned.

Key product strategy input activities include the following:

- Providing input into changing regulatory requirements that may impact key life sciences clients and other industry members.

- Provide input into Liquent product requirements for addressing changing requirements orclient business needs.

Key regulatory advisor activities include the following:

- Perform reviews and summarize relevant guidance.

- Communication and possible training of employees on key regulatory initiatives.

- Willingness to present at industry conferences or other designated functions.

Consulting activities include the following:

- Responsible for delivery of consulting engagements in support of meeting the LIQUENT DIRECT specified financial goals.

Desired Skills and Experience

QUALIFICATIONS

To perform this job successfully, an individual must be able to perform each

essential duty satisfactorily. The requirements listed below are representative of the knowledge, skill, and/or ability required. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.

EDUCATION and/or EXPERIENCE

- Minimum BS/BA, preferably in science related field

- Minimum of 5 years in working with Life Sciences organizations in defining requirements for and/or implementation of regulatory solutions

- Understanding of regulatory processes from early development through product retirement

- Experience in filing various types of submissions (IND, CTD, NDA, NDS, MAA, Annual Reports, labeling changes, etc.) producing both paper and electronic output for delivery to regulatory agencies.

- Knowledge and understanding of regional regulations and guidance and ICH guidelines

- Familiarity with CTD and eCTD specifications and lifecycle concepts

- Familiarity with evolving regulations such as CDISC data standards, RPS (eCTD 4.0) and IDMP

- Understanding of electronic labeling requirements including SPL.

TECHNICAL SKILLS

- Experience with document management and publishing solutions in use by Life Sciences clients, such as Documentum, InSight Manager, InSight Publisher, and SCubed

- Knowledge of software development and deployment process

- Understanding of system validation requirements

SOFT SKILLS

- Clear, concise communicator

WORK ENVIRONMENT

The work environment characteristics described here are representative of those an employee encounters while performing the essential functions of this job. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.

- Role may be further defined to a specific region, such as the United States, Europe, Japan, or other identified region.

- Role may be conducted in an office or remote work environment as deemed appropriate by the head of Regulatory Affairs and Writing Services.

- Willingness for domestic and international travel. Travel time estimated to average 50%, but may include times when travel percentage is higher.

About this company

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PAREXEL International Corporation (PAREXEL) is a biopharmaceutical services company, providing a range of capability in clinical research, medical communications services, consulting, and informatics and technology products and services to the worldwide pharmaceutical, biotechnology, and medical device industries. The Company's product and service offerings include clinical trials management, data management, biostatistical analysis, medical communications services, clinical pharmacology, patient recruitment, regulatory and product development consulting, health policy and reimbursement, performance improvement, industry training and publishing, medical imaging services, interactive voice response systems (IVRS), clinical trial management systems (CTMS), Web-based portals, systems integration, patient diary applications, and other drug development services. In August 2008, PAREXEL completed the acquisition of ClinPhone plc.