Compliance Manager, GCP Regulatory Research Compliance

PAREXEL - Greater Boston Area

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Job description

The Sponsor Audit and Inspection Compliance Manager will have a level of knowledge and experience of appropriate GxP compliance and other applicable regulations and laws, PAREXEL procedures and appropriate PAREXEL processes to host and coordinate audits and provide expert advice to internal and external clients. To effectively lead, manage, develop, and implement assigned projects. To provide leadership and management support and guidance to the team. To exhibit a high degree of flexibility and initiative, demonstrate the ability to follow up on multiple tasks and projects, and possess the ability to handle confidential information diplomatically. To be able to effectively communicate quality issues to the senior management team of PAREXEL.

Key Accountabilities
• Work independently and as part of the RRC management team
• Work with Global team members to coordinate Sponsor audits and Inspections; including: preparation meetings, audit agendas, etc.
• Collaborate with Sponsors (as assigned) to coordinate audits.
• Monitor entry of audit and inspection information into QAAD, i.e. collection, QC and coordination of documents to be entered, feedback/questions to RRC/operational staff, as well as tracking of audits, reports, and responses.
• Arrange with other departments to gather necessary information on Sponsor confidentiality agreement documentation.
• Communication and consultancy with clients, PAREXEL management, and staff.
• Train new and existing RRC personnel.
• Train and educate operational staff by the development and presentation of training courses.
• Be a leader in the promotion of compliance within the company and represent RRC management, as required.
• Build, develop, and maintain good working relationships with internal and external customer groups.
• Monitor the work of the Sponsor Audit and Inspection Lead team to ensure consistency and quality within the group.
• As required, communicate with members of Regulatory Authorities and / or sponsors.

• Maintain knowledge of project / audit status in assigned areas and provide Senior Management with current informational reports upon request.
• Maintain current records / documents related to assigned areas.
• Maintain SAIG-related Outlook Calendars and other RRC internal databases as applicable.
• Contribute, monitor and review the information provided to RRC management to summarize quality issues arising from sponsor audits and other related activities, as requested.
• Ability to review and, if necessary, identify improvements that enhance the quality and clarity of processing sponsor audit reports.

Desired Skills and Experience

Skills

• Ability to develop relationships with a culturally diverse group of key stakeholders within PAREXEL and the client's business
• Excellent interpersonal, verbal, and written communication skills, including experience in making presentations at conferences, meetings, and training sessions
• Experience with Microsoft based applications and ability to learn internal computer systems
• Willingness to work effectively with multiple supervisors in a matrix environment and to value the importance of teamwork
• Ability to work flexibly and adjust to changing priorities and unforeseen events
• Diplomatically address sensitive issues confidentially and professionally
• Excellent knowledge of, and working experience with, relevant national / international regulations
• Lead team / project to successful conclusion
• Analyze complex situations / issues and effectively communicate situations / issues, along with potential recommendations, to various functional groups
• Work professionally with highly confidential information
• Work independently, pro-actively and consistently in a fast-paced environment
• Ability to train and coach team members
• Willingness to travel 10-30% of the time, as needed

Education
• Educated to degree level (technology, biological science, pharmacy or other health related discipline preferred) or equivalent qualification or clinical research experience.
• Master's degree in a science, technology or industry related discipline, preferred.

Minimum Work Experience
• Extensive experience in quality assurance, regulatory affairs, auditing, clinical research, monitoring, data management, pharmacy, laboratory, or other relevant area, including applicable management

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.