1. Overview of the organization

The Puerto Rico Consortium for Clinical Investigation (PRCCI) was formed as part of a strategy that aims to develop Puerto Rico as a clinical research hub. PRCCI is a non-for-profit organization, which is supported by the Puerto Rico Science, Technology & Research Trust (PRSTRT), a private non-for-profit organization. PRSTRT was created in 2004 to encourage and promote: innovation, transfer and commercialization of technology & research, and foster the creation of jobs in the technology sector.

The goal of PRCCI is to promote and enhance clinical research and development for the benefit of patients, the Puerto Rican economy and global scientific innovation. PRCCI aims to improve the impact, quality and speed of clinical research in Puerto Rico. PRCCI provides a single point of contact connecting sponsors with an experienced, cooperative network of high quality Clinical Trial Units (CTUs), providing access to a variety of patient populations, and improving speed of clinical trials through faster patient recruitment and start-up processes.

2.0 Job Description

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| **Job Title:** | Quality and Performance Assurance Manager |
| **Reports to:** | Executive Director |
| **Location:** | San Juan, Puerto Rico |
| **Purpose:** | To monitor and enhance the quality and performance of the Clinical Trial Units (CTUs) within the consortium. PRCCI will perform quality and performance monitoring and audits and share global leading practice within our network of CTUs. This includes on-boarding and overseeing the selection process for new CTUs into the consortium. The ideal candidate will need to have a good understanding of the process and Key Performance Indicators (KPI)s to monitor CTU quality and performance beyond GCP compliance and be able to work with each of our consortium’s CTUs as well as with third party partners.  |
| **Key Responsibilities and Duties** | Manage Quality Assurance of the Consortium* Work with CTUs to manage the overall quality assurance schedule across the consortium and track status
* Perform risk-based monitoring to change the overall quality assurance schedule, as required
* Manage alliance partnerships’ delivery of GCP compliance audits in all areas of clinical operations and undertake the compliance audits directly, where needed
* Plan, undertake and document study audits to verify the integrity of the data and determine whether studies are undertaken in compliance with GCP, legislation, industry guidelines and procedures
* Undertake system audits and document specific audits to determine whether procedures and systems are adequate, relevant to current operational practices and compliant with SOPs
* Interpret audit reports from external quality assurance providers, regulators and sponsors

Manage CTU Selection and Upskilling* Review and enhance the process and tools for CTU selection and on-boarding to the consortium
* Assess the risk of non-compliance by performing analytics on Key Performance Indicators (KPI) from CTUs while liaising with the Clinical Operations Manager to build a performance improvement plan, when needed
* If CTUs require process and / or regulatory training, manage training delivery to CTUs as required

Manage PRCCI’s quality management* Develop and maintain quality management processes and tools
* Maintain PRCCI’s process descriptions, flow and associated SOPs in line with relevant regulations

Provide regulatory updates/advice and support audit readiness* Provide advice on site readiness for any upcoming regulatory audits
* Provide a consultation, advisory role for any GCP issue that arises and support PRCCI and the CTU to develop remediation plans
* Provide regular updates to internal stakeholders on quality activities and advise on approaches to meeting future GCP/Regulatory requirements
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| **Qualifications & Technical Job Requirements** | * Relevant Bachelor’s or Master’s degree, preferably in a scientific or health care discipline
* Proficient in GCP / ICH guidelines and regulations
* Experience with FDA reporting requirements (physician payments; pharmacovigilance etc.)
* Knowledgeable of external and internal auditing processes and reports for clinical trials
* Understanding of quality management systems and audit remediation activities
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| **Experience** | * 3 - 5 years’ experience in clinical trial monitoring, including systems and documents
* 3 – 5 years’ experience in writing and communicating audit findings to various stakeholders
* 3-5 years’ managing CTU compliance and remediation activities
* Demonstrated ability to proactively identify issues and risks, and put in place mitigation and improvement measures where needed
* Demonstrated ability to comprehend, analyze and interpret process and systems information, technical procedures, reports and regulations to make decisions in GCP environment
* Significant experience in developing strong relationships with senior stakeholders
* Strong project management skills, including milestone delivery and resource allocation
* Fluent in oral and written English and Spanish
* Excellent oral and written communication skills
* Excellent presentation and negotiation skills
* Excellent interpersonal and coaching skills
* Strong attention to detail
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3.0 Applying for this position

All interested candidates should submit a cover letter and resume with references included to ***PRCCI@prsciencetrust.org***.