

JOB DESCRIPTION

Job Title	Quality Control
Department	Quality Assurance
Specific Tasks	<ul style="list-style-type: none"> • Overall day-to-day management of the Quality Assurance activities • Scheduling of all audits • Database audits • Vendor audits for vendors contracted for associated studies • Statistical audits and Clinical Study Report audits • Computer System Validation audits for computer systems and programs used at Acclaim Pharma Research and Mediprobe Research (e.g., data management system; programs for data management edit checks, etc.; statistical programs) • Work with the operational heads to develop strategies, processes, and quality systems for these groups, for improving efficiencies, consistency, and compliance • QA review of protocols, Informed Consent Forms, Case Report Forms, Data Management Plans, Statistical Analysis Plans, Shell Reports, etc. • QA oversight of Computer System Validation activities for Acclaim Pharma Research and Mediprobe Research to ensure compliance with 21 CFR Part 11 and other applicable regulations • With the operational heads determine SOP requirements and provide QA review of SOPs for these groups • Assist with organization and coordination of sponsor and regulatory audits. • Provide guidance for the company with respect to ICH and the following regulatory bodies: HPFB, FDA, EMEA, MHRA, TGA, and ANVISA • Participate in training sessions • Execute other duties as may be required by the President.
Reports to	Director of Clinical Development and Operations
Communications	To interact with physicians when necessary, Clinical Managers, and Supervisors.
Requirements	<ul style="list-style-type: none"> • Bachelor of Science (B.Sc.) degree, Post-Secondary Diploma in scientific, healthcare or pharmaceutical field, or equivalent • 4 - 6 years experience in clinical quality assurance • Current with existing and emerging regulatory requirements pertaining to clinical research and a solid understanding of the philosophies behind these regulations • Decisive, good decision making skills, able to escalate response to situations when relevant • Well developed analytical and problem solving skills • Strong organizing and planning skills to work independently with efficiency and accuracy • Excellent verbal and written communication skills • Strong interpersonal and customer service skills • Familiar with MS Office Suite (Word, Excel, Access, Project)

This job description should not be constructed to imply that these requirements are the only duties, responsibilities and qualifications for this position. Employee may be required to follow any additional related instructions, acquire job skills and perform other related work if deemed necessary.