Job Title: Freelance Clinical Trial Coordinator - IVD Medical Devices

Job Summary: We are seeking a highly motivated and experienced freelance Clinical Trial Coordinator to join our team of experts in the field of clinical studies for in vitro diagnostic (IVD) medical devices. The Clinical Trial Coordinator will be responsible for coordinating and managing clinical studies to ensure compliance with applicable regulations and guidelines, as well as company policies and procedures.

Key Responsibilities:

- Manage all aspects of clinical studies for IVD medical devices, including planning, initiation, execution, monitoring, and closeout.
- Ensure compliance with applicable regulatory requirements, such as FDA, ISO, and other relevant guidelines.
- Develop and maintain study documentation, including protocols, informed consent forms, case report forms, and study reports.
- Identify and evaluate potential study sites, and liaise with investigators and site staff to ensure adherence to study protocols and timelines.
- Manage study budgets and contracts, and ensure timely payment to sites and vendors.
- Perform ongoing review of study data to ensure accuracy and completeness, and identify and resolve data queries.
- Manage adverse events and safety reporting, and ensure timely reporting to regulatory authorities and ethics committees.
- Coordinate with cross-functional teams, including quality assurance, regulatory affairs, and product development, to ensure timely completion of study milestones and deliverables.
- Participate in study team meetings and provide regular updates on study progress and issues.

Requirements:

- Bachelor's degree in a relevant field, such as life sciences, nursing, or clinical research. Master's degree preferred.
- Minimum of 3 years of experience in clinical trial coordination, preferably in the field of IVD medical devices.
- Strong knowledge of applicable regulations and guidelines, such as FDA, ISO, and ICH.
- Excellent organizational, communication, and interpersonal skills.
- Ability to work independently and as part of a team in a fast-paced, deadline-driven environment.
- Strong attention to detail and ability to multitask effectively.
- Proficiency in Microsoft Office and other relevant software applications.

If you are a freelance Clinical Trial Coordinator with a passion for clinical studies for IVD medical devices and want to make a meaningful impact on patients' lives, we encourage you

to apply for this exciting opportunity. Please submit your resume and a cover letter outlining your relevant experience and qualifications to gonzalo.ladreda@pockitdx.co.uk.