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Clinical Research Associate

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Overview:As a Clinical Research Associate (CRA), you will play a pivotal role in the development and execution of clinical trials Working closely with research teams, regulatory bodies, and clinical sites, you will ensure compliance with protocols, regulatory requirements, and industry standards throughout the trial process.Responsibilities:1.Trial Preparation: Assist in the development of study protocols, informed consent forms, and other essential trial documents. Coordinate with investigative sites to ensure proper training and understanding of trial procedures. Participate in the selection and qualification of clinical sites and investigators.2. Trial Execution: Conduct site initiation, monitoring, and close-out visits to ensure adherence to protocol, regulatory requirements, and GCP guidelines. Perform source data verification and data review to ensure accuracy and completeness of clinical trial data. Act as a liaison between clinical sites, sponsors, and regulatory authorities, addressing any queries or issues that arise during the trial. Monitor subject safety and report adverse events in accordance with regulatory requirements.3. Documentation and Compliance: Maintain accurate and up-to-date trial documentation, including regulatory files, trial master files, and study documentation. Ensure compliance with India FDA, drugs & Cosmetics Act and other relevant regulatory guidelines and standards. 4. Communication and Collaboration: Communicate effectively with internal stakeholders, including project teams, clinical operations, and regulatory affairs. Foster collaborative relationships with external stakeholders, including clinical investigators, study coordinators, and contract research organizations (CROs).5. Regulatory: Preparing scientific documents, dossiers, Assist in the preparation of regulatory submissions and responses to regulatory inquiries. Government regulatory

submissions as per Clinical Trial guidelines 5. Quality Assurance: Participate in internal and external quality assurance audits and inspections, Identify and mitigate risks to trial integrity and data quality.6. Site Monitoring: Conduct regular site visits to ensure compliance with study protocols, Good Clinical Practice (GCP) guidelines, and applicable regulatory requirements.7. Qualifications: Bachelor's degree in a scientific or healthcare-related field - Certification as a Clinical Research Associate (CCRA) or equivalent.- Experience with cell therapy clinical trials, including knowledge of cell processing techniques and regulatory requirements specific to cell-based therapies.- Familiarity with advanced therapy medicinal products (ATMPs) and cell therapies, autoimmune, oncology and Clinical Trial.8. Skills:- Strong organizational skills and attention to detail.- Excellent written and verbal communication skills.- Ability to work independently and collaboratively in a fast-paced environment.- Proficiency in MS Office and clinical trial management systems.

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