Our client is a NASDAQ listed biotechnology company with the global Headquarter in Germany. The companies focus is the research and development of new medicines for the treatment of inflammatory diseases within a global development approach. Our client stands out for an excellent team of highly motivated and skilled individuals who put strong emphasis on a team effort

To support their expanding Quality Assurance Team we are looking for a:

Director Quality Assurance GCP (m/f/d)

Standort: München
Kennziffer: 26657

Your tasks

- Work collaboratively with internal Clinical R&D/Clinical Operations Team to ensure compliance standards are achieved
- Providing help, advice and guidance to operational departments on matters of quality/GCP
- Identify and assess compliance risk areas and develop and implement risk mitigation measures
- Develop and manage GCP audit program to include routine and non-routine quality assurance audits of clinical investigator sites, vendors, processes, systems and study documents to ensure integrity and accuracy of study data and assure quality compliance with internal procedures as well as regulatory guidelines
- Develop and implement detailed audit plans and annual GCP audit schedules
- Direct/perform GCP audits of clinical investigator sites, vendors, processes, systems and study documents
- Prepare written audit reports and communicate findings and recommendations and evaluate the adequacy and completeness of corrective and preventive action plans
- Ensure the timely and effective follow up of all identified or assigned quality issues
- Conduct QA review of study protocols, ICFs, CSRs and other clinical trial specific documents as requested
- Review and approve Clinical Quality Documents (SOPs, WIs, etc.)
- Develop and implement Clinical QA Quality Documents (SOPs, WIs, Forms etc.)
- Ensure continuous qualification/training of staff regarding GCP direct/deliver (annual) GCP training for staff
- Further develop the existing quality system in line with the expansion of the clinical R&D activities
- Align with Quality Assurance GMP on quality systems;
- Organize and host authority inspections
- Support process improvement initiatives; Lead continuous process improvements within Quality
- Maintain required knowledge of applicable regulations, guidelines and company standards and procedures
- Budget and resource planning.

Your qualifications

- Academic degree in a scientific, medical or related field
- Minimum of 8+ years' current work experience in biotech/pharmaceutical industry Quality Assurance
- Demonstrated Quality Management System experience (GCP specific QMS experience preferred)
- Profound knowledge of current GCP regulations and best practices, as well as experience in FDA and EMA inspections;
- Experience with global late-stage clinical trials leading to market authorization
- Good combination of strategic and operational skills; ability to make flexible, but thorough
- decisions in a highly dynamic environment
- Demonstrated Issue Management and CAPA experience in a clinical environment
- Experience with FDA or other Regulatory Inspections of Investigator sites, Sponsors or CROs
- Strong leadership with demonstrated ability to interface with different levels of organization
- Excellent written/oral communication skills in English and German and interpersonal skills to build
- key networks and business relationships across all levels of the business
- Attention to detail with an ability to detect and correct errors/inconsistencies in various types of documents
- Self-starter and team-player
- Knowledge in Microsoft Office applications, Adobe
- Experienced in working with EDC, IRT, eTMF, EMR systems
- Willingness to travel (national and international).

Seit 2003 vermittelt Optares Medical erfolgreich Fach- und Führungskräfte an Unternehmen der pharmazeutischen, biotechnologischen und medizintechnischen Industrie. Dabei profitieren Sie als Kandidat (m/w/d) durch unsere langjährige Branchenexpertise und unser weit reichendes Netzwerk zu den jeweiligen Entscheidungsträgern. Wir ermöglichen Ihnen somit den Zugang zu passgenauen Positionen inklusive echten Herausforderungen und entsprechenden Weiterentwicklungsmöglichkeiten.

Die professionelle, diskrete und transparente Betreuung unserer Kandidaten (m/w/d) während des gesamten Bewerbungsprozesses steht dabei für uns im Mittelpunkt.

Ihre Ansprechpartnerin
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