

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:

Quality Assurance Manager GCP (m/f/d)

Standort: München
Kennziffer: 26658

Your tasks

- Plan, prepare and conduct (external) audits (investigator sites, vendors, processes, systems, documents etc.)
- Plan, prepare and conduct internal (GCP) audits
- Write 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
- Provide help, advice and guidance to operational departments on matters of quality/GCP
- Coordinate, conduct and track GCP training of new and existing staff;
- Create, maintain and revise departmental Quality Documents (SOPs, WIs, Forms etc.)
- Management of Quality Documents according to the respective written procedures
- Provide support/participate in authority inspections
- Maintain required knowledge of applicable regulations, guidelines and company standards and procedures
- Support the Director Quality Assurance GCP

Your qualifications

- Academic degree in a scientific, medical or related field
- Minimum of 3+ 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
- Demonstrated Issue Management and CAPA experience in a clinical environment
- Experience with FDA or other Regulatory Inspections of Investigator sites, Sponsors or CROs
- Excellent written/oral communication skills in English and German and interpersonal skills
- 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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Folgen Sie uns auf

