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 an

Interim Qualified Person & Director QA GMP (gn)

Biologics

Standort: München, Jena, homeoffice
Kennziffer: 26747

Your tasks

- Ensure that the (investigational) medicinal products have been manufactured and checked in accordance with applicable laws and in accordance with EU-Good Manufacturing Practice (GMP) principles and guidelines
- Evaluation, confirmation and certification of batches on the basis of GMP compliant manufacture and testing according to the EU GMP guidelines, Annex 16
- Act/perform the tasks of a Qualified Person (QP) in accordance with Annex 16 of the EU GMP Guidelines and the Code of Practice for Qualified Persons for products manufactured or packaged by contracted manufacturing organizations
- Review of batch records and disposition of batches as a QP under EU Directive 2001/83/EC and comply with all the applicable GMPs, national legislation and requirements of the relevant Quality Agreement
- Monitoring the compliance with pharmaceutical regulations
- Evaluation of deviations and changes
- Review and approval of Quality Assurance Agreements
- Support, develop and maintain the Quality Management System (QMS), and drive continuous improvement within the QMS
- Perform internal audit/self-inspections
- Perform vendor selection, maintenance & for cause audits (contract manufacturers, testing facilities, raw material suppliers, etc.)
- Primary resource for pharmaceutical product release, ensures batches meet manufacturing authorization requirements and fulfil requirements in Quality and/or Technical agreements as applicable
- Assist in the drafting and approval of master batch manufacturing records
- Review and approve SOPs, validation protocols, change requests, annual Product Quality Reviews and Planned Process Variations in accordance with company procedures and guidelines
- Provide support in the preparation and hosting of regulatory inspections

Your Requirements

- Degree in pharmacy with license to practice as a pharmacist or equivalent
- Qualification/legibility to perform the duties as QP in accordance with §15 AMG
- Three or more years' experience performing the duties of a QP with expertise (practical experience) in the release of multiple licensed and unlicensed dosage forms (biologics and sterile product manufacture and supply)
- Thorough understanding of US, EU and local regulatory requirements governing the duties/role of a QP, sterile (biological) product manufacture, testing and release
- Previous experience in implementation of quality management systems and processes supporting the development of large molecule biologics
- Thorough understanding of national and international laws, regulations and guidelines regarding GMP
- Good understanding of the EU Clinical Trial Directive
- Several years of professional experience in a GMP-regulated environment
- Lead Auditor with expertise in IT systems audits, excipient/raw material suppliers, Contract Manufacturing Organizations, Contract Distribution and Manufacturing Organizations and wholesale dealers/equivalent organizations
- Fluent in written and verbal English and German
- Excellent organization and communication skills
- Assertive and team-oriented personality
- Highly motivated, self-driven and dependable
- Champions a top down quality culture within the business

Further information

- Start: asap
- Capacity: minimum 60% (full-time desireable)
- Region: flexible (onsite & homeoffice)
- Daily Rate: Upon request / negotiable

Optares Corporate Functions vermittelt fokussiert kaufmännische Fach- und Führungskräfte im Rahmen der Direktvermittlung an Unternehmen unterschiedlichster Branchen. Dabei profitieren Sie als Kandidat (m/w/d) durch unsere langjährige Expertise und unser weitreichendes 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.

Ihr Ansprechpartner
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Folgen Sie uns auf