

Clinical Quality Assurance Manager

Do you want to be part of building a fully integrated biopharmaceutical company together with a team of highly skilled colleagues who are passionate about developing best-in-class therapeutics that address significant unmet medical needs? Then Ascendis Pharma is committed to support your personal development on our journey towards becoming a leading rare disease company.

Ascendis Pharma is looking to hire an experienced Clinical Quality Assurance Manager to join our team. This is an exciting opportunity to join a rapidly growing, innovative company!

Position Summary

The Clinical Quality Assurance Manager is a working member of the Clinical Quality and Corporate Quality team focused on the delivery of clinical quality services to the company.

- Designs and modifies policies, systems and procedures associated with clinical quality
- Assists in external audits
- Executes internal audits
- Provides expertise and guidance to various departments to assure clinical trials are conducted in accordance with Good Clinical Practices (GCP)
- Works with Contract Research Organization staff in the proper execution of GCP
- Works with internal stakeholders in complying with and developing new SOPs
- Demonstrates the highest level of detail within clinical quality compliance

Key Responsibilities

Position specific requirements

- Experience in conducting clinical trials under GCP
- Familiarity with internal audits of clinical quality systems
- Experience in working with CAPA closure and audit finding remediation
- Experience in maintaining databases

Other valuable capabilities

- Familiarity with electronics solutions supporting clinical trials
- Extensive knowledge of MS Word, Excel, Access, Visio and PowerPoint
- Demonstrated ability to work well with others within and across functions/teams

Knowledge, Skills and Experience

- Minimum 5 years' experience in Biopharma industry with five years' experience in clinical quality assurance or clinical operations as a clinical trial assistant or clinical research associate
- Bachelor's degree required, science related field preferred



Want to apply? Please send your resume to US_jobs@ascendispharma.com. Please write “Clinical Quality Assurance Manager” in the subject field.