



Quality Assurance Senior Director

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 Quality Assurance Senior Director to join our team. This is an exciting opportunity to join a rapidly growing, innovative company!

Position Summary

The Quality Assurance US Sr. Dir. is part of the Global Quality Leadership Team and is accountable for Quality Assurance at the California facilities and for US commercial operations

Main tasks:

- Ensure Regulatory Compliance at US sites
- QA for Pharmacovigilance
- Quality operations support for new therapeutic development areas (Oncology, Localized application)
- QA for US market feedback- and local complaint management
- Drive US inspection readiness activities at Ascendis sites
- Host Health Authority Inspections
- Quality business partner to key stakeholders (RA, Clinical, Pharmacovigilance, Commercial)
- Provide input to the Global Quality Management Review
- GMP, GDP, GPVP Training

Key Responsibilities

Position specific requirements

- Experience in GxP, Quality Systems and Regulatory Compliance, Health Authority Inspections, Pharmacovigilance, Complaints, etc.
- Experience in Product Development and with Commercial products
- Demonstrated Leadership within and across functions/teams

Knowledge, Skills and Experience

- Minimum 15 years' experience in Biopharma industry with min. of 10 years' experience in Quality Management and Quality Assurance
- Minimum of 8 years leadership experience
- Leading roles at Authority Inspections, Quality Systems and reporting, and Regulatory Compliance
- Master's degree required, science related field preferred

Want to apply? Please send your resume to US_jobs@ascendispharma.com. Please write "Quality Assurance Senior Director" in the subject field.