Quality Assurance Manager

Are you ready to take the lead on Quality Assurance in a company where things are moving fast and the team is growing?
At Scantox Ballerup, we are looking for a dedicated Quality Assurance Manager who can ensure that our processes, systems, and Investigational Medicinal Products meet the highest quality standards—today and in the future.
You will play a key role in securing compliance with GMP and regulatory requirements, and you'll be part of a company on an ambitious growth journey where your experience will make a real difference.

Your role:

- As our new QA Manager, you will have overall responsibility for Quality Assurance operations at site level, while also taking on the Qualified Person (QP) responsibilities.
- You will lead QA tasks hands-on and contribute strategically to the development of our Quality Management System (QMS), ensuring it stays robust and inspection ready.
- We are growing, and the QA team is expected to expand. This gives you the opportunity to help shape the function and be part of building a strong team culture.

Your key responsibilities:

- Oversee and maintain the Quality System, including SOPs, Site Master File, deviations, change controls, CAPAs, and documentation.
- Prepare Quality Agreements and QP-QP responsibility documents
- Approve all key Quality documents (SOPs, MBRs, deviations, CAPAs, changes, qualifications, stability protocols, CoAs, etc.).
- Ensure status allocation to raw materials, bulk and finished product
- Ensure QP certification and release of all batches, ensuring compliance with GMP guidelines and specifications.
- Manage audits, self-inspections, and regulatory interactions.
- Lead QA review and oversight of Investigational Medicinal Products (IMPs) and all associated documentation.
- Oversee archiving of GMP documentation
- Drive in-house GxP training and contribute to yearly Quality Management Reviews.
- Ensure good documentation practice and the overall efficiency of the Pharmaceutical Quality System.

What we are looking for:

- Solid experience from the pharmaceutical industry, working within Quality Assurance and GMP.
- Several years' experience with regulatory guidelines, QA processes, and management responsibilities.
- Education and competencies to be approved as a Qualified Person (QP) by the Danish Medicines Agency according to applicable regulations.
- A proactive, structured, flexible and hands-on mindset.
- You enjoy working closely with both internal teams and external stakeholders.

Why join Scantox Ballerup?
At Scantox Ballerup, we specialize in formulation development and manufacturing of pharmaceuticals for both preclinical and clinical trials. As part of the growing Scantox Group, we're scaling up—and this is your chance to shape both your role and the future QA team. You'll join a site where collaboration, flexibility, and professional pride are part of our DNA. If you're eager to make a real impact, we'd love to hear from you.

About Scantox Group:
Scantox is the leading Nordic contract research organization (CRO) within preclinical research. We support the pharmaceutical, medtech, and biotech industries by conducting studies that contribute directly to the development of new medicines.

Headquartered in Ejby near Køge, we employ around 170 talented professionals with diverse backgrounds. Scantox also has subsidiaries in Denmark, Sweden, Austria, and the UK.
Founded in 1977, we are on an ambitious growth journey—nationally and internationally—together with our investor, Impilo

How to apply:
Would you like to continue your career in an exciting, growing company characterized by an informal tone and a dynamic workday? Then please send us your application and CV as soon as possible.
Application deadline: June 13th, 2025

Please note that we might invite relevant candidates for interviews before the application deadline. If you have any questions about who we are—or if you'd like more details about the role—you're more than welcome to reach out to our Site Manager, Helle Kirstein Erichsen, at hke@scantox.com.
We look forward to hearing from you!