SEQENS

Long term contract – Quality Director M/F
Newburyport (USA)

SEQENS is an integrated global leader in pharmaceutical synthesis and specialty ingredients, delivering outstanding performance, unrivalled market responsiveness and tailor-made solutions to our customers. Our mission is to bring R&D and industrial performance to our clients' projects with our unique skill set and a broad range of technologies.

SEQENS operates 24 manufacturing plants and 3 R&D centers in Europe, North America and Asia with 3,200 employees. More than 300 scientists, engineers and experts develop tailor-made solutions for our customers and ensure that products are successfully transferred into production.

As a member of the senior management team reporting to the COO, you will manage and nurture the company's quality assurance, compliance and regulatory personnel to support the company's overall success and growth.

Main tasks:

- Direct staff of 8 professionals including 2 managers of Quality Assurance and Regulatory Affairs
- Proactively oversee Quality Assurance function in full compliance with current Good Manufacturing Practices
- Demonstrated working knowledge of 21 CFR 211 and ICH Q7
- Coordinate all regulatory submission activities for FDA site registration, drug product listings, and Drug Master Files
- Serve as primary company liaison with quality regulatory bodies (e.g. FDA)
- Represent Quality Program priorities and performance to company management
- Responsible for:

- Process deviations, investigations, corrective or preventive actions,
- Final Product release, including final data and batch record review,
- Document control system, including Part 11 compliant quality management software as available,
- Change control procedures, including documentation, equipment and process changes,
- Supplier Qualification, Customer Complaint system, Quality training program,
- Oversight of the internal audit program to ensure continued compliance to the Quality Program and cGMPs.

Required skills:

- Bachelor's degree, science based or technical equivalent (advanced degree preferred)
- 10 years minimum in a cGMP quality, regulatory, and drug substance / drug product manufacturing environment, and thorough knowledge of GMP principles is required
- Excellent written and spoken communication ability, detail oriented and willing to follow through on all aspects of a task required for successful completion

Please send your resume via email:
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