



VP, Regulatory Affairs and Quality Assurance

Duties and Responsibilities:

- Manage the RA/QA department, including staffing, development and training of personnel.
- Provide regulatory and quality leadership for product development, operations, and commercial activities.
- Develop and implement regulatory strategies for worldwide approvals of new products.
- Lead multi-disciplinary group to complete successful domestic and international regulatory submissions.
- Ensure compliance with regulations in all applicable markets (including US, EU, Canada, Brazil, China, Taiwan, Hong Kong and Japan).
- Review labeling and promotional activities in accordance with approved indications and claims.
- Provide regulatory oversight of company-sponsored clinical studies.
- Establish, maintain, manage and continuously improve the Quality Management System in compliance with FDA and international regulations and standards including FDA QSR, ISO 13485:2016, and MDSAP.
- Liaison with US FDA, international regulatory agencies, notified bodies and in-country representatives:
 - Regulatory inspections and compliance issues
 - Quality system certifications
 - Regulatory strategies, product submissions, licenses and registrations (including 510(k), de novo classification, CE mark)
 - Clinical investigations
- Management Representative to the Quality Management System.
- Person Responsible for Regulatory Compliance per EU Medical Devices Regulations 2017/745

Education & Certifications:

- B.S. Engineering, Science or other technical field. Regulatory Affairs Certification (RAC) preferred

Work Experience:

- Minimum 15 years' experience in medical device regulatory affairs and quality assurance.
- Large and small company experience with need to have diverse skill set.

Knowledge, Skills & Abilities:

- In depth knowledge of US and international medical device regulations and quality management systems
- Leadership, management and communication skills (oral and written)
- Collaborative and cooperative team player

About TriSalus™ Life Sciences

TriSalus Life Sciences is committed to transforming outcomes for patients with pancreatic cancer and other solid tumors. Our solution is bold: to integrate novel and proprietary therapeutics with the TriSalus Pressure-Enabled Drug Delivery™ (PEDD™) technology. It's a comprehensive approach intended to improve treatment response and ultimately outcomes. For more information visit www.trisaluslifesci.com.

To Apply:

Qualified candidates may apply by sending their resume and cover letter to HR@trisaluslifesci.com.