NOW HIRING
Director of Quality Assurance and Regulatory Affairs

About us:
Delasco started in 1980 by a dermatologist for dermatologists and has been creating solutions for over 40 years. With customers from over 81 countries around the world, Delasco is a trusted expert to healthcare providers. We manufacture and distribute specialty dermatology products, instruments, and equipment. Our in-house chemicals are used for continuing education and preferred by industry-leading dermatologists and plastic surgeons.

Our Values:
Curiosity • Determination • Discipline • Teamwork

Position Overview:
The Director of Quality Assurance and Regulatory Affairs is responsible for managing and maintaining the Company's regulatory compliance and quality assurance programs. Oversees regulatory inspections and ensures the timely filing of documents, records, and reports with the various regulatory agencies. Serves as the Designated Representative, responsible for ensuring compliance with state and federal laws and regulations regarding wholesale distribution. Stays abreast of regulatory updates and changes, trains staff and aligns the Company's operating procedures, compliance standards and quality assurance program, accordingly.

This Role Will Be Responsible For…

- Develops, implements, manages, and integrates an effective QMS that aligns with management's corporate vision, Company goals and objectives and state and federal regulatory requirements. Establishes and implements metrics (process capability, control charts, measurement quality) for monitoring system effectiveness and to assist management in making sound product quality decisions.
- Serves as the internal and external resource on compliance related issues and concerns, regulatory requirements and quality control program. Answers employee/management questions, interprets regulatory requirements, serves as primary contact during regulatory inspections, assists in problem identification, resolution, loss reporting and continuous improvement plans. Investigates non-conformances, deviations and customer complaints and identifies effective corrective actions and process improvements.

- Maintains Unique Devise Identification (UDI) listings in FDA's Global UDI database, files FDA, DEA and state registrations, reviews and updates medical device listing and Master Production Records and Product Examination reports, reviews, maintains and updates Standard Operating Procedures (SOP's) and files appropriate documents, maintains Safety Data Sheets for all products, and submits trademark renewal and copyright applications for Company catalog, as required.
- Designs, implements, and documents procedures for process control, process improvement, testing and inspection.
- Participates in product and label reviews on all manufactured products and supports engineering and design efforts by participating in product development projects to determine if design changes warrant regulatory submission with the FDA.

The Idea of a Perfect Candidate Is Someone With…

- Knowledge of scientific principles and practices.
- Strong computer skills.
- Strong negotiation skills.
- Strong written communication skills.
- Ability to effectively and fluently read, write and speak the English language.
- Ability to work independently.
- Ability to listen attentively and use skillful questioning to clarify a situation.
- Ability to handle multiple projects/tasks and meet deadlines.
- Ability to organize and prioritize work responsibilities.
- Ability to effectively function under pressure and maintain control.
- Ability to read, analyze, understand, and accurately interpret both the oral and written word.
- Ability to express oneself in a clear, concise, and professional manner in interactions with others and in written communications.
- Ability to analyze situations using logical, systematic, and sequential approach in order to make difficult decisions and effectively solve problems in a timely manner.
- Ability to anticipate the implication and consequences of situations and take appropriate action.
- Ability to effectively speak in front of groups, co-workers, and vendors.
- Ability to gain others' support for ideas, proposals, and solutions.
- Ability to be flexible and modify one's preferred way of doing things.
- Ability to cooperatively collaborate with others and function as a team player.
- Bachelor's degree in science related field or equivalent required. A minimum of 6 years previous Quality Management and Regulatory experience. Experience in quality systems regulations including 21 CFR 820, and ISO 9001 or 13485. Experience in leading FDA medical device registration submission and maintenance including 510(k) submissions.

Apply today and become part of the Delasco family!

Delasco is growing company that offers a great team oriented and collaborative culture, in addition to, a competitive pay and excellent benefits package! Delasco is an Equal Opportunity Employer. Check out our website at: https://www.delasco.com/

If this sounds like your ideal position, we would love to hear from you!

Apply by sending cover letter and resume to: careers@delasco.com