NORLASE
Compact Diode Systems

Norlase ApS
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VP QA & RA for Medical Lasers

Norlase has created a next generation medical laser device poised to disrupt a large medical market segment. We are embarking on an exciting growth journey to establish Norlase as a dominant force within our chosen market. As a successful spin-out from DTU, we are a talented and passionate team with a strong sense of urgency, and we are seeking an individual that shares our passion. We will move to new production facilities in the greater Copenhagen area in Q4 2017.

As VP of Quality Assurance & Regulatory Affairs, you will establish the regulatory & quality requirements for a growing medical device company introducing their first product to market. You are a self-starter and willing to accomplish the needed goals of the company with minimal staff and outside support. Experience in CE & FDA regulatory submissions and quality systems management is a requirement, as well as excellent organizational skills.

As part of the Norlase management team you are expected to contribute to the overall development of our company.

Job profile

Reporting to our CEO, your tasks will be highly diversified and will include:

- Overall responsibility for implementation and maintenance of our Quality Management System
- Responsible for the implementation and certification according to ISO 13485:2016 and FDA CFR 21
- Management of key procedures, including management review, CAPA, ECR, internal/external audits.
- Review new product designs and product design changes for potential Regulatory notifications/submissions (e.g. 510(k), PMA, MDD, CE-Mark).
- Establish and oversee the Document Control function
- Close collaboration between stakeholders - such as regulatory bodies, customers, distributors, and suppliers – to ensure compliance and quality
- Inciting a strong quality culture in everything we do within our growing organization

Candidate Profile

Your qualifications should include

- A proven track record and 5+ years of quality management experience in the medical device industry
- An M.Sc. or B.Sc. degree, preferably in science or engineering
- Experience from a high-tech manufacturing company
- Oral and written fluency in English

Furthermore, the ideal candidate would have

- Knowledgeable in ISO 13485:2016 and FDA CFR 21 regulations. Lead Auditor certification for ISO 90001 or ISO 13485 is highly desirable.
- Experience with regulatory approval of medical devices
- Oral and written fluency in Danish

Application procedure

Please send your application to CEO Peter M. W. Skovgaard, at pmws@norlase.com. The CEO can also be contacted for further information.