Norlase ApS • www.norlase.com • +45 9397 7472 • Brydehusvej 13, DK-2750 Ballerup, Denmark • CVR 35644547

Regulatory Affairs Coordinator for Medical Lasers

Norlase is a high-growth, scale-up company developing the next generation of medical lasers for ophthalmology. We are an international team of laser technology and medical device experts, with offices in Ballerup and Silicon Valley. We have launched three revolutionary products, the LEAF, LION, and ECHO laser systems. All three are already in use in the world's top eye hospitals. We are currently looking into expanding our products' reach, especially ECHO, as well as developing the next product for our portfolio.

At Norlase...
... You are given a high level of autonomy and responsibility
... You are working with best-in-class experts, with a high level of drive and ambition
... You are part of a close-knit team, taking care of each other
... You are on a mission to fight preventable blindness through technological innovation - and have some fun along the way!

This position is a unique opportunity to gain broad experience within medical device regulatory affairs and quality assurance, in a successful scale-up company.

Job Description

We are looking to hire a Regulatory Affairs Coordinator to ensure country approvals for our devices worldwide. You will also support other functions within regulatory affairs and quality assurance.

As Regulatory Affair Coordinator you will work closely with one of our US colleagues to coordinate country approvals and be the regulatory point of contact for assigned countries.

Norlase has achieved market approval in Europe and US. In collaboration with our sales team and distributors, you will compile and send the requested documentation packages while some countries may have specific requests and you will be facilitating those responses in a close dialogue with our Norlase team.

You will also coordinate the implementation of new or revised international standards, directives, and regulations for our medical devices.

On a yearly basis, you will take care of our Post Market Surveillance/Product Safety Update Report program to ensure our devices are on par for state-of-the-art laser photocoagulations.

You will also be involved in the regulatory approval process for new products. This includes supporting activities within Risk Management, Usability Engineering, Labelling, EU Technical File, FDA 510(K) etc.

As time passes, you will preferably embrace new responsibilities within the area of Quality, depending on your interests and competencies.

You will report directly to our VP of Regulatory Affairs and Quality Assurance, as part of our Quality team.

Qualifications

You have a deep interest in medical device regulatory affairs and/or quality assurance. You have preferably worked a few years within one of these fields.

You must have oral and written fluency in English to communicate extensively with distributors and partners around the world, as well as with English-speaking colleagues at Norlase.

It is an advantage if you have a driver's license and car, as you will periodically need to visit various ministries and foreign embassies in Copenhagen.

As a person, you must be well-structured and motivated by following good documentation practices. Finally, you are excited by the prospect of joining a small, close-knit team on a start-up journey. Drive and passion are more important than experience for this position.

As part of our Quality team, it's essential that you pursue pragmatic and balanced quality efforts at any given time. You will be seen as a cultural leader for good communication, documentation practice and behaviors in our medical device company.

Application procedure

Please send your CV and cover letter to Jan Forstberg, VP of Regulatory Affairs and Quality Assurance, at e-mail JFO@norlase.com.

We will start the interview process immediately and will be conducting interviews on an ongoing basis until the right candidate is found.