



## **IWA Consulting seeks Medical Device Specialists for Regulatory Affairs**

Are you ready to take your career to the next level?

- By using your broad knowledge within Regulatory Affairs you take a vital role in helping our clients getting their products on market.

We are looking for colleagues to join our fast growing Medical Device Team.

IWA Consulting has long term regulatory experience in the Medical Device and Pharma Industry.

We assist Medical Device companies in achieving their major regulatory milestones, knowing and thoroughly understanding the sense of urgency that applies to this business area and you will attribute to this. Regulatory affairs – in every aspect of the discipline – is our core competence.

You will join a diverse team of skilled professionals in a company that prides itself on our deep insight and thorough understanding of the regulatory field for Medical Devices, Medicines and Combination Products.

Joining our team implies a unique opportunity to learn, develop professionally, and make good use of your knowledge in a vital role to our clients.

Often, we work from our clients' offices where we work as part of their team of regulatory specialists.

At IWA Consulting we work together and help each other on how to approach the many challenges we meet in our daily work.

- Together, we have experience in every corner of the challenging field of Regulatory Affairs.
- This is one of the reasons why we are the preferred partner to our many loyal clients.

### **Working in our Medical Device Team**

Being in charge of projects and clients, you will be planning your working hours and your place of work, in thorough cooperation with the rest of the team and with the clients.

We support clients in a variety of different areas covering Medical Devices, In Vitro Medical Devices and Combination Products.

We have world wide experience with Regulatory Affairs as well as Quality Management Requirements.

## **The job**

We will expect you to assist with several of the following tasks, depending on your experience and interests:

- Support clients in determining the regulatory strategy for planned products
- Development of technical documentation for CE Marking, FDA listing and other product registrations
- Design Control requirements and development documentation in general
- Handling various product maintenance tasks, such as Product Changes, Risk Management updates, Labeling, and other Quality System documentation that requires regulatory review and approval to ensure compliance with national and international legal requirements
- Compilation of submissions for market approvals e.g. PMA and 510(k)
- Assists in development of Quality Managements Systems in compliance with Quality System Regulations including quality system standards ISO 13485 and 21 CFR Part 820
- Performing external, internal and supplier audits

## **You**

- Hold a Master of Science degree (MSc) or other relevant education
- 2+ years of experience with Medical Devices and Regulatory Affairs
- A track record in World Wide product registration and project planning.
- Fluent in English and preferably Danish at a professional level, both written and spoken

You are a person, who is driven by a high commitment to delivering results every time in a dynamic environment where effective time management is necessary.

Being analytical and science-driven, you identify and resolve problems in a timely manner. You are a flexible and adaptable person with a hands-on attitude. You are pragmatic with an open and communicative approach, and have the ability to develop effective working relationships with customers at all levels. You are able to handle and deliver when necessary, while at the same time, have the ability to move projects forward.

## **IWA Consulting**

IWA Consulting offers you an exciting and challenging position in a well-consolidated company with a short line of command and a high degree of responsibility and flexibility in your everyday life.

You will work together with highly skilled and experienced colleagues to support our clients.

IWA consulting is based in Køge, 2 minutes from Ølby train station. Furthermore, we have an office at COBIS. Our clients are mainly based in the Copenhagen area.

Please, read more about us at [www.iwaconsulting.dk](http://www.iwaconsulting.dk) and forward your application and CV to Lise-Lotte Ostermann: [llo@iwaconsulting.dk](mailto:llo@iwaconsulting.dk) before 15 December 2016.

If you need additional information about the position, please do not hesitate to call Head RA Medical Device, Camilla Wamberg Munkesø: [cwm@iwaconsulting.dk](mailto:cwm@iwaconsulting.dk); +45 40186423.