



Quality Management Manager

Occlutech is a leading specialist provider of minimally invasive cardiac devices, with a mission to improve the quality of life for people with heart conditions. The vision is to become a global leading specialist provider in cardiac devices, addressing congenital heart defects, stroke prevention, and heart failure.

Occlutech has a broad and proven portfolio, based on proprietary technology, and over 200 patents with more than 170,000 products sold. The company markets and sells its products in circa 85 countries and has around 320 employees.

Location: Helsingborg, Sweden

With our products entering the US market and new tasks for our Quality Management Department, we are strengthening the team with a Quality Management Manager. We are looking for a candidate with deep and longstanding experience in Quality Management in Class III environment, a strong quality mindset and experience of leading projects and processes.

Your work tasks will be:

- Site-level Quality Management, who will champion the manufacturing quality system requirements (ISO 13485 and FDA QSR) and ensure they are effectively established and maintained as well as reports on the performance of the quality system to management with executive responsibility.
- Driving key processes to include: Quality Plan Creation, Quality Training, Compliance Analysis, CAPA Management, Change Management and Document Control per ISO 13485 and FDA QSR 820.
- Establishing Quality Systems that are compliant with regulatory requirements and meet business needs.

We are looking for a candidate, who:

- holds a degree, Bachelor, Master or Diploma in engineering with a strong quality experience, preferably in the pharmaceutical or medical device industry.
- has a minimum of 5 years' experience in QM/QA in Class III environment in relevant regulations (e.g. MDSAP, FDA, ISO 13485).
- Brings a strong quality Management experience, creative planning, and strategic approach.
- has excellent interpersonal, communication and leadership skills.

We are offering an interesting job in a team of people who like to work together and always focus on helping our customers to save and improve patient's lives with innovative and highest quality products.

Are you interested?

In this recruitment, we are working with SAM International, please apply via the below link that will redirect you to the job ad:

[Apply to the job](#)

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