

A team of 16 consultants support remediation planning over two years.



## Case Study

# FDA Remediation for Cardiovascular Device Maker

### INDUSTRY

Medical Device

### SERVICES

Remediation

Documentation

Corrective & Preventative Action (CAPA)

Quality Systems Improvement

### SKILLS

FDA Compliance

Quality Management Systems (QMS)

## The Challenge

Following receipt of an FDA Warning Letter, a global cardiovascular medical device manufacturer engaged Oxford to support a remediation effort. Our client's large-scale production operation in Germany urgently needed support to remediate technical documentation, processes, and systems in order to pass the FDA re-inspection and remove the warning letter status.

## The Solution

We supplied 16 senior-level consultants over a 2-year period. They were integrated into a classic remediation and warning letter environment that included an internal remediation task force and consultants from multiple agencies. Our consultants worked on several work streams, including:

- Assessing 50-60 technical files in collaboration with the R&D and Regulatory teams, ensuring that the technical and design history files were updated to meet ISO and CFR standards. The products included disposables used in external heart and lung machines, catheters, membranes and oxygenators.
- Taking ownership of CAPAs for sterilization remediation and writing reports and validation protocols for sterilization and bioburden testing.
- Handling all quality-related topics, maintaining and further developing the quality management system in accordance with the requirements of the ISO 13485, GMP and CFR 820.
- Monitoring and optimizing processes and documentation and providing active risk management.

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## The Result

While our client continued to strive towards FDA compliance, Oxford consultants played vital roles in leading and executing compliance programs that were essential to our client's European business. The company selected Oxford as a preferred supplier based on a proven ability to deliver skilled consultants into a very challenging and fast-paced environment at short notice.

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