*4 expert consultants were provided to achieve results within 7 different workstreams.*

Case Study

# Gap Assessment and Workstreams for MDR Compliance

**INDUSTRY**

Life Sciences

**SERVICES**

Regulatory Affairs

**SKILLS**

EU MDR Compliance

## The Challenge

When a European medical device manufacturer needed to achieve MDR compliance, they began the process of performing a gap assessment and developing a roadmap to determine what business requirements needed to be met and how MDR compliance could be achieved. However, due to the lack of available resources within the company at the time, they were unable to carry out the complex, fast-moving project while also maintaining their day-to-day operations.

## The Solution

Oxford Global Resources assessed the client's processes and systems to help them fill knowledge gaps and assist with the many moving parts of the project. We were able to provide 4 professional consultants to support the client's European MDR compliance project, which included an MDR project lead and three SMEs: one each for CERs, PMS, and technical file updates. After working with the client to complete an initial gap assessment and identify areas for improvement, these experts worked alongside internal employees and a dedicated PMO lead to quickly establish 7 individual workstreams. The objectives of these workstreams consisted of:

- Definition of Global SOPs
- Rollout, training, and implementation of the MDR Global SOPs
- Identification of IT tools for tech file preparation, including SAP connection
- Review of product production and priorities
- Confirmation of MDR classification for top-selling devices
- Verification of repackaging and relabeling activities at distributors
- QMS certification status
- Interfacing with relevant parties to plan for the MDR certification of Non-Class I Medical Devices

Although the client had not previously worked on a compliance project of this scale before, our team was able to swiftly integrate with the internal team and familiarize themselves with product lines, QMS, and IT systems.

## The Result

After completion of the gap assessment, the client was able to make noticeable progress on their European MDR compliance project in a short timeframe within each of the 7 established workstreams. We continue to partner with them to assist in this challenging, changeable project.

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