

## Case Study

# Achieving MDR Compliance for a High-Risk Medical Device

### Background:

A leading medical device company faced significant challenges in becoming compliant with the new Medical Device Regulation (MDR) requirements. The company, which was already established in the US and UK markets, lacked the senior expertise needed to navigate the complex regulatory changes for their high risk surgery device.

### Challenges:

- The company had a strong market presence but did not have the necessary senior leadership in regulatory affairs to manage the transition to MDR compliance.
- The MDR requirements demanded substantial updates to the Clinical Evaluation Report (CER), biocompatibility reports, and technical file documentation.

### Solution Provided by Verbatim Life Sciences:

- 1. Initial Assessment and Planning:** Verbatim Life Sciences quickly responded by placing a senior director with extensive experience in MDR compliance. This expert was tasked with performing a comprehensive gap analysis to identify areas in the technical documentation that needed modification.
- 2. Specialized Team Deployment:** To execute the plan effectively, Verbatim Life Sciences assembled a team of six contractors with specific expertise in regulatory compliance, biocompatibility, and clinical evaluation. This team was crucial in supporting the senior director to ensure all aspects of the technical file met the new MDR requirements.
- 3. Long-term Project Support:** Recognizing the complexity and duration of the project, the company extended the senior director's role to a two year contract after just two weeks. The project spanned over two years, during which the team worked diligently to update the CER, revise the biocompatibility report, and overhaul the technical file to align with MDR standards.

### Outcome:

The support provided by Verbatim Life Sciences enabled the company to successfully navigate the regulatory changes. Following an extensive audit, the company's high risk device achieved MDR compliance, securing its position in the market and paving the way for continued growth in the US and UK.

This case highlights the critical role of having the right expertise and resources to manage complex regulatory transitions in the medical device industry.