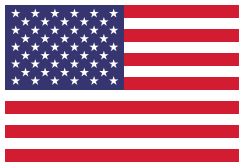
BUSINESS CASE

Case Study Analysis: EU and USA support for Medical Devices

CHALLENGE

A client approached Asphalion after receiving a suspension letter from their Notified Body, triggered by unresolved non-conformities that threatened regulatory compliance.



The client, with an EU CE-marked device, sought FDA clearance but lacked the internal resources and expertise to navigate the U.S. regulatory pathway.

SOLUTION

- **GAP analysis** of deficiencies and strategy for **mitigation**
- Implementation of **corrections** at **Quality Management System** (QMS) and **Technical Documentation** under **MDD**
- **Adaptation of Technical Documentation** of a portfolio with more than 1.000 references **from MDD to MDR**.
- **Gathering** device **validation evidence** (biocompatibility)

- **Gap Analysis** of Technical Documentation under **MDR**
- **Completed gap closure** in line with **FDA consensus standards,** with necessary **re-testing undertaken**
- Predicate **evaluation**, comparative **analysis**
- **Dossier preparation**
- **Clinical study analysis** (FDA GCP vs ISO 14155 – OUS Studies)
- **Submission** and **communication** with **FDA**

OUTCOME

Regulatory suspension resolved and lifted following alignment with the Notified Body.

The project culminated in successful FDA clearance, demonstrating regulatory excellence and strategic execution.

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