Halloran
A ProductLifeGroup Company

Case Study:
Effective Clinical Evaluation Preparation Enables EU MDR Compliance

Situation:

An ophthalmology medical device company – with many devices approved and marketed in Europe – needed to become compliant with the European Union (EU) Medical Device Regulation (MDR) that was adopted in 2017. The EU MDR is a new set of regulations governing the production and distribution of medical devices in Europe, and compliance with the regulation is mandatory for medical device companies to sell (or continue to sell) their products in Europe. As we approach the original compliance deadline of May 2024, the European Commission has proposed extending the transition period. [1]

In order to maintain their devices' CE marking – Conformité Européenne – and show their products still meet all applicable health, safety, and environmental regulations in Europe, and thus, able to sell in Europe – the company needed to submit all clinical evaluations in the form of a Clinical Evaluation Report (CER) for all devices currently in the European market. Failure to submit evaluations and comply would eventually result in product removal.

Challenge:

The company needed to quickly organize and draft their clinical evaluations, which are essential data on a device's safety and performance and used in the conformity assessment process. The company needed to show their devices were still safe for use in patients post-approval. Such safety and efficacy data can be found via clinical evidence in published articles.

The company was up against additional challenges:

- Multiple medical devices in the European market for over 20+ years
- No adequate clinical evaluation expertise in-house

Solution:

The company hired Halloran Consulting Group (Halloran) to write the literature summaries quickly and expertly, provide a remediation strategy, and review their clinical evaluations to prepare the company for regulatory submission to remain compliant with the EU MDR. The company knew they didn't have the resources or the unique skillset to propel evaluations forward to enable submission readiness and could not further delay the preparation process.

Halloran's Approach:

- Assessed clinical evaluation gaps
- Read, reviewed, and summarized 200+ relevant articles published since initial market approval
- Generated clinical summaries for all evaluations in less than industry standard time
- Extended quality control over all summaries enabling regulatory submission readiness
- Reviewed CER supporting documents

Results:

Halloran enabled the company's European products to stay on the market resulting from high quality CER preparation to prepare for submission to Notified Bodies. Such preparation is the foundation for any future regulatory engagement, and the evaluations communicated the safety and efficacy of their products through data-driven summaries.

HALLORAN ENABLED THE COMPANY'S EU MDR COMPLIANCE ACROSS THE ENTIRE PRODUCT LIFECYCLE THROUGH DATA-DRIVEN, HIGH-QUALITY CLINICAL EVALUATION PREPARATION.

Medical Writing At Halloran

Halloran experts have experience in medical writing through the full spectrum of life science development. Halloran utilizes available data for new or existing products, from initial screens and preclinical studies to completed clinical trials, to weave a cohesive story, setting clients up for successful interactions with regulatory agencies and dissemination of results.

About Halloran

Halloran is a life science consulting firm that provides strategic, regulatory, quality, clinical, and organizational support to industry leaders and startup visionaries in the pharmaceutical, biotechnology, and medical device sectors. Halloran experts offer deep expertise in science and advanced knowledge of the development and commercialization lifecycle, leading clients through their most challenging goals to achieve their greatest chance of success.

For more information or to learn how your company may benefit from Halloran's expertise, contact us. We're ready when you are.

Ready to get to work? **Contact us.**

Cited Sources

[1] https://health.ec.europa.eu/system/files/2023-03/mdr_proposal_extension-q-n-a_0.pdf

Halloran Consulting Group, Inc.
@HalloranConsult
Halloran
A ProductLifeGroup Company
hallorancg.com
info@hallorancg.com