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CASE STUDY

Leveraging Aggregate Reporting for EU-MDR Compliance and Proactive Risk Management for a Medical Device company

Product type: Medical device

Class: IIb and III

Therapeutic area: Cardiovascular & Neurology

Geography: European Union

Product life cycle stage: Post-marketing

About the Client

The client is one of the top 10 global medical device companies having multiple medical devices across a diverse range of therapeutic areas and serving people in more than 160 countries with leading medical devices and diagnostics.

Business Challenge

Due to the implementation of the EU Medical Device Regulation (MDR), the client required a trained team to support the preparation of post-marketing surveillance reports (PMSRs)/periodic safety update reports (PSURs) for their complete spectrum of medical devices. Because of the large volume of medical devices aggregate reports, with varying degrees of complexity and report sizes, a team of experts and experienced professionals was needed to effectively manage the substantial workload and to ensure high-quality reports and compliance while being aware of the regulatory changes.

Overview - Aggregate Reporting for Medical Devices

To ensure that patients have access to safe, effective and high-quality devices, various regulatory agencies have laid down stringent regulations across the complete life cycle of a medical device, from design to manufacture to distribution.

Medical device companies must develop a robust vigilance system to protect the health and ensure the safety of patients and to reduce undesirable adverse events.

As per the EU-MDR, a rigorous scientific assessment of medical devices is expected during post-market surveillance to ensure that the devices comply with their pre-determined requirements. The new EU-MDR 2017/745 requires the manufacturer to maintain and submit PSUR or PMSR, depending on the type and risk class of the device, to a notified body or other regulatory agency as part of technical documentation of the post-market surveillance of a medical device. The preparation and submission of high-quality aggregate reports will strengthen the post-market surveillance and vigilance system of medical devices.

To keep track of the upcoming updates and ensure a complete and compliant submission, medical device companies may engage with an expert partner for drafting, review and compilation of medical devices aggregate reports (PSUR/PMSR) to create regulatory-compliant, cost-effective, high-quality aggregate reports within a quick turnaround time.

Solution

To meet the client's expectations and requirements of the EU-MDR:

- A team of experienced healthcare professionals (HCPs) and physicians was dedicated to the project. The team primarily comprehended the client's processes and procedures, underwent a training workshop and then finally structured the process setup.
- APCER also established and aligned a strong governance framework to ensure compliance across the processes and successfully navigate the client's and regulator's requirements by providing specialised solutions and services.
- This resulted in a smooth preparation of the PMSR/PSUR report including authoring, quality review and medical review within a span of 1 month. The team also supported the client in the preparation of several ad-hoc reports, which were due for immediate regulatory submission.

Outcomes

- **Preparation of more than 40 PSURs** (majorly Class IIb and Class III) annually.
- Preparation of **high-quality reports with 100% compliance**.
- **Successful last-minute report assignments** to achieve submission regulations.
- **Strong governance** ensured seamless processes and client satisfaction.

APCER's Aggregate Reporting Capabilities

Aggregate reporting team comprising HCPs with a pool of >30% physicians having an average experience of more than 7 years and expertise in handling aggregate reporting across a range of products, including medical devices.

Manage end-to-end processes for aggregate reporting with standard operating procedures and work instructions.

Global experience in aggregate reporting.

Expertise in providing support for innovator as well as generic products.

Expertise in handling both post-marketing and developmental products.

Qualified person for pharmacovigilance (QPPV)/expert review and oversight.

High-quality deliverables consistently meeting or exceeding client and regulatory expectations.

Customized and fully compliant solutions to meet ever-changing regulatory requirements.

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APCER Life Sciences is committed to improving health in partnership with its clients. We bring together safety, medical, regulatory and technology resources to ensure that patients receive the safest, most effective therapies possible.

We are an ISO 9001:2015, ISO 27001:2022, and ISO 27701:2019 certified company.

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