APCER LIFE SCIENCES
Together for better health

BROCHURE

Ensuring EU-MDR Compliance

For a Seamless Journey to CE Marking Process for Medical Devices

On May 26, 2021, a new European Union Medical Device Regulation (EU-MDR) entered into force replacing the previous Medical Device Directive 90/385/EEC. Notified bodies will now play a more important role in conformity assessment and independently check closely whether medical devices comply with general safety and performance requirements before they are introduced into the market. These new regulations aim to strengthen patient safety and ensure that new devices benefit patients by supporting the availability of devices and enhancing monitoring. This regulation has brought about changes for both EU and US vigilance reporting. APCER has expertise to comply as well as efficiently report to the agencies with streamlined processes.

Key challenges faced by medical device companies include:

- Shortage of medical writers specialized in medical devices
- Adherence to regulatory templates
- Insufficient gap analysis
- Dynamic regulatory landscape
- Lack of first-time quality and a robust quality control review process
- Time constraints and delays in high-quality, submission-ready documentation

APCER's Services Across Devices

At APCER, a highly qualified, dedicated and experienced team supports medical device companies in developing high-quality, submission-ready regulatory documents and scientific communications as well as clinical safety and vigilance reporting in line with applicable guidelines and standards for devices, such as:

- MDR
- Medical Device Coordination Group (MDCG)
- International Organization for Standardization (ISO)

APCER provides end-to-end support throughout the device life cycle, across multiple therapeutic areas, and across different categories of medical devices for submission to regulatory bodies globally.

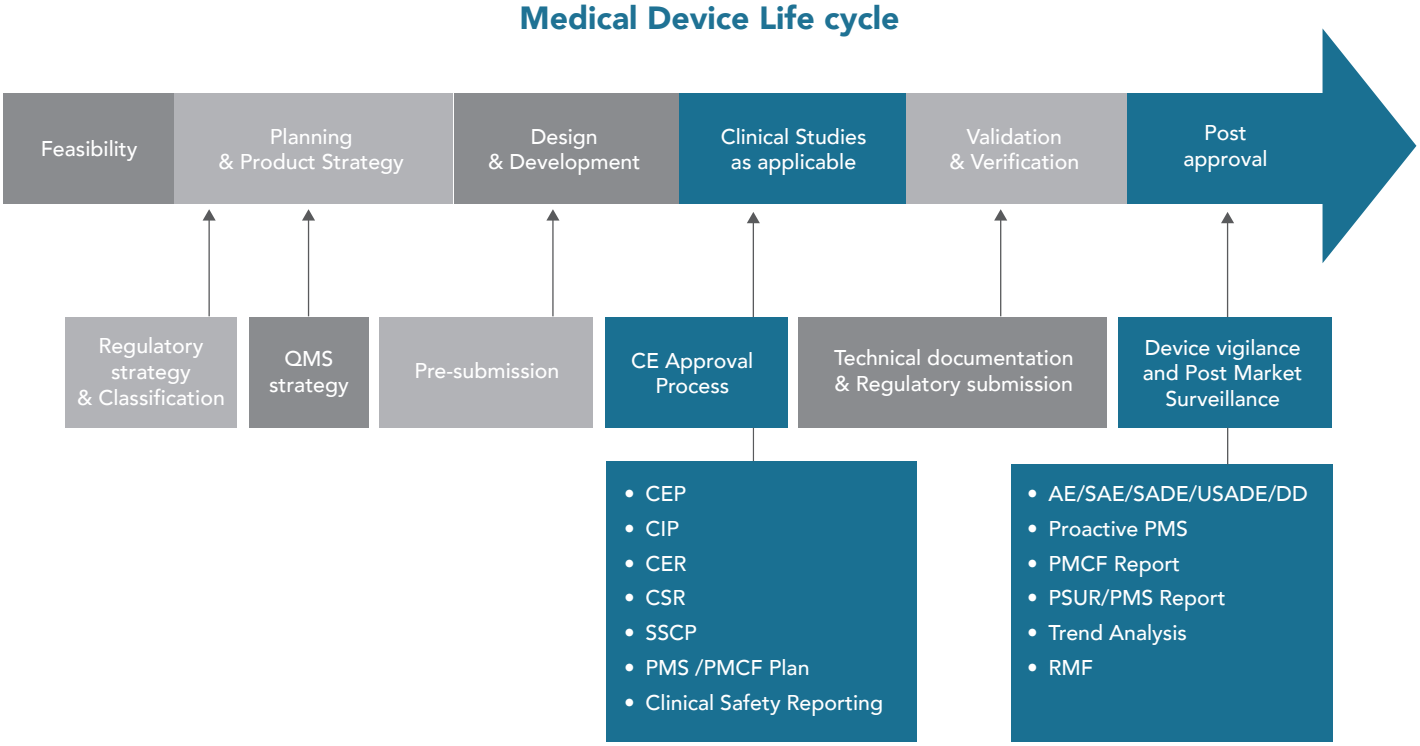
APCER's therapeutic experience includes but is not limited to cardiovascular, neurovascular, ophthalmology, and respiratory diseases.

Product Life-Cycle Reporting as per EU-MDR Guidelines

The EU-MDR revised the responsibilities for medical device companies including stringent requirements for preparation and updates of regulatory documents on a regular basis.

The following graphic represents the process for preparing various plans and reports intended for medical devices. After approval, manufacturers must comply with applicable requirements and prepare these documents in a timely manner throughout the entire life cycle of the device.

Medical Device Life cycle



APCER's Medical Writing Expertise for Medical Devices

APCER completes documentation for medical devices throughout their life cycle as per applicable requirements (MDR) from regulatory agencies and notified bodies. APCER's Medical Writing team has expertise to prepare the following documents specific to medical devices:

- Clinical Evaluation Plan (CEP)
- Clinical Evaluation Report (CER)
- Post-Market Surveillance (PMS) Plan
- PMS Report/Periodic Safety Update Report (PSUR)
- Post-Market Clinical Follow-Up (PMCF)
- PMCF Reports
- Clinical Investigation Plan (CIP)
- Clinical Study Report (CSR)
- Literature Evaluation
- Scientific Documents (Abstracts, Manuscripts, and Poster Presentations)

APCER's Clinical Safety & Device Vigilance Center

APCER's team of healthcare professionals has experience with many types of medical devices for clinical and post-marketing requirements.

Medical Information and Call Center

- Handling medical information (MI)/adverse events (AEs)/incident reports/product quality complaints (PQCs)
- Sample procurements
- Development of standard response letters (SRLs)
- Development of frequently asked questions (FAQs)

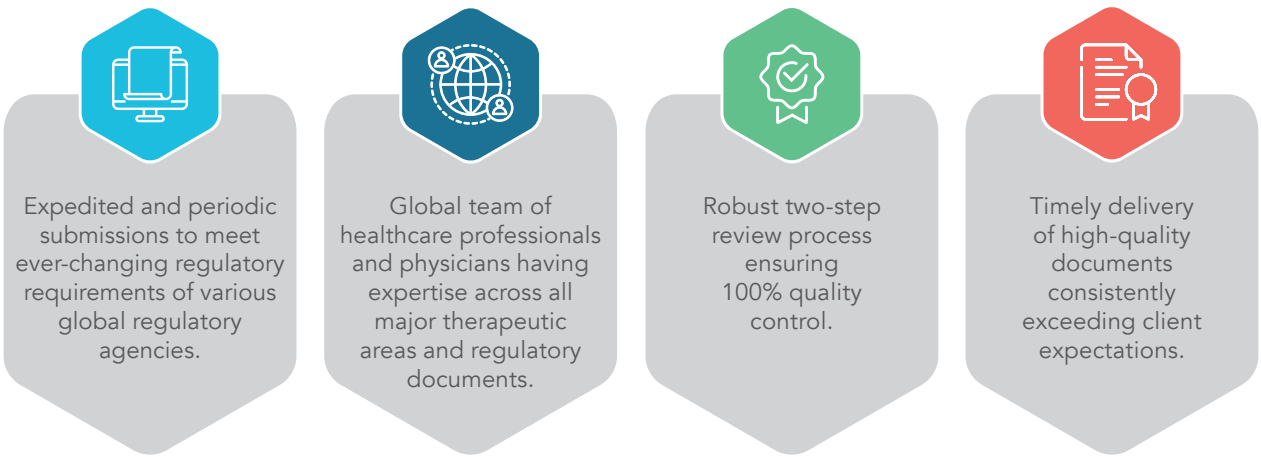
Clinical Safety and Device Vigilance

- Data collation, case processing, and regulatory submissions where applicable
  - AE, serious adverse event (SAE), adverse device effect (ADE), serious adverse device effect (SADE), unanticipated serious adverse device effect (USADE), and device deficiencies (DD))
- Summary Safety Reporting
- Periodic Summary Reporting
- Literature Screening
- Trend Analysis
- PMS Report/Periodic Safety Update Report (PSUR)
- Risk Management File (RMF)

The APCER Advantage

APCER will work diligently with your requirements to develop a robust literature appraisal and review process to identify predicate devices and critically analyze the clinical and performance data gathered from the post-market surveillance data of the device.

Subject matter experts in various therapeutic areas of medical devices and regulatory affairs (RA) will work closely to meet submission requirements as per the MDR regulations. APCER's experienced writers will also perform a gap analysis and CER assessment in compliance with MDR and other applicable ISO standards for all classes of medical devices.



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Part of APC Group

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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