Medical Device

IQVIA offers solutions on global scale to transform the Life Science sector and support clients in their growth and development. They are committed to addressing specific needs on a daily basis.

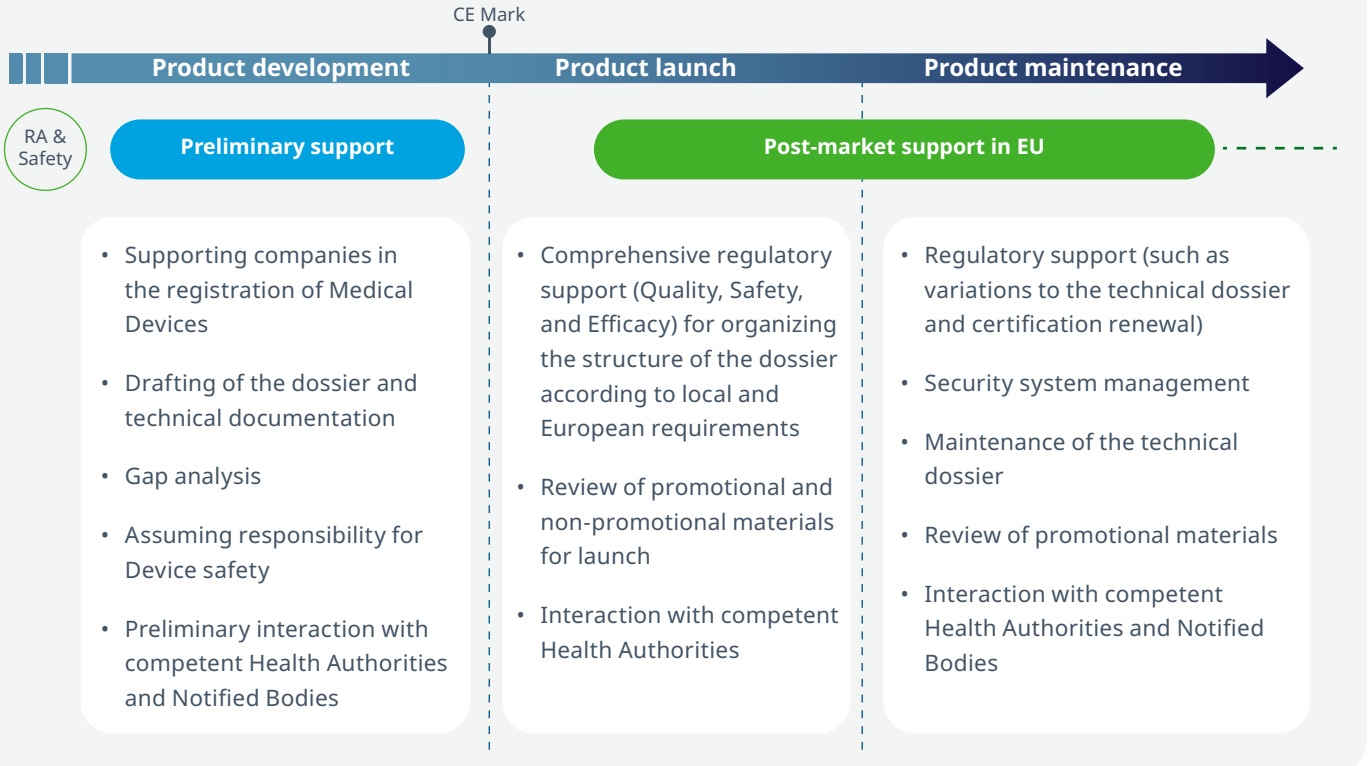
To be successful and differentiate themselves from competitors, MedTech companies must adopt new market dynamics based on innovative technologies and working models.

Those who manage to make their business operations digitally advanced and up to date will gain a competitive advantage, thereby dominating the MedTech industry.

In this context, IQVIA has developed some dedicated services for Italy.

In the field of Medical Devices, **the Regulatory Affairs and Pharmacovigilance (RA and PhV) team** provides a deep knowledge of European legislation and local requirements, suitable to support you during the entire **life cycle of the Medical Device**.

The proposed services can be grouped into different phases:



In a context of significant changes, the definition of a regulatory and pharmacovigilance strategy is **essential** for the successful development of a Medical Device.

Preliminary support

In this initial phase, our goal is to provide you with an initial regulatory assessment focused on the classification of the device and to support you in the analysis of the new regulatory requirements.

1. Development of the regulatory strategy

- Define the impact of the Medical Device Regulation (MDR) on the economic operators involved by outlining all the responsibilities of the manufacturer, authorized representative, importer, distributor, and the person responsible for regulatory compliance.
- Develop the regulatory and safety strategy to ensure compliance with the new responsibilities.
- Define the necessary activities as per the MDR for product launch and maintenance on the market and intervene in the resolution of any critical issues.
- Assume responsibility for safety and implement the ISO 13485 quality management system (if required) to ensure greater harmonization with the MDR requirements.

2. Verification of documentation compliance and essential requirements

- In order to align with the requirements of the new regulation and gather new evidence/data, IQVIA provides crucial support in the analysis of the available documentation (e.g. technical specifications, procedures, clinical reports) in line with both the previous directive (MDD 93/42) and the current regulation (MDR 2017/745).
- Additionally, our team offers guidance during the transition period to the new regulation and advises on necessary actions for **MDR devices and legacy devices**. During this phase, IQVIA will assist you in defining a priority plan based on device classification, existing documentation, and the responsibilities of the involved operators.
- In collaboration with clinical research colleagues, we will support you during clinical studies and conduct device testing to gather additional data for demonstrating the effectiveness of the medical device.

3. Preparation of technical dossiers and contacts with Notified Bodies for CE marking

- IQVIA will handle the review/drafting of technical dossier modules, considering the device classification and MDR requirements (i.e., new clinical and safety requirements, new device classification). Additionally, we will take responsibility for periodic review of the modules to ensure product safety and legal compliance.
- Interaction with Notified Bodies to define strategy, planning, and timing for marketing devices in different countries, addressing issues and clarification requests.
- The RA and PhV Team will support you in obtaining the new CE Mark or renewal.

Post-market support in EU

In this second and final phase, IQVIA aims to provide you with a series of services focused on maintaining your Medical Device (DM) in the Italian and European market, with a strong emphasis on two fundamental and decisive points.

1. Post-marketing surveillance

- Define the post-marketing surveillance plan by collecting data on both serious and non-serious incidents, potential adverse effects, information from trend reports, specialized or technical literature, databases and/or registers, feedback collection, and various publicly available information related to similar medical devices.
- Establish a proactive and systematic process to collect all the above information (e.g., protocols, post-marketing clinical follow-up plan).
- Provide support in drafting the Periodic Safety Update Reports (PSUR), which includes:
  - » Conclusions from risk-benefit determination.
  - » Key results from Post-Market Clinical Follow-up (PMCF).
  - » Sales volume and an estimate of the population size and other characteristics of device users, along with possible device usage frequency.
- Support in drafting the post-marketing surveillance report.

2. Management of additional activities following CE marking:

- Assistance in the export of the Medical Device. In this scenario, some countries outside the European Union may require manufacturers to submit a certificate of free sale issued by the competent health authority.
- Registration of the Device in the Ministry of Health database: providing specific information/ documentation. This notification is mandatory for marketing the devices in Italy.
- Preparation and review of labels and local instructions taking into account MDR requirements, notification to the competent authority and submission to the Notified Body for approval.
- Review of promotional material to confirm compliance with product characteristics.
- Management of periodic audits carried out by the Notified Body.

CONTACT US

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