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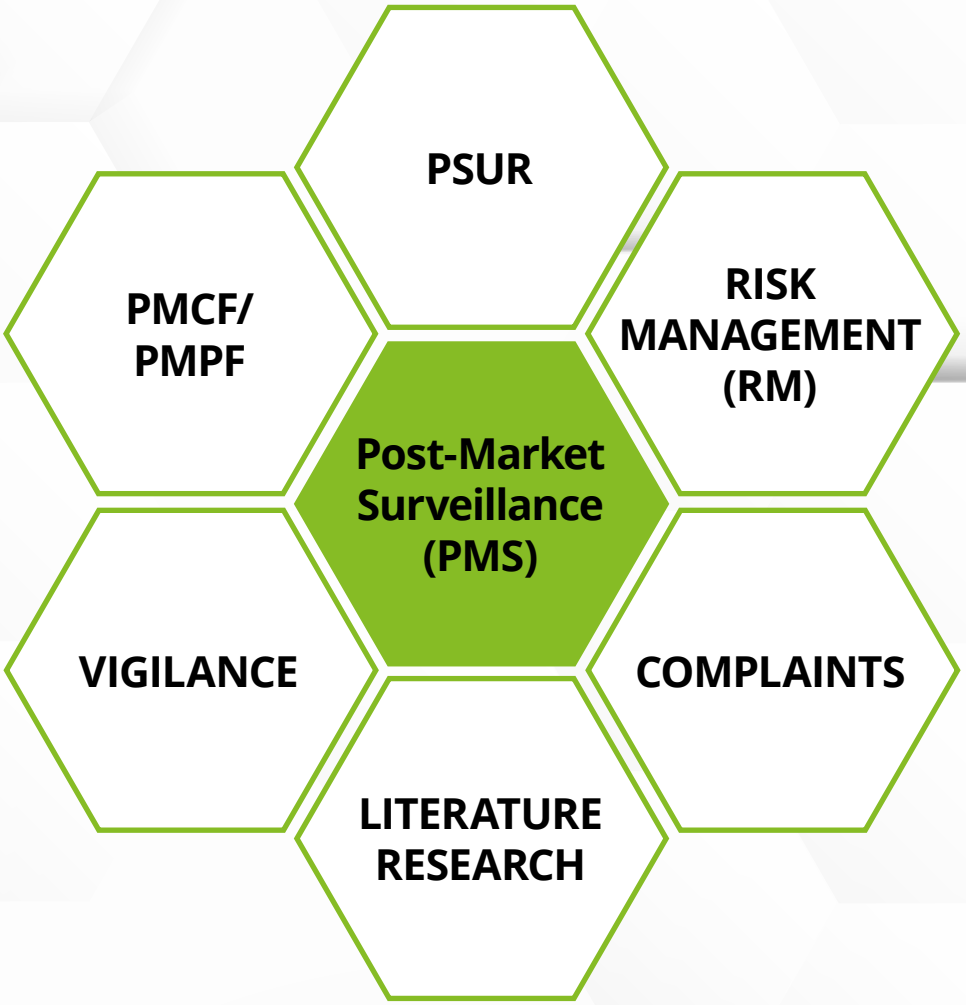

Post-Market Surveillance MD & IVD

PMS solutions from market entry, through data collection and analysis, to documentation creation and management

Provision of complete technical documentation related to PMS and PMCF/PMPF

- Reviewing or creating MDR/IVDR compliant technical documentation
- Preparing for data collection

Risk Management System

- Determination of risks and benefits for specific cases, FMEA analysis
- Calculation of risk-benefit ratio

Complaints

- Setting up a customer data collection system – complaints
- Solutions within the quality management system

Literature research

- Preparation of documents for actualisation of clinical/performance evaluation
- Analysis of publications

Vigilance

- Reporting of serious incidents, and field safety corrective actions

PSUR

- Periodic safety update report

How can we help with the comprehensive provision of PMS and PMCF so that you meet all legislative requirements?

Manage adverse events
Digitalize vigilance process

- Manage full-cycle vigilance process.
- Data-informed decisions on medical device safety profile
- Advance safety case reporting
- Reporting and submissions
- Unified and compliant system
- Flexible solution to support you scaling business and processes
- Quality Management System
- Manage SOPs, audits, incidents, CAPA and all the quality-related activities across company and projects within a single module

Prepare and manage technical documentation and system documentation

- Preparation of comprehensive documentation to meet PMS requirements
- Compliance with QMS requirements, MDR/IVDR conditions
- Post-market surveillance plan a report
- Comprehensive data collection system setup: PMCF/ PMPF, Periodic safety update report, literature search, vigilance, Trend reporting
- Establishing effective and appropriate methods and procedures for assessing the data collected
- Establishing appropriate indicators and thresholds for use in the ongoing reassessment of benefit-risk analysis and risk management according to the latest methods
- Communication with the notified body and regulatory authorities
- Validation of PMS software solutions in the company
- Creation of clinical-economic analyses based on the obtained data.

Key benefits:

Compliance with legislative requirements
MDR/IVDR, QMS,...

Flexible
Quick and simple adjustments

Quick
Ready in weeks, tailored for your needs

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