Post-Market Surveillance (PMS) Plan & Compliance Checklist

EU MDR Requirements (Article 83–86)

- PMS Plan developed and linked to risk management
- PMCF required? Justified clearly in the PMS Plan
- PSUR record timelines, defined by risk class (Class IIa: every 2 yrs; Class IIb & III: annually)
- Updated Feedback and complaint related records and logs, vigilance, user feedback and service data
- Updated records of incidents and related investigations
- Updated Risk management records

FDA PMS Requirements

- Updated distribution records for inside and outside US
- Updated control and Quality Assurance records-aligned with contract manufacturer
- Updated mandatory and voluntary records of reportable and non reportable events
- Trends related to complaints, malfunctions, recall if any should be analysed and raw data available and mapped to distribution records-there should be clear visibility on device and accessories related complaints
- CAPA records should be updated based on PMS findings and trendings
- Quarterly or annual trending reports prepared
- Updated Risk management records

PMS Plan Content

- Device description and intended use
- Risk-benefit analysis and known residual risks
- Data sources: field, literature, registry, and complaints
- Evaluation of collected data and actions needed
- PMS Report (Class I) or PSUR (Class II/III) ready

Continuous Improvement Integration

- PMS plan linked to risk management file updates
- Corrective/preventive actions triggered when needed
- Labeling, IFU, or clinical evidence revised as applicable