Elexes

Post-Market Surveillance (PMS) System Setup Checklist

- **PMS Plan Defined**
  - Document objectives, data sources, responsibilities, and reporting timelines.
- **Complaint Handling Process Established**
  - Set procedures for intake, investigation, and trend analysis of complaints.
- **Clinical Performance Monitoring**
  - Track real-world performance, long-term safety , and clinical outcomes.
- **Adverse Event Reporting Mechanism**
  - Ensure timely reporting of adverse events to FDA, EU Competent Authorities, or other regulators.
- **User Feedback Collection**
  - Capture feedback from clinicians, hospitals, and technical users.
- **Trend & Signal Detection**
  - Periodically analyze the complaints data, device performance metrics, and adverse events to identify safety or performance trends.
- **Corrective and Preventive Actions (CAPA)**
  - Link PMS findings to the CAPA system to ensure corrective and preventive measures for continuous improvement.
- **Software Update & Change Control**
  - Monitor field updates, bug fixes, and cybersecurity patches.
- **Periodic Safety Review**
  - Prepare PMS reports or PSURs as required under EU MDR.
- **Regulatory Compliance Review**
  - Regularly verify alignment with evolving regulatory requirements.