

Webinar Highlights

- **Post Market Surveillance vs. Market Surveillance:** We explored the distinction between PMS (manufacturer's responsibility) and market surveillance (regulator's role). Both are critical to ensuring that medical devices continue to meet safety standards after reaching the market.
- **PMS as a Continuous Process:** It's crucial to treat PMS as an ongoing process, not a one-time event. This involves both **reactive** (complaints, non-conformities) and **proactive** (clinical literature, competitor data) inputs to assess the performance of your device.
- **PMS System Requirements:** Under MDR, manufacturers must have a comprehensive plan in place for PMS, which should cover:
 - Serious incidents
 - Non-serious complaints
 - Risk management and corrective actions
 - Clinical evaluation and post-market clinical follow-up (PMCF)
- **Reporting and Auditing:** The webinar covered the importance of documenting and reporting PMS findings, particularly the difference in requirements for **class 1 devices** (where reporting frequency can be defined by the manufacturer) and **class 2A/B and class 3 devices** (which have stricter reporting timelines).
- **Post Market Clinical Follow-Up (PMCF):** Even for devices with established technology or no residual risk, a PMCF plan must be in place. This is now mandatory under MDR.
- **Challenges in PMS:** Many manufacturers face challenges with resources and ensuring the quality and completeness of PMS data. The webinar discussed strategies to improve these areas.
- **Audience Poll Results:**
 - **Biggest Challenge in PMS:** Limited resources
 - **PMCF Activities:** 70% of participants are actively conducting PMS and PMCF for devices already on the market.
 - **Impact of EUDAMED:** Most manufacturers are not affected by the absence of EUDAMED in PMS activities.

Notable Non-Conformities:

- Lack of documented PMS plans or failure to follow defined procedures
- Inadequate interaction between PMS and risk management, clinical evaluation, or CAPA
- Missing or incomplete post-market clinical follow-up plans

Conclusion:

We encourage manufacturers to **define clear PMS processes** and ensure that all **documentation** is in place, from **PMS reports** to **communication mechanisms** with notified bodies. The goal is to provide clear evidence that the **benefit-risk ratio** of the device continues to outweigh any risks.