

VIII.
POST-MARKET SURVEILLANCE AND VIGILANCE

A well functioning vigilance system is the 'backbone' of a robust regulatory framework in this sector because complications with medical devices that are designed to be implanted or to operate for many years or even decades might come to light only after a certain period of time. Therefore, PMS is an obligation in local and global regulations.

References

EN ISO 13485, U.S. FDA Quality System Regulations (21 CFR PART 820), EU Medical Device Directive (MDD 93/42/EEC) & New EU MDR, Canada Medical Device Regulations (SOR/98-282), local regulation, EU MDR PMS Chapter VII.

This sub-system provide a practical solution on establishment and implementation of Post-Market Surveillance (PMS) to review experience gained from devices in the post-production phase and to implement appropriate means to apply any necessary corrective action.

- Post-Market Surveillance (PMS) - Basic Terms and Concepts
- Back Ground Applicable Regulation & Guidance Standards
- Post-Market Surveillance (PMS):
 - Complaint handling system
 - Vigilance reporting system (incidents and Field Safety corrective Actions-FSCA)
 - PMS methodology for data analysis, trending
 - Integration of PMS in the risk management process
 - Corrective action for safety and improvement
 - Use of PMS data for innovation and device improvement

Our services:
A. Post-Market Surveillance (PMS) Training for Medical Device Companies

This training is conducted on-sites. The training session tailored to the needs of your organization regarding this sub-system.

B. Post-Market Surveillance (PMS) Auditing for Medical Device Companies

Full or partial internal PMS audit. We provide internal auditing services which allow for an independent review of this part of your quality system.

C. Post-Market Surveillance (PMS) - System Implementation Consulting and maintenance

Gap analysis, design solution (custom made system), standard operating procedures, implementation, training, verification of effectiveness, and follow up.