NB Audit of the Post-Market Surveillance (PMS) under MDR 2017/745

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Our Speakers

Daniëlle has more than 15 years of experience in the medical device industry and has been hands-on in international registrations, post-market surveillance, clinical evaluations, and risk management.

With her background in Biopharmaceutical Sciences and experience gained when working for the Medicines Evaluation Board of the Netherlands for 5 years before transferring to the medical device industry, she enjoys working in the medical device field to ensure regulatory compliance while supporting market access.

Daniëlle Sleegers
Director of Regulatory Affairs & PRRC
MedEnvoy Global

Our Speakers

Salman has been in the medical devices industry for over 20 years and has worked in R&D, Manufacturing, QA/RA within the medical devices industry and subsequently worked over a decade as Lead Auditor / Technical Reviewer for reputable European Notified Bodies including LRQA, SGS and NSAI, etc. Salman's notable credentials include:

- Member of ISO 13485:2016 standard development technical committee TC 210
- Recognized Lead / Principal Auditor by International Register of Certified Auditors
- Certified Regulatory Affairs Professional [RAC] # 09144585
- MDSAP Certified Lead Auditor
- QMS Lead Auditor and Technical Documentation Reviewer [MDR 2017/745]

Salman Raza – MEng, MBA, MS

Principal Consultant
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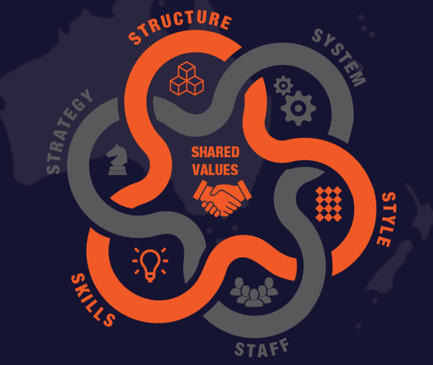
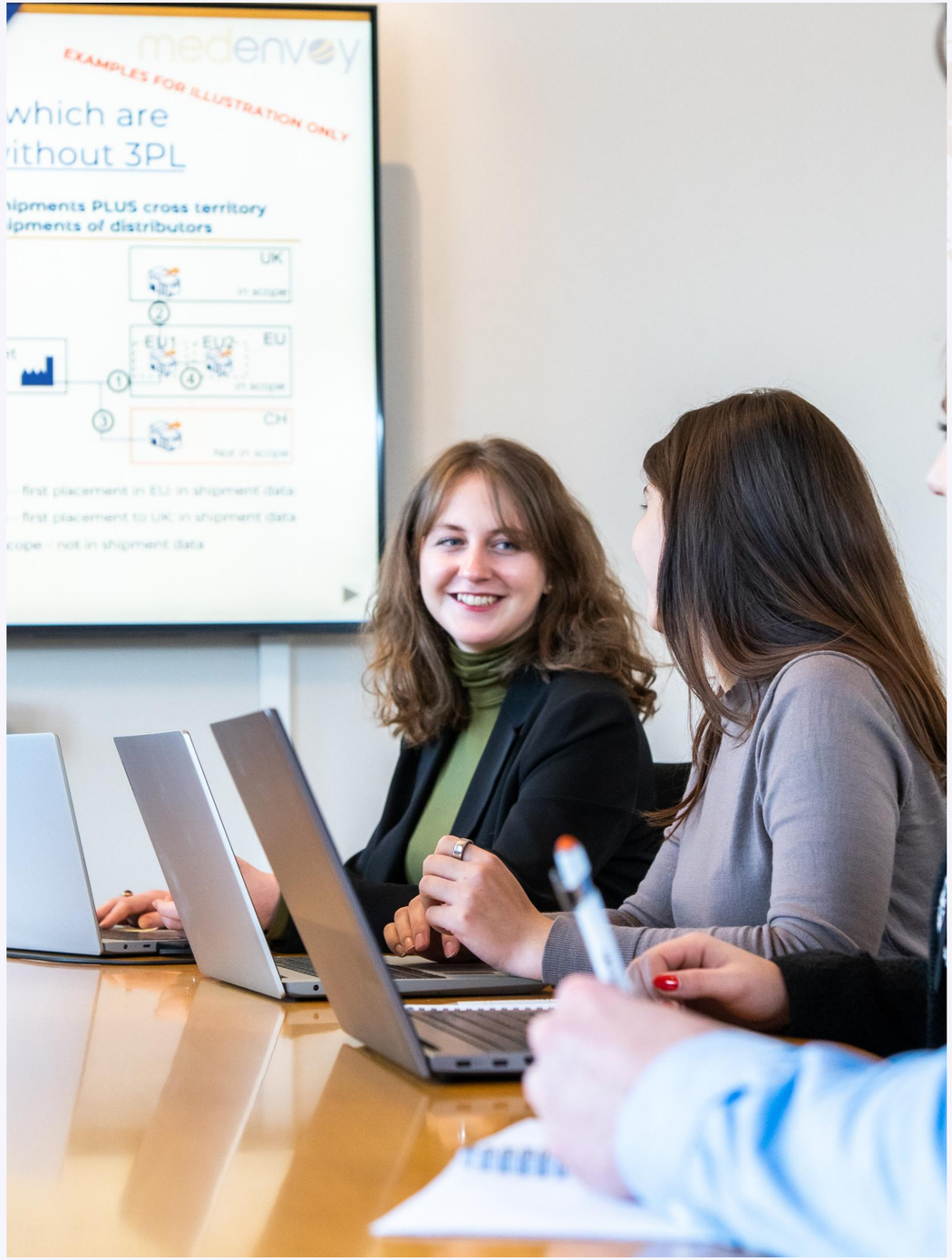




Agenda

1. Auditing PMS Regime under MDR 2017/745
2. Most Common NCs Identified During the PMS Audits
3. Most Common NCs Identified during NCA Market-Surveillance activities

Post-Market Surveillance (PMS) under MDR

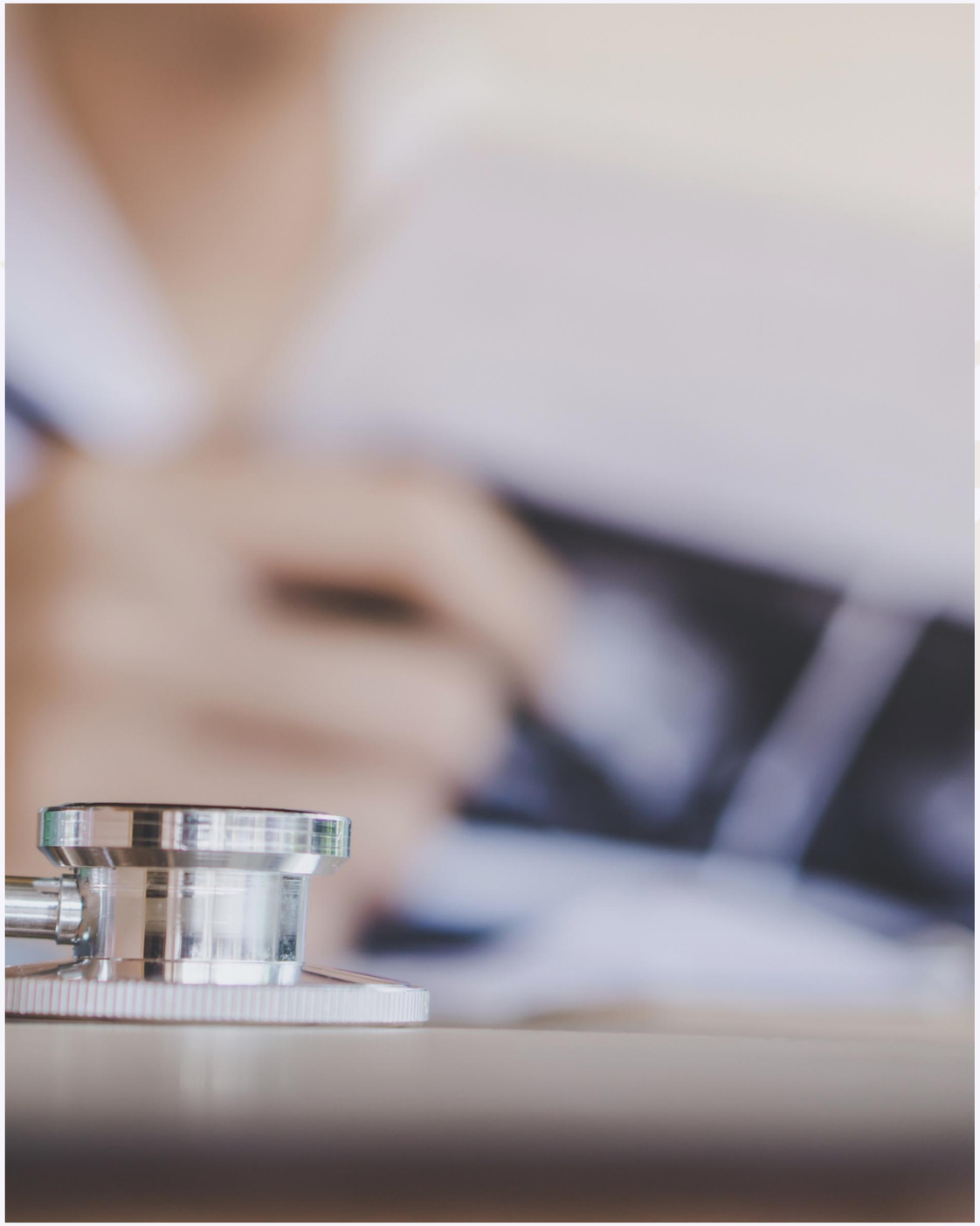
Poll #1

Post-market Surveillance
EU MDR Article 2(60)

“Means all activities carried out by manufacturers in cooperation with other economic operators to institute and keep up to date a systematic procedure to proactively collect and review experience gained from devices they place on the market, make available on the market or put into service for the purpose of identifying any need to immediately apply any necessary corrective or preventive actions”

Market Surveillance
EU MDR Article 2(61)

“Means the activities carried out and measures taken by competent authorities to check and ensure that devices comply with the requirements set out in the relevant Union harmonization legislation and do not endanger health, safety or any other aspect of public interest protection”



Post-Market Surveillance (PMS)

It’s a continuous Process,
Not an Event!

Post-Market Surveillance (PMS) Process

FUNNEL

Representative sources of data to build appropriate capture system.

CHUTE

Required set of processes to handle events in a timely and efficient manner. This will include prioritization and handling algorithms.

DETECTION

Master Data Set that is available for reporting and signal detection.

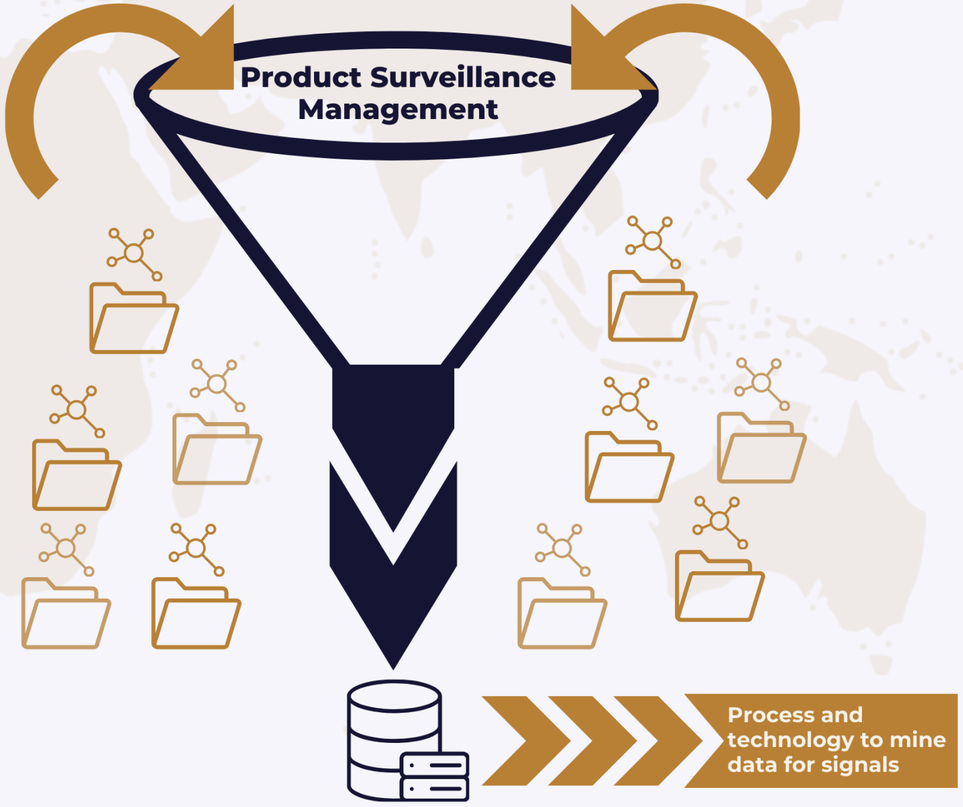
REACTIVE

- MDRs
- Non conformance
- Audits
- Recalls
- Complaints
- OOS

PROACTIVE

- Service Data
- Literature Media
- Social Media
- PM Clinicals
- RWE
- Customer Surveys

Need to bring the current post-market safety data from across company into a centralized system

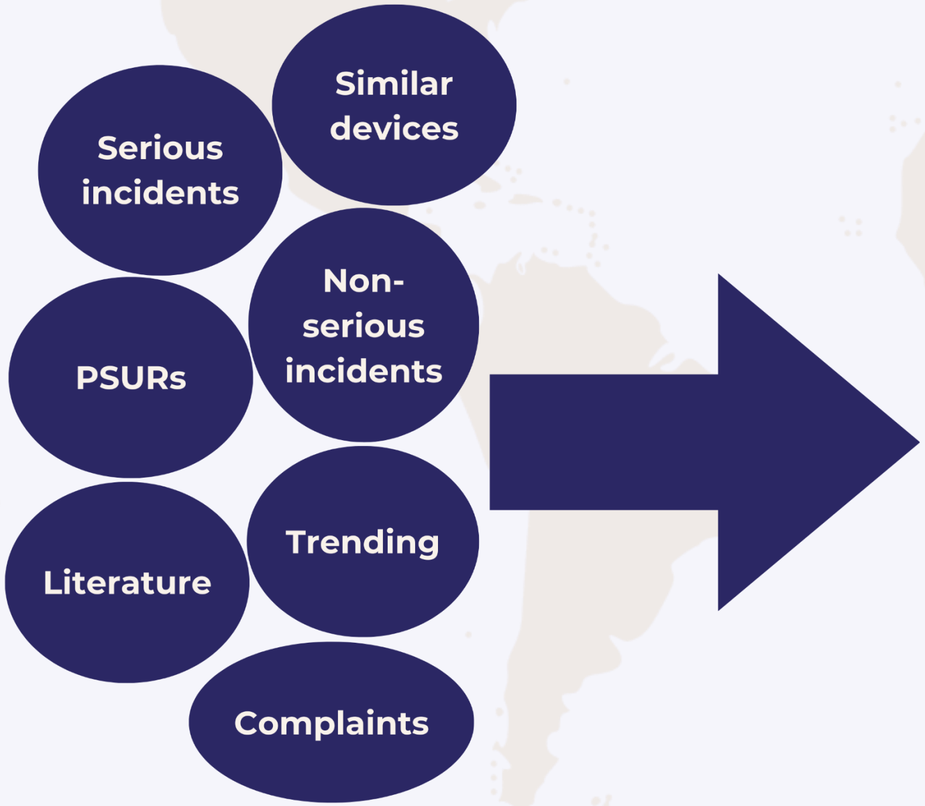


EU MDR Post-Market Surveillance System

- For each device or product family, the manufacturer must develop PMS activities that address:
- Planning
- Establishing processes
- Documenting activities
- Implementing actions
- Maintaining processes and records
- Updating activities during review periods
- The post-market surveillance system must be established proportionate to risk class and for the type of device
- The system must be an integral part of the manufacturer’s QMS

Post-market Surveillance

Post-Market Planning



Review & Update the Following:

- Risk Management
- Clinical Evaluation
- PMCFs
- Design Changes
- QMS Reporting
- Corrective Action
- PMSR / PSUR

Poll #2

EU MDR Post-Market Surveillance Plan Must Cover:

- A proactive and systematic process to collect the required information and allow correct characterization for device performance
- Comparisons made between the subject device and similar products available on the market
- Effective and appropriate methods and processes to assess collected data, including analysis
- Suitable indicators and threshold values used in continuous reassessment of the benefit-risk analysis and risk management
- Effective and appropriate methods and statistical tools to investigate complaints and customer feedback
- Analysis of market-related experience collected in the field
- Methods and protocols to manage events subject to trend reporting

The Post-Market Surveillance Plan Must Cover - Contd.:

- Establishment of any statistically significant increase in the frequency or severity of incidents and observation period
- Methods and protocols to communicate effectively with Competent Authorities, Notified Bodies, economic operators, and users
- Reference to procedures fulfilling the manufacturer’s obligations to Articles 83 through 86
- Systematic procedures to identify and initiate appropriate measures, including corrective actions
- Effective tools to trace and identify devices for which corrective actions might be necessary
- A PMCF plan, or a justification if it is not applicable

EU MDR Post-market Surveillance Reporting

Poll #3

PMSR
Class I Devices Reporting

Manufacturers must:

- Prepare a **post-market surveillance report (PMSR)**
  - Summarize results and conclusions of analyses of PMS
  - Include a rationale and description of any preventive and corrective actions taken
- Update the report when necessary
- Internally should have a defined period for updating
- Make the report available to their Competent Authority upon request

Class IIa, Class IIb, and Class III Devices Reporting

- Manufacturer prepares Periodic Safety Update Report (PSUR)
  - This applies to each device and, where relevant, to each category or group of devices
    - The PSUR summarizes results and conclusions of analyses of post-market surveillance data
    - Include a rationale and description of any preventive and corrective actions taken
    - Specific to Class III and implantable devices:
  - PSUR uploaded into an electronic system for regulatory agencies to review and assess – viewable by CAs and the Commission
  - Electronic system managed by Notified Body

PSUR Content

- Throughout the lifetime of the device, the PSUR must set out the following:
  - Conclusions of the benefit-risk determination
  - Main findings of the PMCF, if applicable
  - Volume of sales of the device
  - Estimated evaluation of the size and other characteristics of the population using the device
  - Where practicable, the usage frequency of the device
  - MDCG PSUR template regarding presentation of data included in MDCG 2022-21

PSUR For Higher Risk: Updates

When to update the PSUR:	
Class IIa	▪ When necessary* and at least every two years
Class IIb	▪ At least annually
Class III	▪ At least annually

- * “When necessary” = Changes to the product risk profile, significant serious incidents, or other actions that pose a risk to the public

Note: The PSUR, except in the case of custom-made devices, must be part of the technical documentation

PSUR For Higher Risk: Updates

Where to store or submit the PSUR:	
Custom-Made devices	• The PSUR is part of the documentation referenced in Section 2 of Annex XIII Procedure for Custom-Made Devices
Class III Devices or Implantable Devices	▪ Manufacturers must submit PSURs to the electronic system of the NB involved in the conformity assessment ▪ The NB must review the report and add its evaluation to the electronic system with details of any action taken – The PSURs and Notified Body evaluation shall be made available to Competent Authorities through the electronic system
Devices other than Class III Devices or Implantable Devices	• Manufacturers must make PSURs available to the NB involved in the conformity assessment and, upon request, to Competent Authorities

PMS Audit Expectations

Poll #4

Audit Intent

- Is there a documented procedure for PMS that meets MDR requirements?
- Is it being used proactively for all devices for which the client is the legal manufacturer?
- Does the procedure include how the manufacturer is kept informed of PMS data received by any virtual manufacturers that the client supplies manufactured, and CE-marked devices to?
- Does the procedure include data from customer complaints, vigilance, users, patients, and the market, and how to manage PSUR?

What Auditors are Looking For:

- Does the procedure meet the requirements of MDR (Article 83) Vigilance (Article 87-89), and PMS Guidelines (MEDDEV 2.12-1 and MDCG 2023-3)?
- Which other data sources are utilized?
- Is a post-market surveillance report available for class I devices and PSUR for other classes of devices?
- Does the PMS Plan include a proactive and systematic process to collect information including information from serious incidents (including PSUR and FSCA), non-serious incidents and any undesirable side-effects; information from trend reporting (including processes used); relevant specialist or technical literature, databases/registers; publicly available information about similar devices?

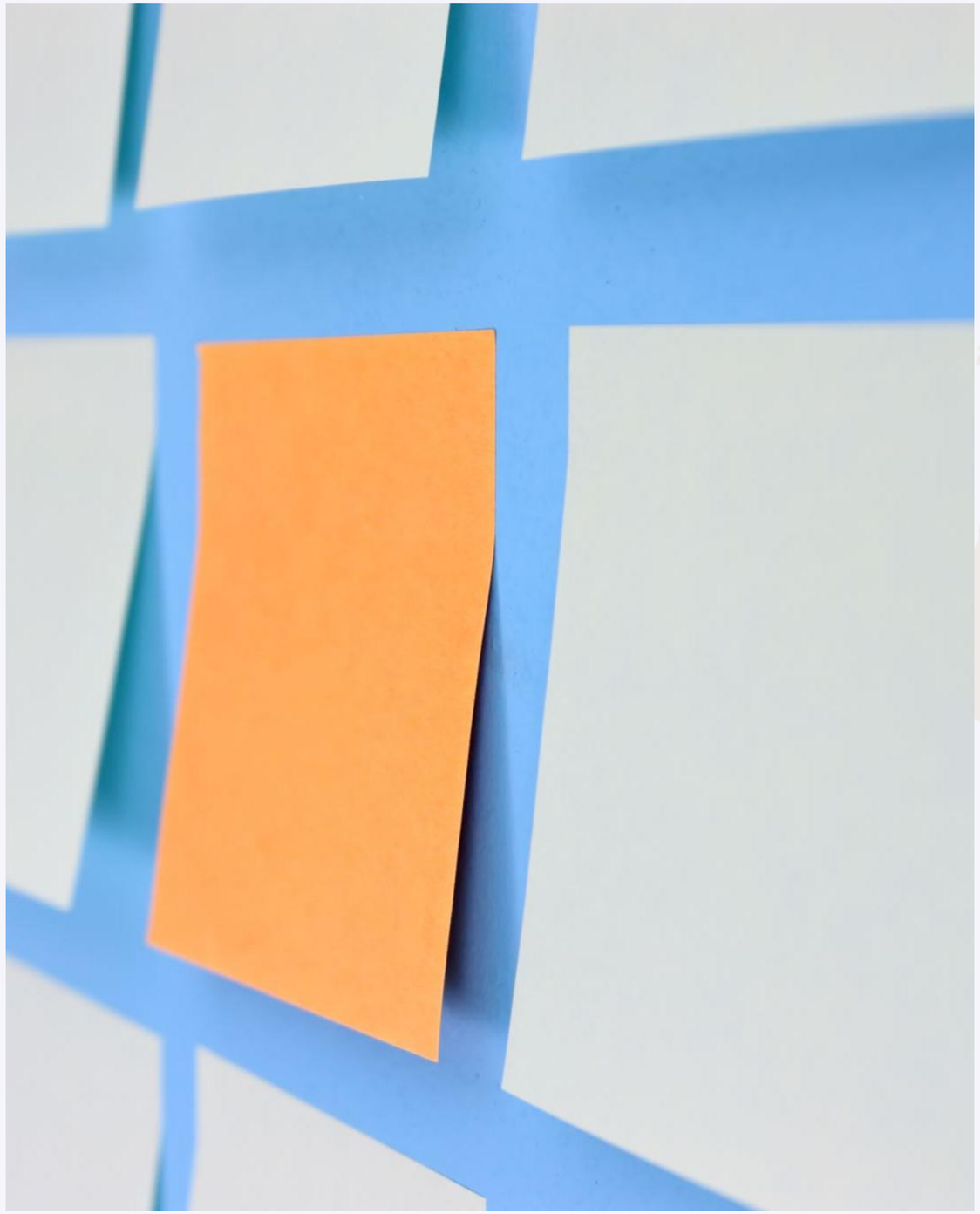
What Auditors are Looking For:

- Is clinical literature relevant to the condition being treated with the device or on clinical literature relevant to similar devices?
- If the methods and protocols to communicate effectively with competent authorities, notified bodies, economic operators, and users?
- Is there evidence for the established methods and tools to investigate complaints or market experiences?
- If there is a PMCF plan as part of the PMS plan. If not, is a justification provided in the PMS plan?

What Auditors are Looking For:

- Are post-market surveillance reports defined and available for Class I? Are they actively updated per Plan?
- For class IIa, IIb, and III devices is there a periodic safety update report (PSUR) for each device defined or per group, and available as relevant?
- For manufacturers of Class IIa PSUR should be updated at least every two years and for Class IIb and III updated at least annually.
- Is the PSUR submitted to the notified body for reviewing Class III (annually) & Class IIb (every two years) in the absence of EUDAMED?

The use of templates for PSUR as included in MDCG 2022-21 is recommended but not mandatory to be used by the manufacturer.



The Common NCs

Tales from the Trenches

Poll #5

Post Market Surveillance

- No PMS Plan or Report.
- Reports are not prepared in accordance with the PMS Plan.
- Proactive inputs are not visible.
- No documented links from PMS to Risk Management or Design Control.

Post Market Clinical Follow-Up (PMCF)

- No documented PMCF Plan.
- Even if it is not required, a PMCF Plan must be documented.

Takeaways - Conclusion

- Understanding the PMS requirements of the MDR is only one of the steps in the journey of compliance. Translating these requirements into your QMS is equally as important.

- Clearly and explicitly documenting all the requirements with precise details is fundamentally important for an effective compliance regime.

- Auditors only accept objective evidence. Subjective and anecdotal evidence is never satisfactory to demonstrate compliance.

Thank You For Listening!

Questions?