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NB Audit of the QMS Documentation 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 Slegers
Director of Regulatory
Affairs & PRRC
MedEnvoy Global

Our Speakers

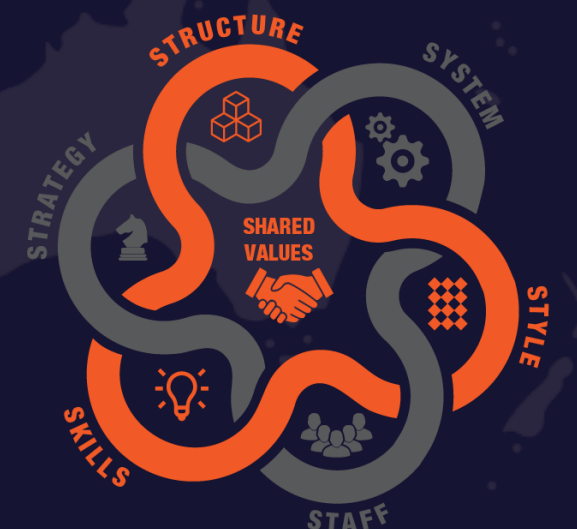
Salman has been in the medical devices industry for over 20 years and has worked in R&D, Manufacturing, QA/RA within the medical devices industry and subsequently worked over a decade as Lead Auditor / Technical Reviewer for reputable European Notified Bodies including LRQA, SGS and NSAI, etc. Salman's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

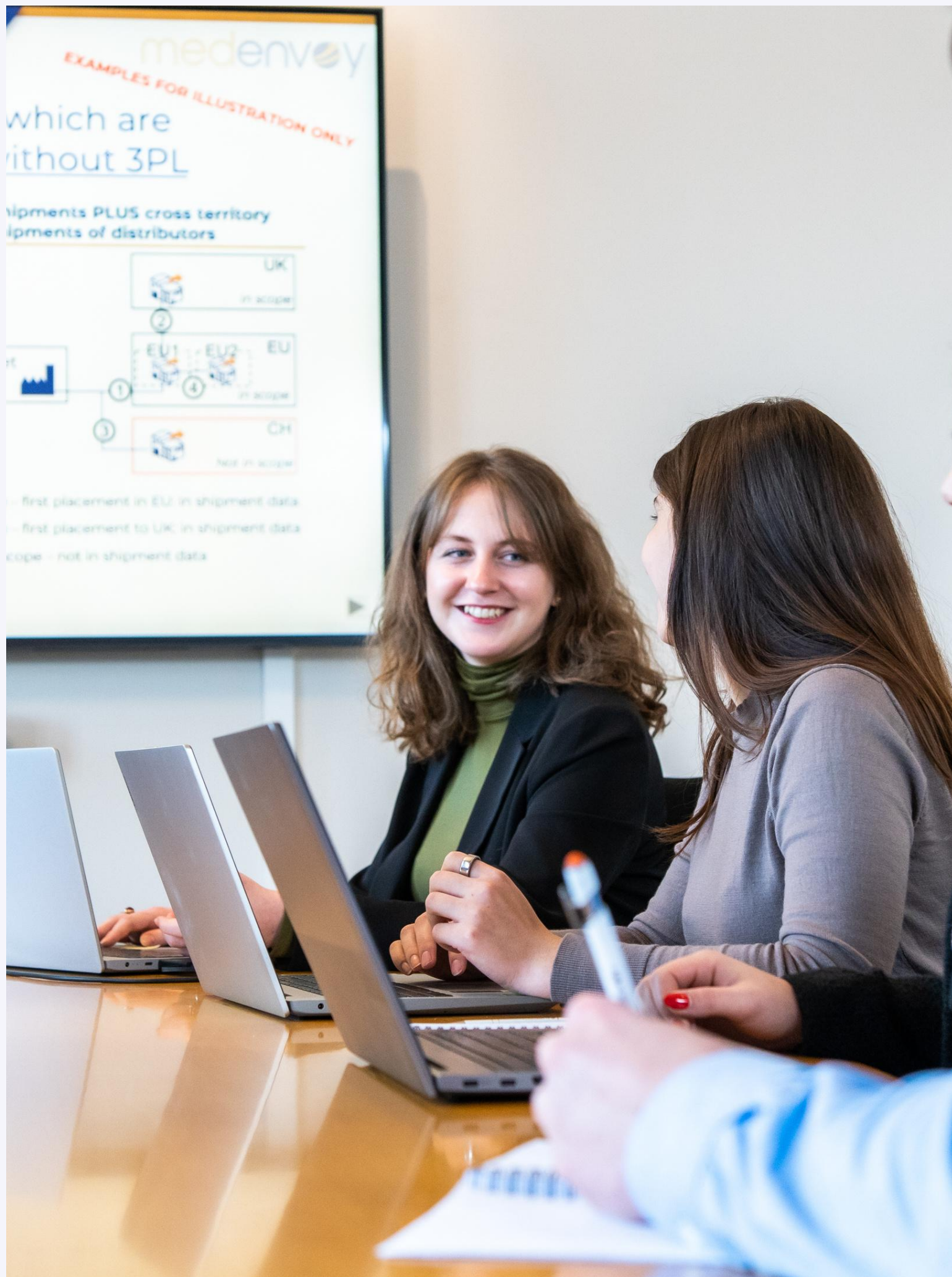
**Principal Consultant
Razalution Bureau**



Agenda

1. Auditing QMS under MDR 2017/745
2. Most Common NCs Identified During the Audits

Poll #1



QMS Audit Expectations



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QMS Requirements – Annex IX

There are approximately 35-40 questions covered during an on-site QMS Audit under the MDR 2017/745.

Poll #2

Sub-Contracted Activities

- **Intent:**

Are sufficient controls in place on a third party where the manufacturer sub-contracts design, manufacture, final inspection, testing, sterilization, or regulatory compliance of a medical device, and does the manufacturer retain all final responsibility?

- **What Auditors Are Looking For?**

Evidence of any agreements that need to be in place with third parties (outsourced parties / critical sub-contractors) and also review QMS to see if the interaction(s) with key third parties are clearly defined.

Unannounced Audits

- **Intent:**

Does the manufacturer have an adequate process for managing unannounced audits, providing the NB with the appropriate information, and contracts with identified relevant subcontractors/suppliers that give the NB right of access?

- **What Auditors Are Looking For?**

Evidence of the manufacturer's Unannounced Audit procedure. Additionally, if the manufacturer has contracts in place with the critical/relevant contractors and relevant suppliers associated with manufacturing activities, allowing access for UA's.

Product Classification Process

- **Intent:**

Is there a documented procedure for defining the classification of devices and following the correct assessment route?

- **What Auditors Are Looking For?**

This may be documented, with rationale, as part of the original Technical Documentation of the device for classifying the device and tools used, or a separate procedure giving the rationale on how classification decisions are made.

Notification of Changes

- **Intent:**

Is there a documented procedure for informing the NB of significant changes in the quality system, product ranges, clinical investigations (MDR), regulatory actions, etc.?

- **What Auditors Are Looking For?**

Evidence of any change notified to the NBs (Change Log Review and NB Database of received change notifications).

Registration Process

- **Intent:**

Is there a documented procedure for medical device registration (e.g. Class I, Custom-made device, procedure pack according to Article 22, etc.) and have appropriate products been registered where required by the manufacturer or their authorised representative?

- **What Auditors Are Looking For?**

Procedure and Process for EUDAMED Registration (as appropriate) and Changes submitted to the EUDAMED.

Authorized EU Representative

- **Intent:**

Are there adequate arrangements and controls in place for the EU Rep?

- **What Auditors Are Looking For?**

Details for the EU Rep (Name, Address, etc.), Contractual Agreement (Clear demarcation of responsibilities), written acceptance of the EU AR for the mandate given by manufacturer, SRN, AR's PRRC details, etc.

Poll #3

Declaration of Conformity

- **Intent:**

Is there a documented procedure for the production of EC Declarations of Conformity and are they available, and correct?

- **What Auditors Are Looking For?**

Sample DoC and compare against the requirements of Annex IV of the MDR 2017/745.

External Documents

- **Intent:**

Does the manufacturer have access and use all relevant EU guidance and interpretive documents including MDCGs, MEDDEVs, NB MED, harmonised standard Annex Z's (Harmonised standards are not mandatory), and current CS and implementing acts?

- **What Auditors Are Looking For?**

They will check the control of external documents to ensure that the manufacturer has access to all the applicable regulations, standards, and guidance documents. Ideally, external documents should be controlled through the adopted document control process.

Document and Record Retention

- **Intent:**

Are documentation and record retention times correctly specified (in a procedure) and are documents retained according to the organisation's document retention policy/procedure?

- **What Auditors Are Looking For?**

If the defined lifetime of devices correlates with the retention time of documents, and the procedure. The manufacturer shall keep up to date a list of all UDIs (UDI-DIs and UDI-PIs) that they have assigned (Article 27(7) MDR. Retention time cannot be less than 10 years.

Responsibilities, Authorities and the PRRC

- **Intent:**

Is the structure of the organisation, the authorities, responsibilities, qualifications and competency of managerial staff adequate to ensure MDR compliance? Does the manufacturer have a designated person responsible for regulatory compliance (PRRC) with appropriate qualifications and responsibilities?

- **What Auditors Are Looking For?**

Org. Chart, Job Descriptions, particularly for the PRRC and Alternative PRRC per the MDCG 2019-7.

General Safety and Performance Requirements (GSPR) & Risk Management

- **Intent:**

Are there documented procedures for risk management that ensure compliance with GSPR's 1-9 (MDR) and in particular that: all hazards have been identified; all risks have been evaluated and have become part of the overall risk-benefit evaluation; all risks have been reduced as far as possible; all remaining risks have been subject to protection measures and safety principles have been applied in a way that is compatible with the state-of-the-art.

- **What Auditors Are Looking For?**

Alignment of Risk Management Procedure with GSPRs - Focus is on the QMS Process, not on the claims.

Design Control & Design Changes

- **Intent:**

Do design procedures demonstrate conformance to GSPR and legal requirements?

- **What Auditors Are Looking For?**

They will sample a design project and assess the coverage of GSPR in design documentation.

Technical Documentation

- **Intent:**

Is there a documented procedure to ensure appropriate technical documentation is adequate, valid and controlled for CE products and is consistent with current production? On a sample basis, is production consistent with the technical documentation? Technical documentation must be kept up to date and shall be compliant with requirements set out in Annex II and III of the MDR

- **What Auditors Are Looking For?**

Does the manufacturer have a procedure for producing technical documentation according to Annex II and III? Does this procedure require production aspects to be included in the technical documentation? A process walk of the product line is usually used to verify that production is consistent with the technical documentation.

Process Validation

- **Intent:**

Are critical manufacturing processes including sterilisation documented, validated and adequately controlled and recorded?

- **What Auditors Are Looking For?**

Is there a documented procedure? Have all the critical processes been validated? If the process is running within its validated parameters. They will verify validated settings in real-time for validated processes / critical equipment on process-walk.

Labelling & IFU (including the CE Mark and e-Labelling) **UDI Management**

- **Intent:**

Assess if there is a documented procedure for ensuring labels and IFUs meet the General Safety and Performance Requirement (GSPR) 23 for MDR? Are they controlled, reviewed and approved?

- **What Auditors Are Looking For?**

The focus is on the process, how the contents for the labels and IFU are reviewed and approved against the requirements of GSPR 23. How are the labels and IFUs controlled? If e-labels are used, then they will assess their applicability and compliance against (EU) 2021/2226.

- **Intent:**

Is there a documented procedure for producing UDI and placing it on the device in accordance with articles 27 to 30 of MDR (EU) 2017/745?

- **What Auditors Are Looking For?**

If the procedure covering requirements. Registration with UDI Agencies (e.g. GS1), Management of Basic UDI-DI; Process for UDI-PI generation. Verification through sample.

Vigilance, FSCA and FSN

- **Intent:**

Is the EC Vigilance Procedure fully incorporated into the documented process of the client and in line with current EC Guidelines?

- **What Auditors Are Looking For?**

If the procedure covering requirements from Article 87-89, and Vigilance Guidelines (MEDDEV 2.12-1 and MDCG 2023-3. Are reporting timelines correctly identified? Evidence through Sampling.

UDI Management

- **Intent:**

Is there a documented procedure for producing UDI and placing it on the device in accordance with articles 27 to 30 of MDR (EU) 2017/745?

- **What Auditors Are Looking For?**

How is UDI managed and controlled? They verify if a lot number, serial number, software identification or expiration date appears on the label that they are part of the UDI-PI.

Device Testing

- **Intent:**

Is the approved device consistently produced?

- **What Auditors Are Looking For?**

Observe and verify tests critical for the device release, especially those that are referenced in the technical documentation.

Pre-Clinical & Clinical Evaluation

- **Intent:**

Is there a documented procedure to plan, conduct, report, and update pre-clinical, and clinical evaluation of the product?

- **What Auditors Are Looking For?**

The focus is on the process (not the content).

Post Market Surveillance & Post Market Clinical Follow-Up

- **Intent:**

Is there a documented procedure for PMS which meets MDR requirements? Is there an on-going PMCF study protocol being implemented?

- **What Auditors Are Looking For?**

The focus is on the process. If the process has both pro-active and reactive inputs? Is the frequency defined? Is the generated PMS Report (Class I) or PSUR compliant? Are methods of communication with the NB and CA defined? Is the manufacturer aware of the guidance documents, e.g. MDCG 2022-21 for PSUR?

Liability Insurance

- **Intent:**

Does the manufacturer have measures in place to provide sufficient financial coverage in respect of their potential liability under Directive 85/374/EEC, without prejudice to more protective measures under national law?

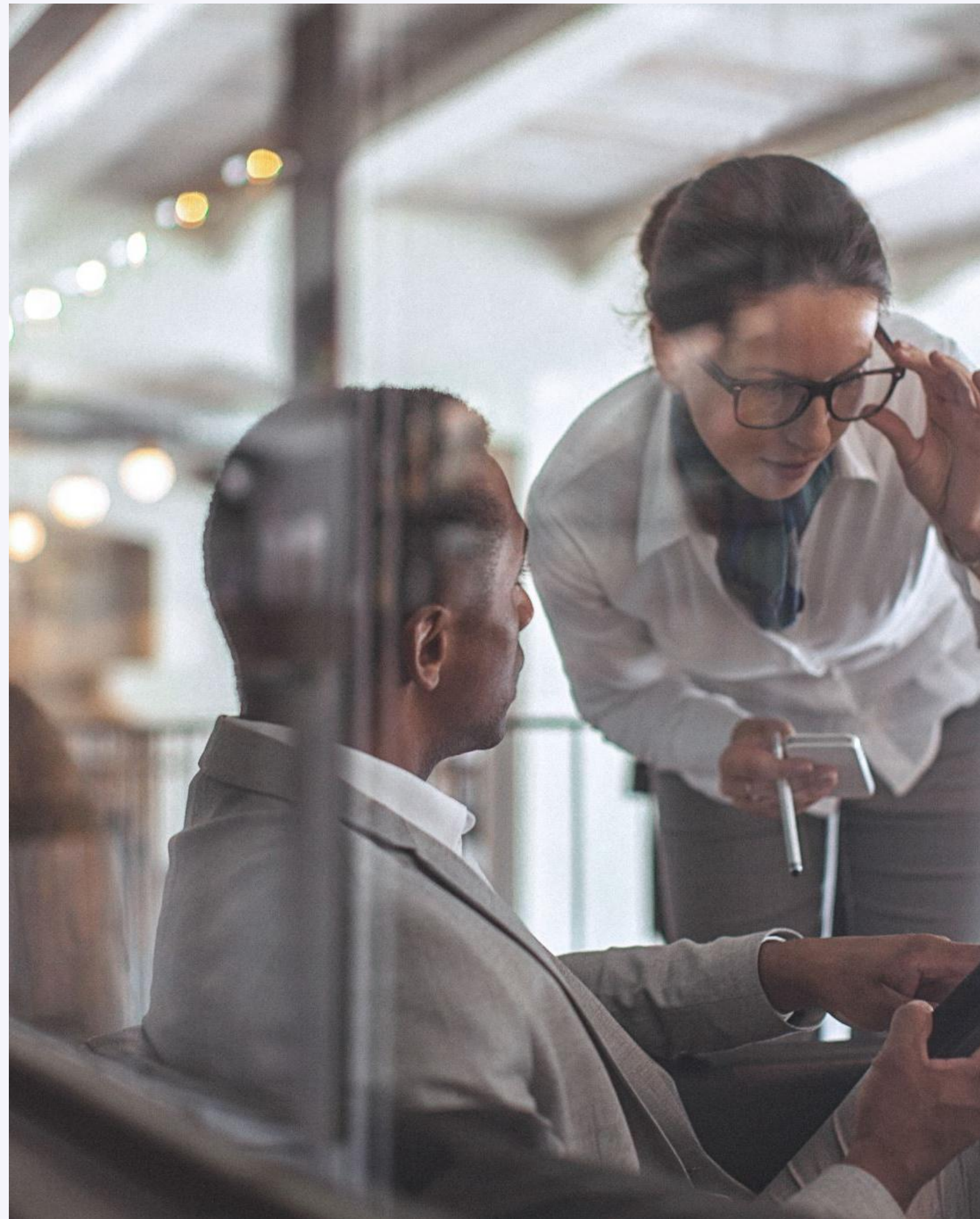
- **What Auditors Are Looking For?**

Review the liability insurance and if it covers sufficient financial coverage. How thorough is the insurance?

Poll #4

Some Other Aspects

- Device Specific – Alignment of QMS and the Contract with NB
- Incoming, In-Process & Final Inspection
- Continuous Improvement
- Class III MDR Specific Requirements
- Custom-made Devices
- Article 22 – Procedure Pack
- EC Type Test Examination Certificates



The Common NCs

Tales from the Trenches

Poll #5

The Common NCs

Sub-Contracted Activities

Sub-contracted activities are not identified and no demarcation of the responsibilities.

Unannounced Audits

The contract with the critical suppliers does not cover a clear indication for allowing the NBs to conduct unannounced audits.

Notification of Change

Changes were not notified to the NB.

Registration

No indication of who the EU Importer is? No clear and explicit contractual agreement with the EU Importer. No demarcation of responsibilities between Economic Operators, i.e., the manufacturer, the Authorized EU Representative, the Importer, Distributors, etc.

The Common NCs

Person Responsible for Regulatory Compliance

Qualification and competence for the PRRC is not adequately justified as per Article 15. OR Job Description of the PRRC does not identify responsibilities as required by Article 15.

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.

Liability Insurance

No liability insurance or no clear indication for how a liability claim will be assessed and compensated.

Takeaways – Conclusion

- Understanding requirements of Annex IX 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?