Thank you to all who joined us for our webinar on **Quality Management System (QMS) Documentation under MDR**, featuring expert presenter Salman Raza. During the session, Salman shared key insights from the perspective of a notified body, providing a detailed breakdown of MDR compliance requirements, particularly focusing on auditing QMS during onsite assessments.

**Key Topics Covered:**

1. **Auditing QMS Under MDR**: Salman explained the fundamental steps that auditors take when assessing a manufacturer's QMS to ensure it meets MDR requirements, referencing Annex IX of the regulation.
2. **Most Common Non-Conformities**: We discussed common non-conformities identified during audits, such as:
    a. Lack of documented procedures
    b. Insufficient controls over subcontracted activities
    c. Missing unannounced audit procedures
    d. Inadequate change notification processes
3. **Subcontracted Activities and Unannounced Audits**: A focus was placed on the need to properly document and control subcontracted activities, as well as ensure that procedures are in place for handling unannounced audits.
4. **Change Notification Procedures**: The importance of having clear and effective procedures for notifying notified bodies of significant changes was emphasized.
5. **EU Representative & Contractual Obligations**: An in-depth discussion on the role of the EU representative, their contractual obligations, and the requirements for demonstrating compliance within the QMS.
6. **Post Market Surveillance and Clinical Follow-Up**: We highlighted the importance of a robust post-market surveillance plan and ensuring a clinical follow-up is in place, even when not explicitly required.

**Key Takeaways:**

- **Process Focus**: Auditors primarily focus on the processes you have in place, not necessarily the content of your documents. Ensuring that processes are well-documented and followed is crucial.
- **Continuous Compliance**: For successful MDR compliance, procedures must be maintained and followed, with emphasis on post-market surveillance, clinical follow-ups, and ensuring compliance with all relevant standards.
- **Regular Audits**: Notified bodies conduct frequent and sometimes unannounced audits to assess compliance, and manufacturers must be prepared.