

In our latest webinar, we delved into the roles and responsibilities of economic operators under the MDR and IVDR, from the perspective of notified bodies. Here are some of the key topics and insights shared by our expert speakers:

Key Topics Covered:

1. **Economic Operators Overview:**
 - a. Manufacturers, Authorized Representatives (ARs), Importers, and Distributors are the four key economic operators under MDR/IVDR.
 - b. The importance of clearly defining these roles within your Quality Management System (QMS) and ensuring proper contracts are in place.
2. **Authorized Representatives (ARs):**
 - a. ARs act as the liaison between manufacturers and the EU market, bearing significant legal responsibility for ensuring compliance with regulatory requirements.
 - b. Their role has become more critical with the MDR, as they share liability with manufacturers.
3. **Importers and Distributors:**
 - a. Importers are responsible for ensuring that products meet regulatory requirements when entering the EU.
 - b. Distributors handle product storage, transportation, and delivery to end users. Their compliance duties were also emphasized.
4. **Practical Challenges:**
 - a. A common non-compliance issue encountered during audits is the lack of clearly defined roles and responsibilities among economic operators. Clear documentation and contractual agreements are crucial to avoid major non-conformities during audits.
 - b. The importance of having a documented process for handling complaints, recalls, and Field Safety Corrective Actions (FSCA) was also highlighted.

Questions Answered:

- **What are the most common non-compliance issues during audits of economic operators?**
Key issues included the lack of clear contracts, improper documentation of roles, and confusion over responsibilities between the different operators.
- **What steps should economic operators take to ensure compliance during recalls or FSCA?**
It's crucial to have a well-defined communication flow and responsibility assignment in place, ensuring all economic operators understand their roles in the process.
- **How do economic operators stay informed about changes in the MDR/IVDR?**
While notified bodies may not directly inform you about regulatory updates, it's important for manufacturers and economic operators to stay informed via resources like newsletters, regulatory updates, and through active collaboration with ARs and other stakeholders.

Additional Insights:

- The role of the **Person Responsible for Regulatory Compliance (PRRC)** was touched upon, specifically for manufacturers and ARs. The PRRC ensures ongoing compliance, including post-market surveillance and product recall management.