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# **NB Audit of the Economic Operators Under MDR 2017/745**

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# Our Speakers

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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

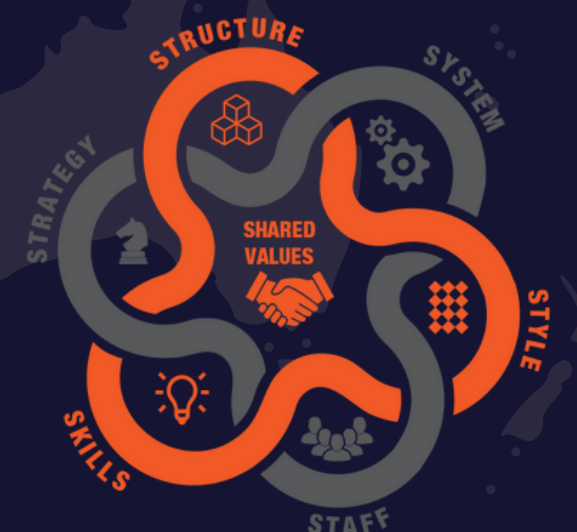
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Salman has been in the medical devices industry for over 20 years and has worked in R&D, Manufacturing, QA/RA within the medical devices industry and subsequently worked over a decade as Lead Auditor / Technical Reviewer for reputable European Notified 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

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1. Auditing Economic Operators Under MDR 2017/745
2. Most Common NCs Identified During the Audits



# Economic Operators

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as Defined under the MDR

Poll # 1

# Economic Operators

The term “economic operators” is defined in EU MDR 2017/745 as a

- Manufacturers
- Authorized Representatives
- Importers
- Distributor

Or a person” that is part of the product supply chain (SPP producers/Suppliers).

# Manufacturers (Article 10)

## Definition:

- A natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished, and markets that device under its name or trademark

**Key point:** They are the legal entity that owns the technical documentation and of the product.

## Responsible For:

- EU MDR Compliance
- Device and manufacturer registrations
- Design, development and manufacture of medical devices
- Quality Management System
- Post-Market Surveillance
- Labelling
- Safety and performance

# Authorized Representatives (Article 11)

## Definition:

- Any natural or legal person established within the Union who has received and accepted a written mandate from a manufacturer, located outside the Union, to act on the manufacturer's behalf in relation to specified tasks with regard to the latter's obligations under this Regulation.

## Responsible For:

- Liaison between EU regulatory authorities and manufacturers outside of the EU. **AR Perspective.**
- Maintaining the Technical Documentation and Declarations of Conformity on behalf of the manufacturer
- Notifying authorities of serious incidents and corrective actions

**Key point:** They are the legal entities within the EU with written agreements to act on behalf of a manufacturer located outside the EU to meet MDR obligations.

# Importers (Article 13)

## Definition:

- Any natural or legal person established within the Union that places a device from a third country on the Union market.

**Key point:** They are the legal entity that has financial ownership over the product once it crosses the border into the US and are responsible for placing the product on the EU market for the first time.

## Responsible For:

- Placing a non-EU product on the EU market
- Confirming EU MDR regulatory compliance of devices
- Maintaining records of devices and manufacturer details
- Notifies the manufacturer and authorities of any known safety issues
- Note: They do not act on the manufacturer's behalf
- Importer Perspective

Poll # 2

# Distributors (Article 14)

## Definition:

Any natural or legal person in the supply chain, other than the manufacturer or the importer, that makes a device available on the market up until the point of putting into service.

- This could include individual shops, pharmacies, or retailers or other natural or legal persons meeting this definition.

## Responsible For:

- Handling storage, transport and delivery of medical devices within the EU
- Provide a product of another manufacturer up to the time of commissioning
- Ensures compliance through the supply chain

**Key point:** They are the legal entity that takes the product once it has already been placed on the EU market and transfers it to another distributor or the end user.

# Person Responsible for Regulatory Compliance (PRRC) (Article 15)

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- Ensures and maintains device conformity within the QMS, recall processes, post-market surveillance, and availability of device declaration of conformity and technical documentation when requested.
- The person chosen as PRRC must have at least one year of experience with Quality Management Systems (QMS) for medical devices, a formal certification such as a university degree or diploma, and enough expertise in the relevant medical device.
- This is a requirement for Manufacturers and Authorized Representatives. PRRC is not required for Distributors and Importers\*

# Definitions per MDR Article 2

## ‘Making available on the market’

- Any supply of a device, other than an investigational device, for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge.

## ‘Placing on the market’

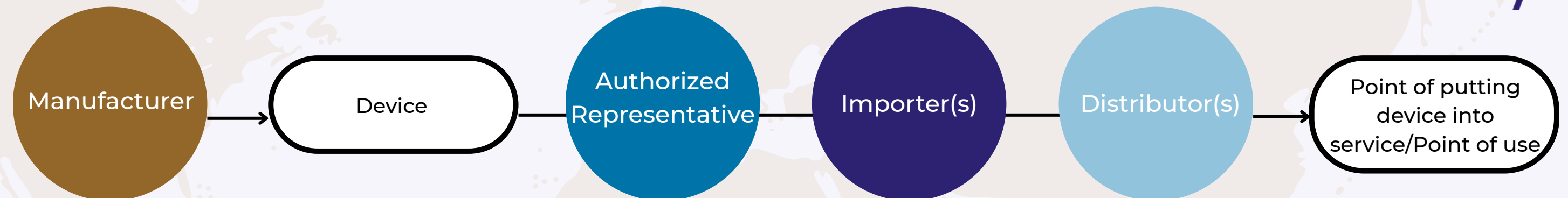
- The first making available of a device, other than an investigational device, on the Union market.
  - Note: This would be the responsibility of an importer.

## ‘Putting into service’

- The stage at which a device, other than an investigational device, has been made available to the final user as being ready for use on the Union market for the first time for its intended purpose.

Poll # 3

# Economic Operators Relationship



**Importer**  
Any natural or legal person established within the Union that places a device from a third country on the Union market.  
(MDR Article 2(33))

**Distributor**  
Any natural or legal person in the supply chain, other than the manufacturer or the importer, that makes a device available on the market, up until the point of putting into service  
(MDR Article 2(34))

**Point of Use**

**Health institution**  
Organization the primary purpose of which is the care or treatment of patients or the promotion of public health.  
(MDR Article 2(36))

**Placing on the Market**  
The first making available of a device, other than an investigation device, on the Union market.  
(MDR Article 2(28))

**Making available on the Market**  
Any supply of a device, other than an investigational device, for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge.  
(MDR Article 2(27))

**User**  
Any healthcare professional or lay person who uses a device.  
(MDR Article 2(37))

# What Auditors Are Looking For?

## Clear Agreements between the manufacturer and the importer which requires:

- The importer to inform the manufacturer or authorized representative if information in the electronic system is not included or is incorrect
- The importer registration in EUDAMED and any changes (the link between importers and manufacturers in EUDAMED are made by the importer)

## Clear Agreements between the manufacturer and the Authorized Representative which requires:

- The authorized representative registration
- Now to be Critical Supplier
- Notification of changes

# What Auditors Are Looking For?

(Cont.)

- Agreements should follow any additional requirements per Article 16 – cases in which obligations of manufacturers apply to importers, distributors or others
- If an entity is both the EU Authorized Representative AND the Importer, it must be clearly documented as such



# The Common NCs

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## Tales from the Trenches

Poll # 4

# Economic Operators

- Not Defined with the QMS.
- Contracts not in place.
- Roles of EU Rep, Importers and Distributors are not defined.



# CARs

## **A Major CAR would be raised if:**

- There are no agreements with the Authorized Representative and Importer
- The agreement in place does not cover applicable requirements of Article 16

## **A Minor CAR would be raised if:**

- The agreement in place does not cover registration and changes

# Takeaways - Conclusion

- Understanding the 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.

Poll # 5

# Thank You For Listening!

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Questions?  
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