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VIRTUAL PANEL DISCUSSION

Essential Strategies for Completing the Transition to MDR/IVDR

Wed, May 17th, 2023

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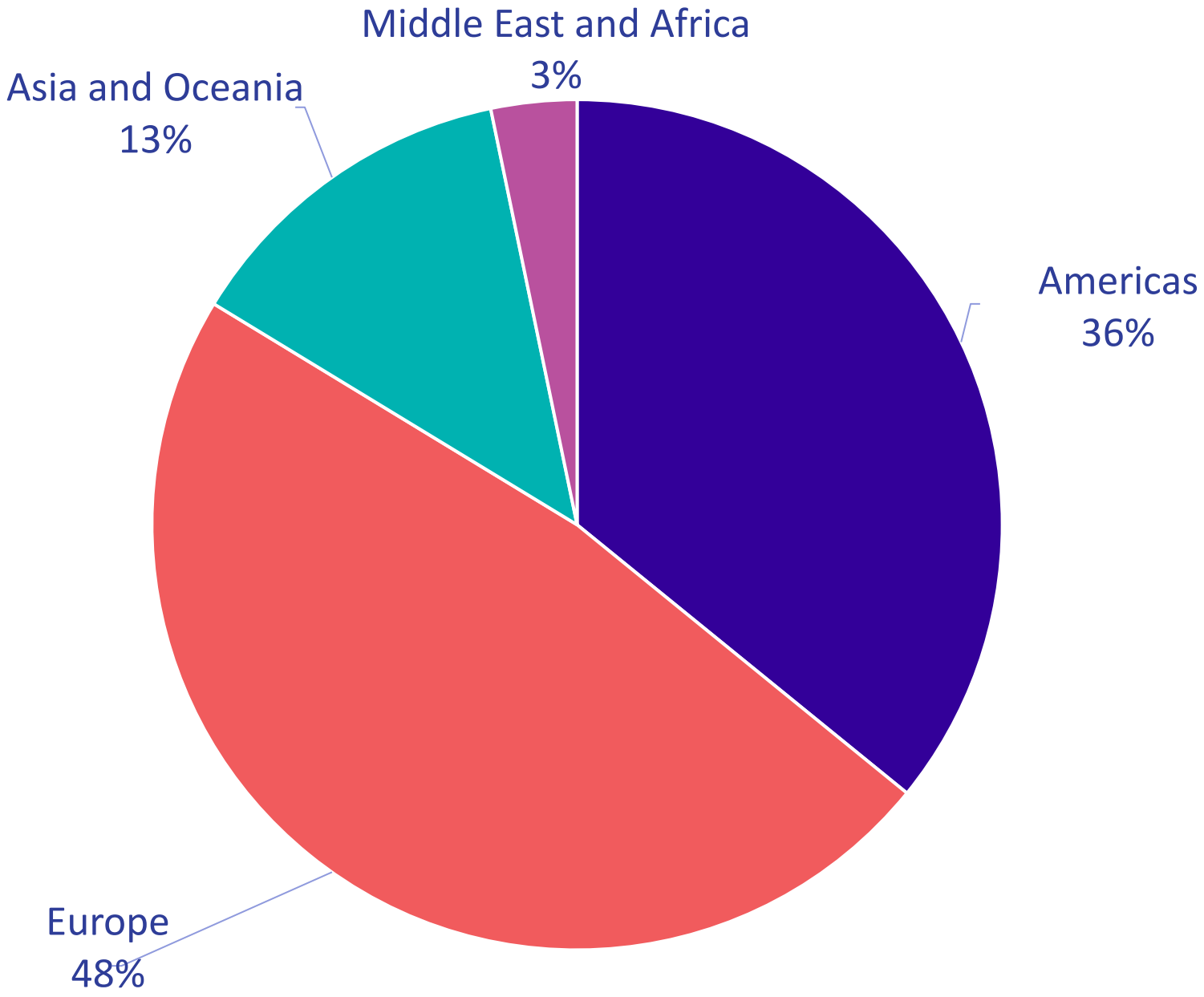

90% of currently valid AIMD/MDD certificates were set to expire in 2023.

50% of resubmitted applications were deemed incomplete.

Failure to comply with the EU MDR can result in inability to market devices in the European Union.

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Essential Strategies for Completing the Transition to MDR/IVDR

European Commission

Agenda

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- What's EU MDR/IVDR
- Background
- Timeline
- EU MDR/IVDR Requirements
- Major additions from MDD/IVDD to MDR/IVDR
- Transition strategy from MDD/AIMDD to MDR
- Transition strategy from IVDD to IVDR
- Case studies
- Q&A

Note to Audience

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This presentation is built off our prior experience working with various manufacturers ensuring their compliance with EU-MDR and EU-IVDR.

The strategies we are presenting here are at a high level, and while this can get you started, each manufacturer and product are unique, and the requirements for compliance may vary depending on the risk-profile and intended use of the product.

The Regulations

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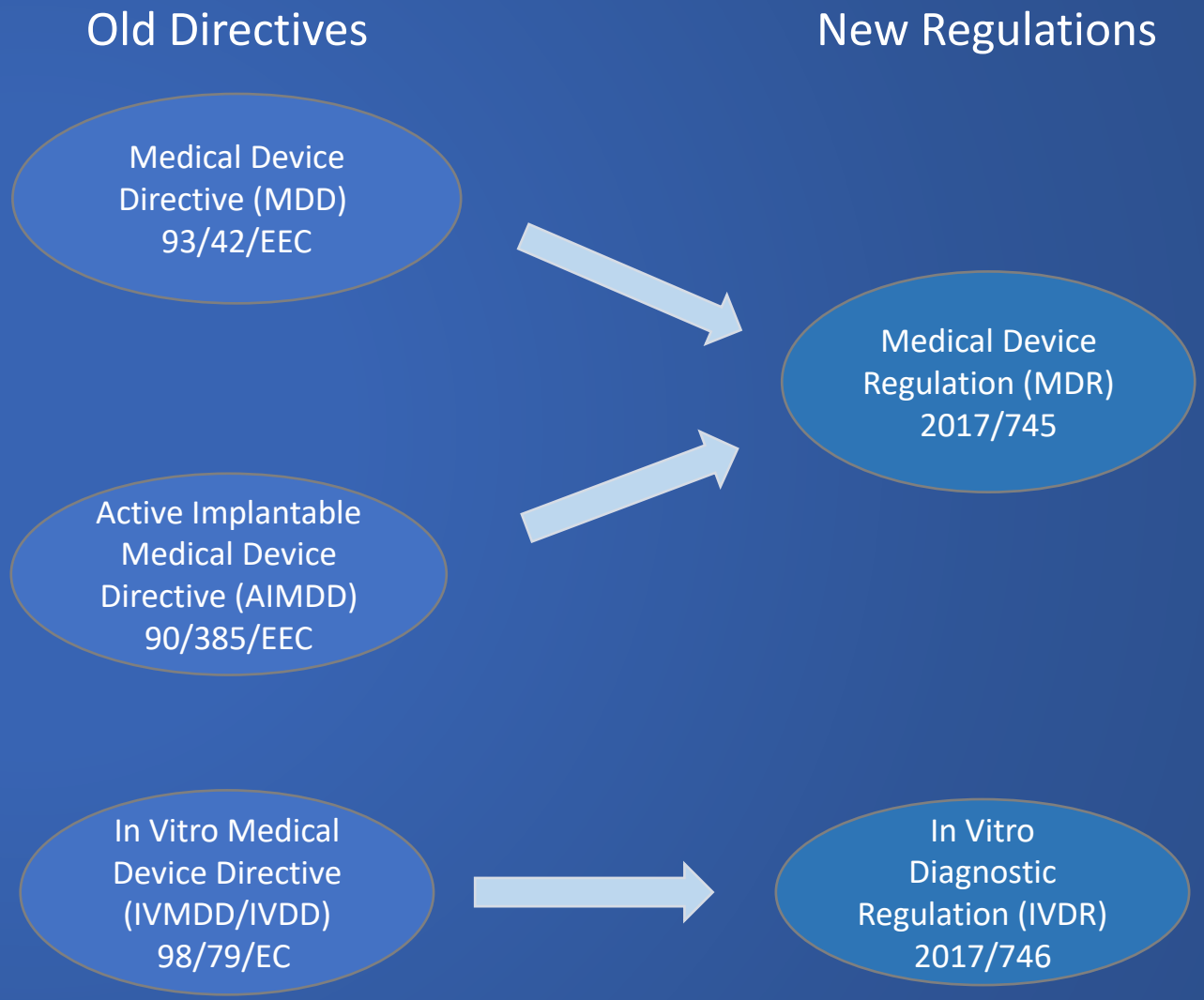
The European Union Medical Device Regulation (EU MDR) 2017/745 and In Vitro Diagnostic Device Regulation (EU IVDR) 2017/746 were developed to replace the existing Medical Device Directives (MDD) and In Vitro Diagnostic Directive (IVDD).



What is EU MDR/IVDR

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- It is considered a legal and binding regulation for medical device manufacturers doing business in the EU
  - applies to all manufacturers who intend to begin or continue to sell/import medical devices into the European Union countries
  - which will have legal ramifications for noncompliance

- All Medical Device performance, quality and regulatory attributes must comply with the applicable requirements of EU MDR 2017/745 and EU IVDR 2017/746 regulation which comprises of applicable Articles and Annexes.

MDR/IVDR Impact

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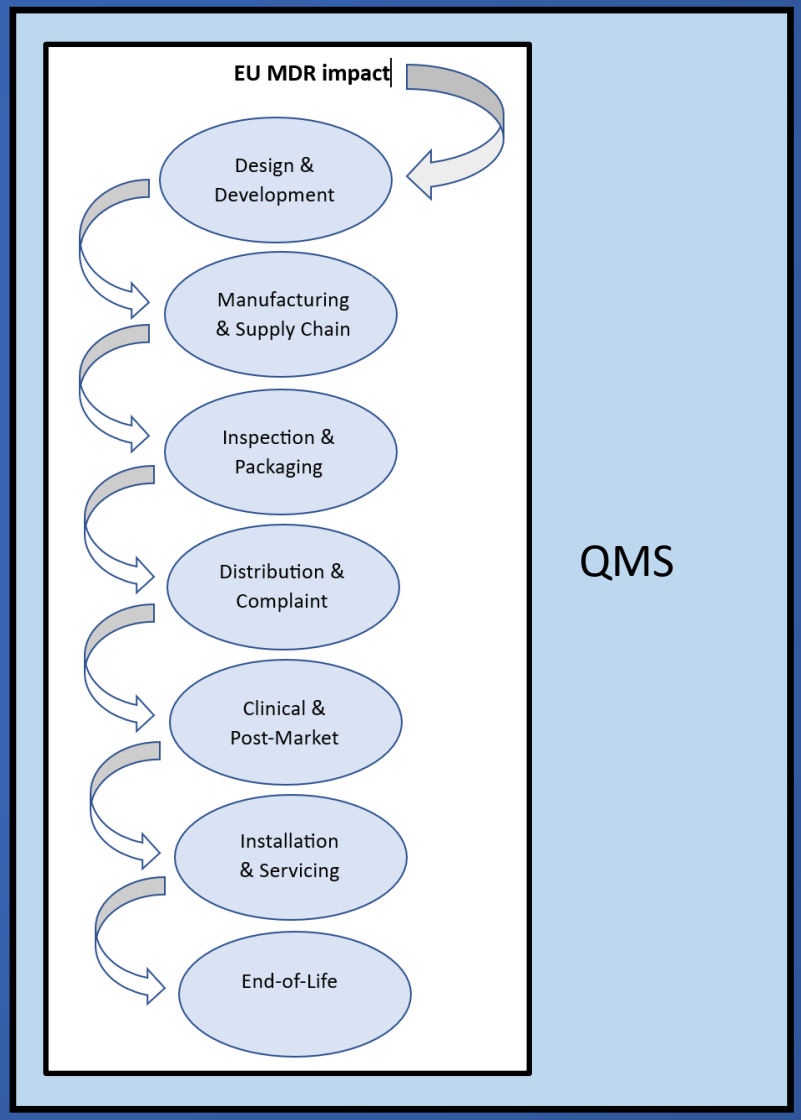
EU MDR/IVDR impacts total product lifecycle processes, including:

- Design and Development
- Purchasing
- Facilities
- Manufacturing
- Inspection
- Packaging
- Distribution
- Clinical
- Installation and Servicing
- Complaints
- Post-Market



Why the changes?

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In general, the changes and enhancements to the directives are aimed to ensure that regulations improve patient safety by ensuring that medical devices and IVDs placed on the market are safe and effective, and meet the intended use and purpose[1].

[1] *Regulation (EU) 2017/745*

Reason for change…

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Poly Implant Prothése (PIP)

- Manufactured breast implants around the world:
  - First with silicone – FDA stopped the use of industrial silicone
  - Next with saline – there were issues with rupturing implants
  - Finally, PIP was approved to sell implants with medical grade silicone
- PIP began making “home-made” industrial grade silicone implants
- Over time, abnormally high rates of implant ruptures were observed leading to PIP having significant regulatory and legal challenges
- TUV Rhineland was accused of keeping “*PIP on the European and global market for a further ten years before the French sounded the alert*”.[1]
- All PIP products removed from market, company liquidated, French government recommended 30,000 women with PIP implants remove them as a precaution.
- Legal ramifications for PIP CEO and TUV Rhineland.

How new Regs better protect

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- The new EU MDR and IVDR regulations place a greater emphasis on ensuring safety and efficacy, with increased requirements for clinical evidence and post-market surveillance, a duty to report serious incidents, compiling important identification, safety and efficacy data in a database, and to update this information on an on-going basis.
- Overall, while these changes to the regulations may not guarantee the prevention of another PIP, they will significantly reduce the risk of it occurring again.

New Regulations History

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The regulations have been phased in since 2017, with the intention that:

- **EU MDR take effect in May 2021**, and
- **EU IVDR in May 2022.**

However, over the past few years, the timelines have changed several times.

New Timeline (MDR)

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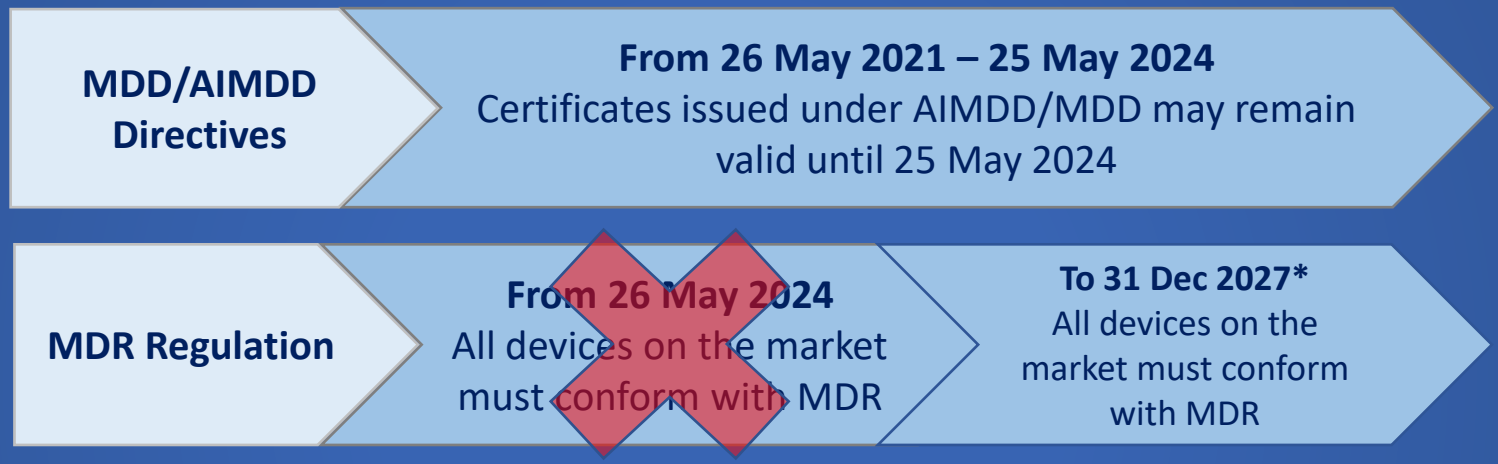

Medical Device Product extensions:

- The European Commission in Jan 2022 adopted a proposal to extend the transition for products under the EU MDR to:
- 26 May 2024 to 31 December 2027 (high-risk)
- 31 December 2028 (low-risk), depending on the risk class of the device.

New Timeline (IVDR)

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In-vitro diagnostic product extension include:

- 26 May 2025 for high-risk in vitro diagnostics
- 26 May 2027 for lower-risk in vitro diagnostics
- 26 May 2028 for certain provisions concerning devices manufactured and used in health institutions

EU MDR/IVDR Requirements

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Overall, the requirements have become more prescriptive and rigorous, which includes:

- Up-classification rules
- Unique device identifier (UDI)
- EUDAMED database to enhance traceability and transparency
- Enhanced clinical evaluation
- Enhanced post-market surveillance
- Reinforcement of regulatory requirements - stay current
- Regulatory representative responsibilities
- Extended scope on products with no medical purpose but that are equivalent to devices with a medical purpose – e.g accessories.
- Enhanced quality management system (QMS)

Major Additions MDD/IVDD and MDR/IVDR

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In general, both EU MDR and IVDR have new additional compliance requirements. They include:

Scope	The MDR has a broader scope, covering more products, including certain products that were previously classified as accessories under MDD.
Classification	The MDR has sticker classification rules for medical devices including software. Some devices that were classified as low-risk under the MDD may now be classified as a higher risk class. The IVDR has different classification rules for IVDs. The IVDD classifies IVDs based on risk, while the IVDR classifies IVDs based on their intended use.
Clinical evaluation	The MDR requires a more detailed clinical evaluation process. Manufacturers must provide more detailed information on the clinical performance and safety and update this information on an ongoing basis. The IVDR requires manufacturers to provide clinical data for all IVDs while the IVDD requires manufacturers to provide clinical data for certain classes of IVD's.
Clinical evidence	MDR and IVDR now require manufacturers to provide clinical evaluation reports that include clinical performance and safety. The information must be updated on an ongoing basis.
Post-market surveillance	The MDR has stringent post-market surveillance requirements, including the establishment of a post-market surveillance **SYSTEM** and the reporting of serious incidents and field safety corrective actions. The IVDD requires manufacturers to have a post-market surveillance plan and to report any incidents or field safety corrective actions, while the IVDR requires manufacturers to have a post-market surveillance **SYSTEM** and to report any serious incidents or field safety corrective actions.
Regulatory Representative	The MDR and IVDR requires a designated regulatory representative Person Responsible for Regulatory Compliance - PRRC.

Major Additions
MDD/IVDD and MDR/IVDR cont'd

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Unique Device Identification (UDI)	The MDR requires medical device manufacturers to include a unique device identifier (UDI) for better traceability and identification. This requirement was not present in the MDD. The IVDR requires a Basic UDI-DI (Device Identifier).
EUDAMED database	The MDR and IVDR requires manufacturers to submit PRODUCT information such as product registration, clinical investigation and post market surveillance to EUDAMED,
Vigilance and market surveillance	The MDR and IVDR introduced new requirements for vigilance and market surveillance, including reporting of serious incidents, periodic safety update reports (PSURs), and more frequent inspections of manufacturers and devices.
Conformity Assessment	The MDR/IVDR conformity assessment is now more heavily scrutinized and requires conformity assessments for all devices.
Economic operators	The MDR and IVDR introduced new or expanded roles and responsibilities for economic operators, including manufacturers, importers, distributors, and authorized representatives.
Notified Bodies	The MDR requires Notified Bodies to meet higher standards for competence and independence. The IVDD requires notified bodies to be designated by member states, while the MDR and IVDR requires notified bodies to be designated by the European Commission.
Implant cards	The MDR introduced new requirements for implantable medical devices, including the requirement for an implant card to be provided to patients. The implant card must include information about the device, including the device name, model, and serial number, as well as the name and contact information of the manufacturer.

MDD/IVD to MDR/IVDR Transition Overview

MDD/IVD to MDR/IVDR

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- **Step 1:** Develop a Plan: prepare a plan to outline the activities, timeline and deliverables
- **Step 2**: Gap Analysis: conduct a gap analysis to evaluate product classification, labeling, Quality Management System and product portfolio against the requirements of the MDR.
- **Step 3:** Person Responsible for Regulatory Compliance (PRRC): appoint a PRRC who has the necessary knowledge and expertise in regulatory compliance to ensure compliance with the regulations. The PRRC should be responsible for overseeing the transition process and ensuring that all regulatory requirements are met.
- **Step 4:** Quality Management System (QMS): update QMS to include risk management, clinical evaluation, post-market surveillance, and labeling requirements.
- **Step 5**: Technical Documentation: perform an evaluation of documents including clinical data, technical file, essential requirements checklist, RoHS technical file and design dossiers.
- **Step 6**: Clinical Evaluation Plan: maintain a clinical evaluation plan to include the collection of clinical data to demonstrate the safety and performance.
- **Step 7:** Conformity Assessments: perform a conformity assessment.
- **Step 8**: Product Portfolio: update product portfolio including changes to labeling, instructions for use, and packaging.

MDD/IVDD to MDR/IVDR cont'd

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- **Step 9**: Supply Chain: update supply chain process to include the requirements for traceability and transparency.
- **Step 10:** Unique Device Identification: obtain UDI codes for the product(s).
- **Step 11:** Training: roll out training on the requirements of EU MDR
- **Step 12:** Recertification: notify your Registrar and Notified Body for certification.
- **Step 13**: Submit Technical Documentation: submit the updated documents to Notified Body to demonstrate compliance with the MDR requirements.
- **Step 14:** Post Market Surveillance Plan: prepare and maintain a post-market surveillance plan to include monitoring the performance and reporting any adverse events to the competent authorities.
- **Step 15:** EUDAMED: register and upload applicable product data to EUDAMED.
- **Step 16:** Regulatory Changes: maintain compliance with regulatory changes.

Supporting Standards

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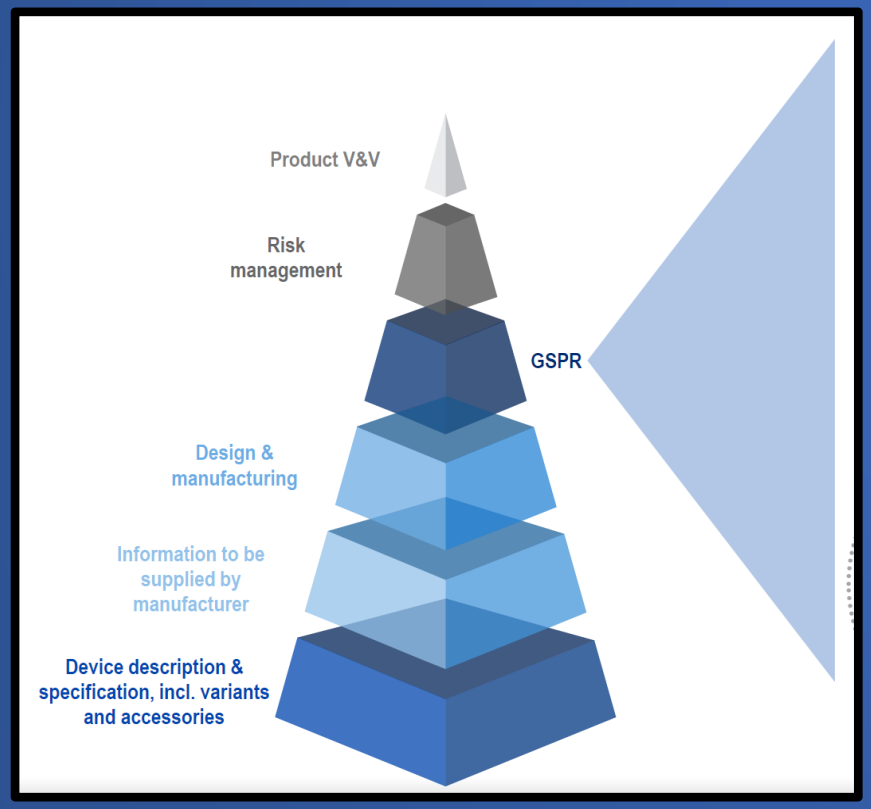
1. Global Safety and Performance Requirements (GSPR):

Medical device manufacturer selling product in the EU must comply with the requirements of GSPR. They are aimed at ensuring the safety and efficacy of medical devices. They objective evidence should be included in:



- V&V activities
- Risk management process
- Design and manufacturing compliance
- Intended use
- Labeling

Supporting Standards cont'd

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2. General Data Protection Regulation (GDPR)

- A data privacy standard to provide rules for the protection and privacy of EU citizens' personal data.
- It specifies personal data protection and management processes including cybersecurity and third-party vendors involved in the data protection process.

- Any businesses with customers in the EU, regardless of whether the company is located in the EU or not, is obligated to meet the GDPR requirements.
- Lack of compliance with the applicable requirements may include fines and/or potential loss of doing business in the EU.

Supporting Standards cont'd

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3. The **Medical Device Coordination Group (MDCG):**

- The group was created to protect the health and safety of EU citizens. Ensuring that medical devices are safe and effective and implementation regulations in the EU is consistent, transparent, and effective.
- To provide expert advice, develop common specifications, and promote harmonization among EU Member States.
- Address emerging issues, input on scientific and technical matters, and support the European Commission in its decision-making related to medical device regulations.

4. Medical Device Documents (MEDDEV)

Similar to MDD, MDR also incorporates/references the requirements of MEDDEV guidance from classification of devices to market surveillance.

Case Study 1

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Company X, a medium-sized manufacturer of a Class IIa medical device has been distributing product in the EU under MDD for over 10 years.

Objectives:

- Plan the MDD to EU MDR transition activities (timeline, resource, cost)
- Implement the new requirements

Transition Plan:

- They formed a cross-functional team with representatives from quality, regulatory, clinical, engineering and external experts to carry out the activities which included:
  - conducting a gap assessment on QMS, risk management, product classification, clinical evaluation, manufacturing, labeling, packaging, post-market surveillance, Technical Files, and conformity assessment.
- Develop a detailed report based on the gap assessment to determine the required activities.
- Identify the preferred Registrar and Notified Body for certification and registration.

Case Study 1 cont'd

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Transition Outcome:

- Updated the existing QMS
- Worked with their Registrar on EU MDR certification
- Submitted updated technical documentation to the Notified Body
- Conducted internal audits to assess the effectiveness of the updated QMS and product documentation
- Conducted employee training on the new requirements
- Implemented measures to ensure ongoing compliance.

The Results:

They successfully obtained EU MDR certification and CE registration. Maintained distribution in the EU, supplying products to their customers without interruption.

Note: although the company could have continued distribution under MDD, early planning and proper implementation ensured continuous business continuity.

Case Study 2

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Company-Y, a small-sized company that manufactured and distributed Class IIa medical devices for dental surgery. The company had been distributing product under MDD for about 5-7 years.

Objectives:

Not defined

Transition Plan:

Rather than clearly identifying the objectives, they quickly formed a cross-functional team to conduct a gap analysis and implement transition activities.

Despite these efforts they encountered several challenges during the implementation:

Challenge 1: Insufficient resources

The company's resources were limited, underestimating the efforts required to become compliant with the new requirements. The team struggled to complete the necessary changes to the quality system, regulatory, manufacturing, clinical, post-market, technical documentation, DHF and DMR (fragmented records).

Case Study 2 cont'd

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Challenge 2: Lack of understanding of new requirements

The team did not fully understand the new requirements. They ***struggled*** to interpret the regulations, leading to delays in the implementation.

Challenge 3: Incomplete technical documentation

They failed to correctly update technical documentation, which has caused delays in obtaining the CE certification. They provided inadequate information on device design, manufacturing, clinical and post-market processes.

The results:

They company failed to complete the transition as quickly as desired. They faced with a long delay in certification, additional cost, and potential business impact.

Moral of the Story

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Transition to MDR/IVDR requires:

- Proper planning, resourcing and budgeting
- Clear understanding of the regulations as applicable to the intended product(s)

Impact:

- Lack of resources, lack of understanding of the new requirements, under-estimating the process and cost, can result in delays on getting certification to continue distribution in the EU.
- This ultimately can lead to significant financial costs to the business.

Helpful Links Reminder

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- EU MDR 2017/745
- EU IVDR 2017/746
- PIP reference articles
  - https://www.theguardian.com/world/2013/dec/10/french-breast-implant-pip-jean-claude-mas-jailed
  - https://www.reuters.com/world/court-orders-germanys-tuv-pay-compensation-faulty-breast-implant-victims-2023-02-02/
  - https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3676226/

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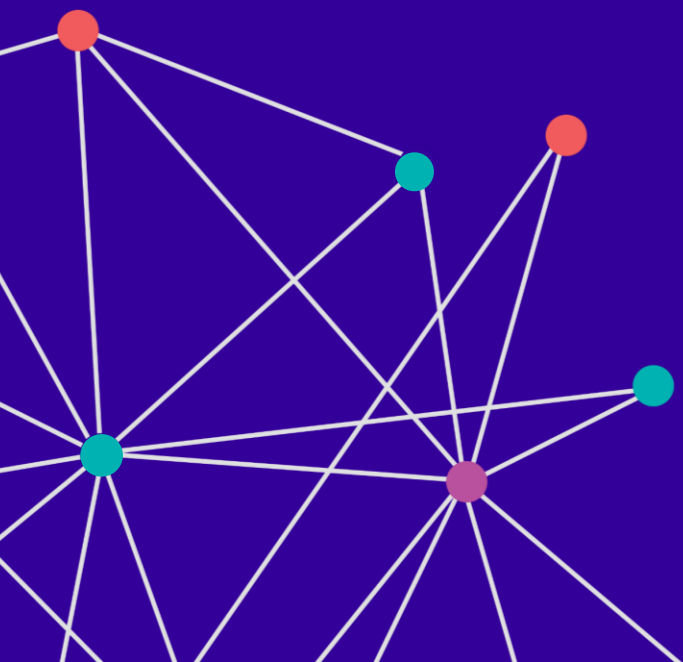

Thank you for attending!

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