Medical Devices – Managing Evolving Standards in Multiple Jurisdictions

Ella Shaw, BSc, *Samarind RMS,* Application Specialist

Dr. Dr. Michel Mikhail, Expert in Global Regulatory Affairs

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Worldwide Presence

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- Liverpool, UK
- Cambridge, UK
- London, UK
- Bury St Edmunds, UK
- Philadelphia, USA
- Shanghai, China
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- Pune, India

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Global Provider of Leading Software Solutions and Services to the Life Sciences Community

Helping our clients bring life enhancing products to market faster





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We help clients collect, analyze, report and submit to regulatory agencies with confidence. We also help reveal new insight from their data while helping them maintain regulatory compliance for their products

Preclinical Study Management

Solutions that empower organizations to more efficiently collect, review and manage preclinical safety evaluation study data

eStudy Data & Regulatory Information Management

Software and outsourced services for managing, storing, sharing, submitting and maintaining information compliant with FDA, EMA and other agency regulations

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Big Data Analytics & Information Sciences

Allowing researchers to generate new scientific insights through the identification, extraction and analysis of actionable information

Early Phase Clinical Study Management

Cutting edge integrated Electronic Data Capture and site automation solutions driving the processes of Phase I Clinical trials for evaluating new drugs or treatments

- *Shorter Cycles & Reduced costs*
- *Streamlined workflows*
- *Better management controls*
- *More effective resource utilization*
- *Consolidation of isolated technologies & processes*
- *Greater staff satisfaction*
- *Increased regulatory compliance*
- *Improved product launch planning*

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Agenda

- The Challenge of “Managing Evolving Standards in Multiple Jurisdictions”
- A global regulatory expert’s advice, Dr. Dr. M. Mikhail
- Instem’s solution, *Samarind RMS*
- Questions & Answers

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Variation Around the UDI Theme

	Canada UDI	FDA UDI	EU MDR	EU IVDR
Governed by…	Health Canada	FDA	Each sovereign nation of the EU	Each sovereign nation of the EU
Expected to be compliant by…	TBD	2018	2020	2022
Following the IMDRF guideline?	Yes, directly same as IMDRF guideline	Yes plus FDA specific clauses	Yes plus EU specific clauses	Yes plus EU specific clauses
Transparency	UDI	UDI	UDI	UDI
Legal Compliance Responsibility?	TBD	Owner/Operator responsibility for legal compliance	Dedicated Person responsible for legal compliance with MDR requirements	
Safety determination	Health Canada Centralized System	FDA Centralized System	EU Centralized Portal	

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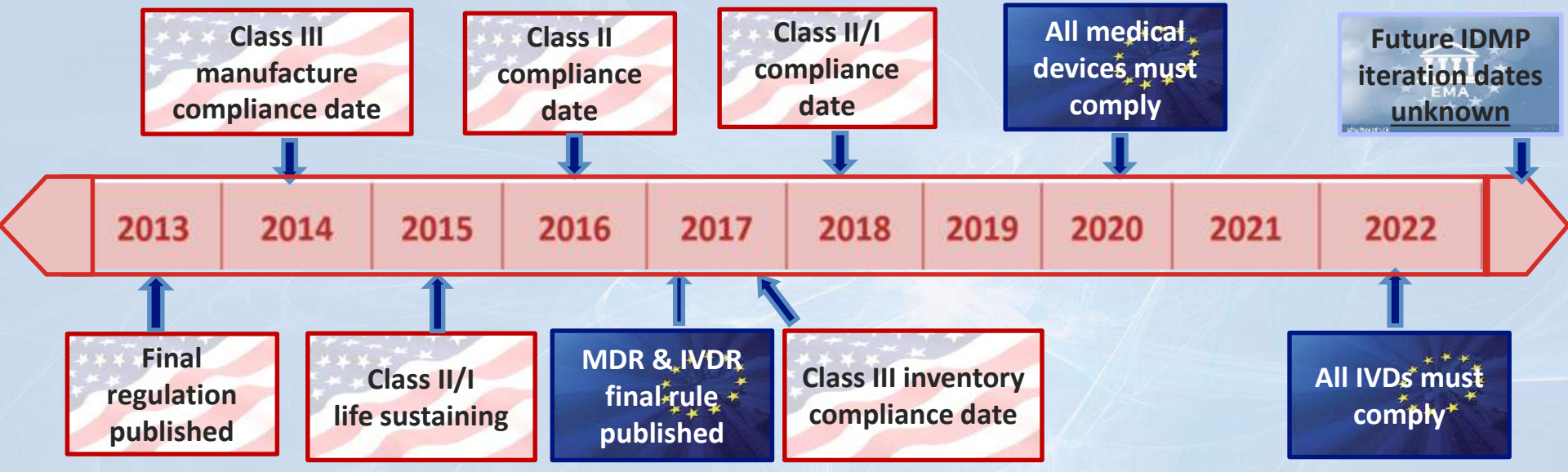
"Change is the only constant"

- Heraclitus, Greek Philosopher



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A Current Example:

The challenges of evolving standards

- IDMP's impact examples include:

  Basic research, Clinical Research, Medical and Safety, Regulatory Affairs, Manufacturing & Packaging

- Issues with IDMP
  - Moving content & scope
  - Moving timelines
  - Short implementation time
  - Complexity
  - Across departmental impact
  - Data collected from a vast number of sources

An industry perspective

Dr. Dr. Michel Mikhail
Expert in Global Regulatory Affairs

What does the industry need to manage the regulatory standards successfully?

Dr. Dr. Michel Mikhail,
Expert in
Global Regulatory
Affairs

- Start early, don't leave it till last minute!
- Ensure you remain compliant
- Don't miss your deadlines
- Manage your documents
- Everything in one place
- Validation
- Ensure you're not only compliant now but in the future as well

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Instem's Medical Device Solution

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Tackling the issue:

- Maintain your data integrity
- Remain compliant
- Be specific!

Using an industry leading example

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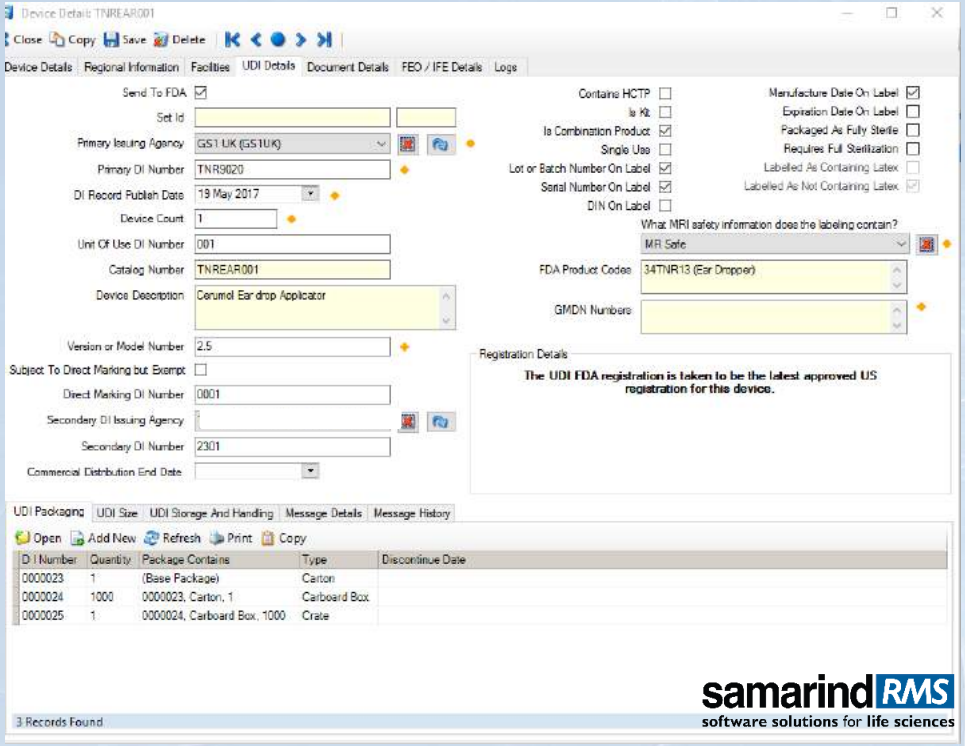
Maintaining Regulatory Data Integrity



- Maintain your data all in one place
- One core set of data for your standards
- Identify which information is needed for each standard

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Maintaining Compliance

- Manage the whole process from one place
  - Launch your product,
  - Maintain day to day regulatory processes
  - Ultimately keep your product on the market

Upcoming Device Registration Events: 01 Jan 2017 to 31 Dec 2017

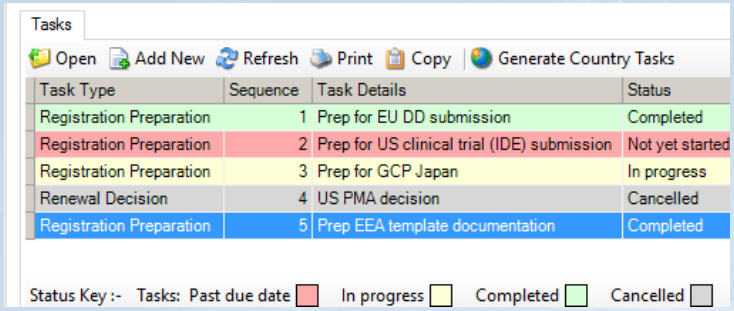
2017-01-01 to 2017-12-31

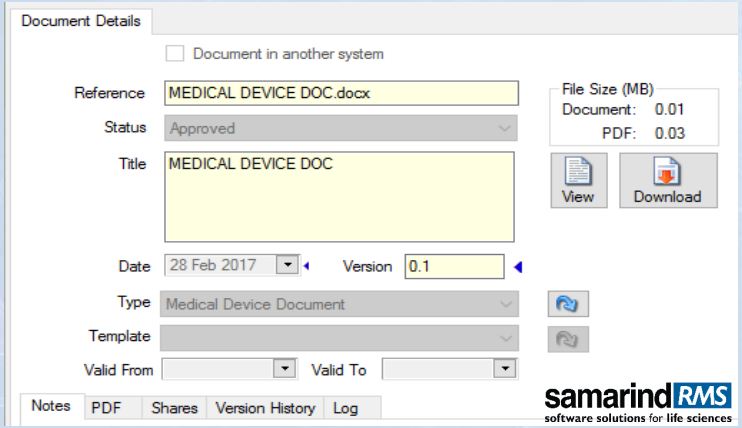
Showing 1 to 5 of 5 entries

Copy

Event Type	Due Date	Countdown	Registered Product Name	Country	Registration Process	Registration Type	Class
Registration Renewal Submission	23 May 2017	8 days ago	Hypo Gloves	European Economic Area	Approval	EEA CE Marking	I
Registration Renewal Submission	06 Jun 2017	in 6 days	Sam MD Biorhythm Mark 1	European Economic Area	Approval	EEA CE Marking	III
Registration Renewal Submission	09 Jun 2017	in 9 days	Wound Dressing	USA	Approval	Full Dossier	I
New Registration Application Submission	29 Jul 2017	in 2 months	Wound Dressing	USA	Notification	FDA 510(k)	
Registration Renewal Submission	21 Sep 2017	in 4 months	Hypo Gloves Lined 2014	Uruguay	Approval	Full Dossier	I

Maintaining Compliance cont'd





- Manage & coordinate all team members globally
- Sync team tasks with product key dates
- Link, maintain and archive within a secure EDMS

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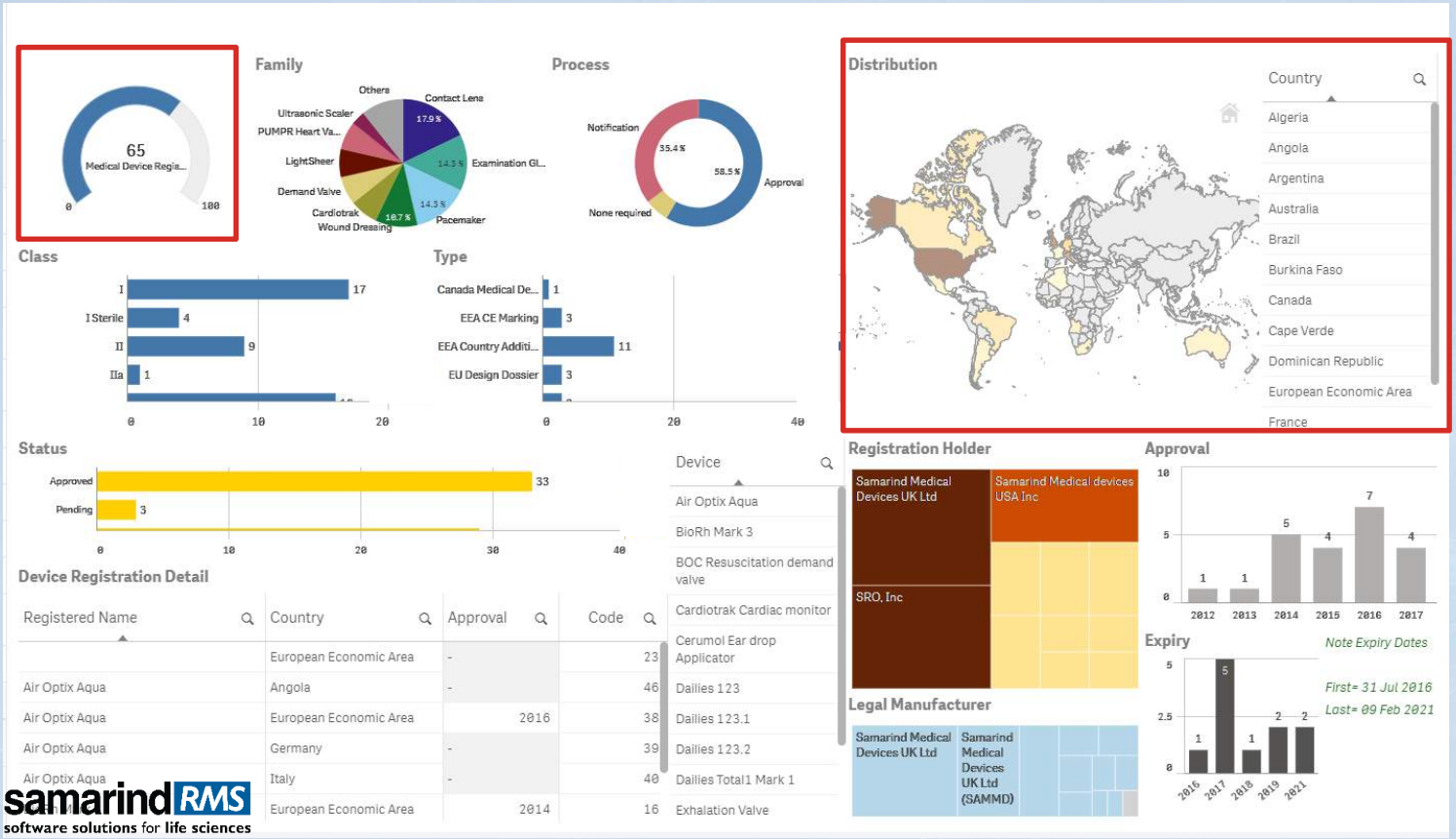
Maintaining Compliance



Determine the impact of the standard

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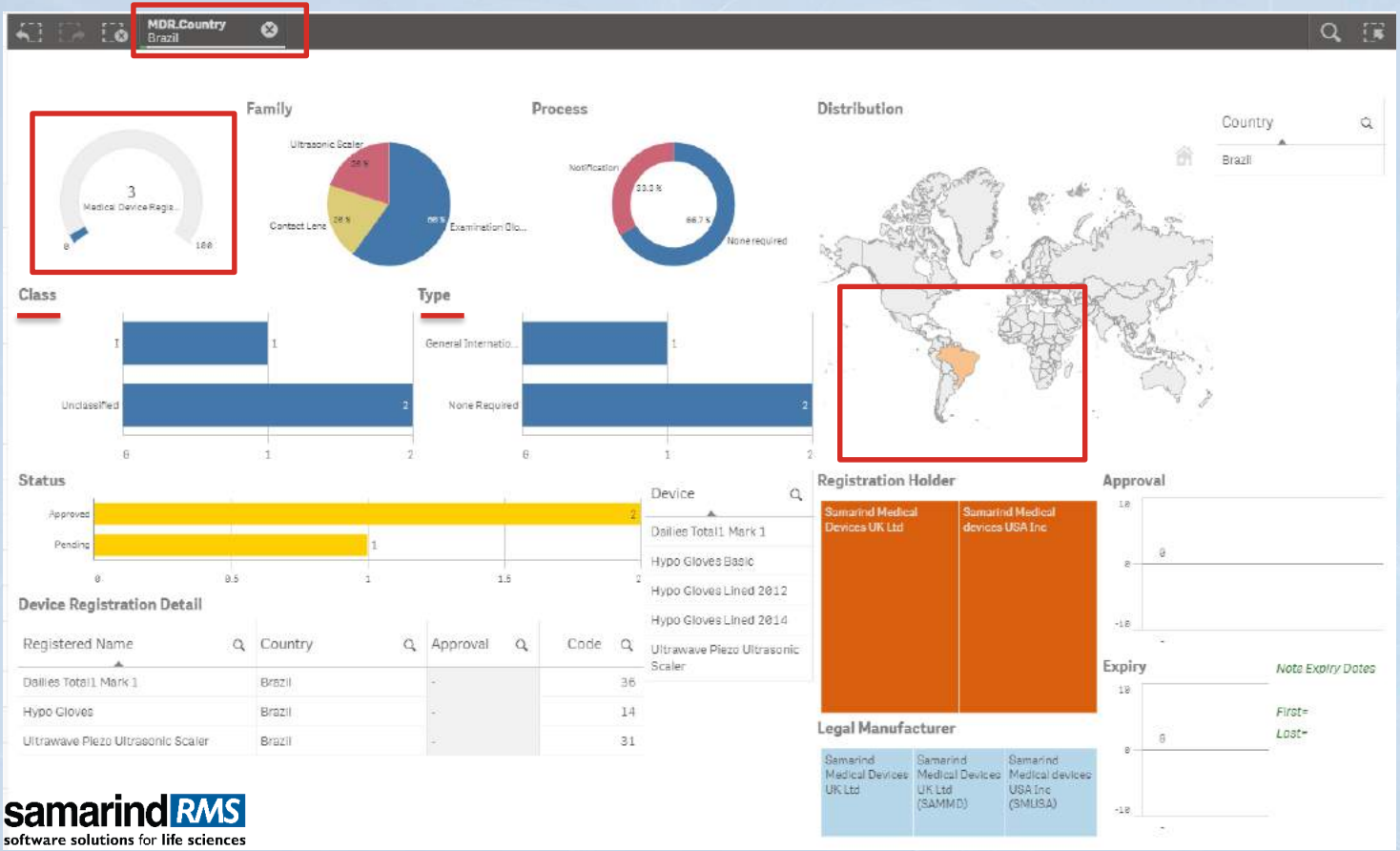
Maintaining Compliance

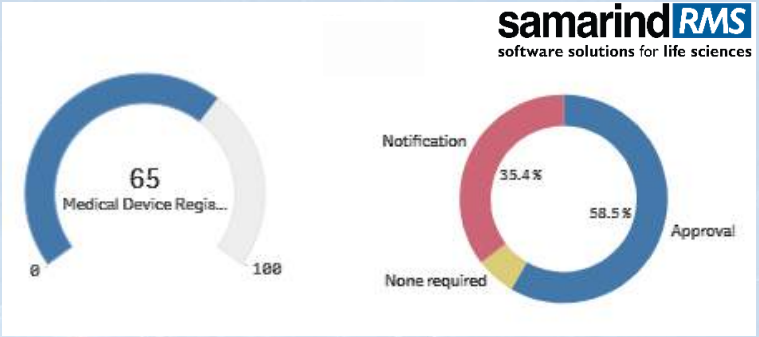


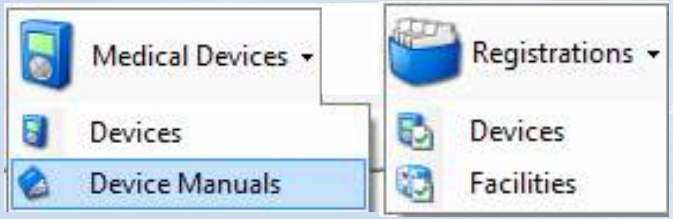
The standard in Brazil has changed, what is the impact?

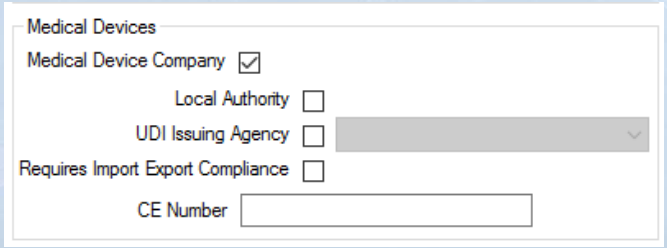
Medical device specific

- Ensure your solution is specific to your medical device needs

e.g. Facility Registration capabilities







- Ensure it's a long term solution and has commitment to compliance

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Summary

- Global UDI deadlines are quickly approaching
- Ensure you have medical device specific functionality
- One system that provides a single source of truth
- Ownership leads to action!

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Next Steps & Resources

- **Contact us for a free 30-minute *consultation***
- Arrange for a customized demo
- Request literature
- Request a copy of this presentation / recording

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Abbreviations

- **IMDRF** – International Medical Device Regulators Forum
- **UDI** – Unique Device Identifier
- **MDR** – Medical Device Regulation, specifically in reference to the EU MDR the regulation for UDI in the EU
- **IVDR** – In Vitro Diagnostic Regulation
- **IDMP** - Identification of Medicinal Products
- **EMA SPOR** - The European Medicines Agency (Substance, Product, Organisation and Referential)
- **RMS** – Reference Management System
- **OMS** – Organisation Management System
- **SMS** – Substances Management System
- **PMS** – Product Management System