

Medical Devices - Managing Evolving Standards in Multiple Jurisdictions

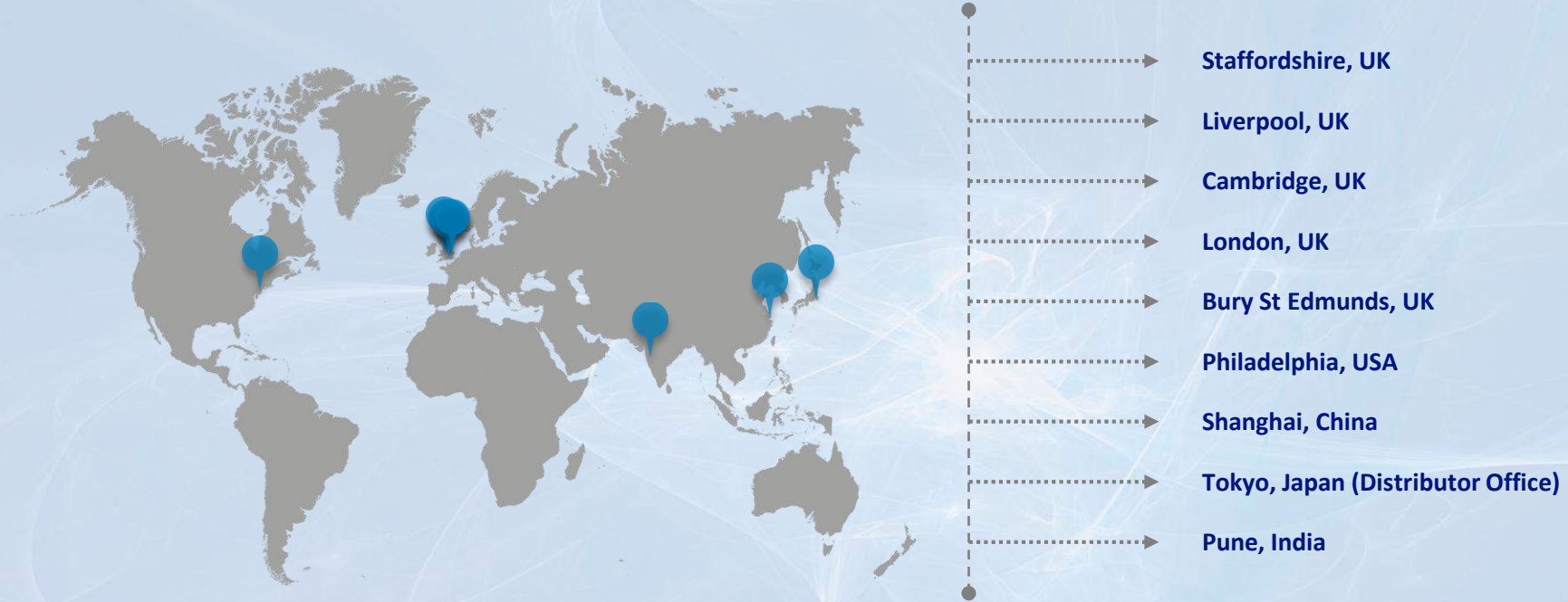
Ella Shaw, BSc, *Samarind RMS*, Application Specialist

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



Information Solutions For Life

Worldwide Presence



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

Helping our clients bring life enhancing products to market faster



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



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

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

- *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*

Medical Devices - Managing Evolving Standards in Multiple Jurisdictions

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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*



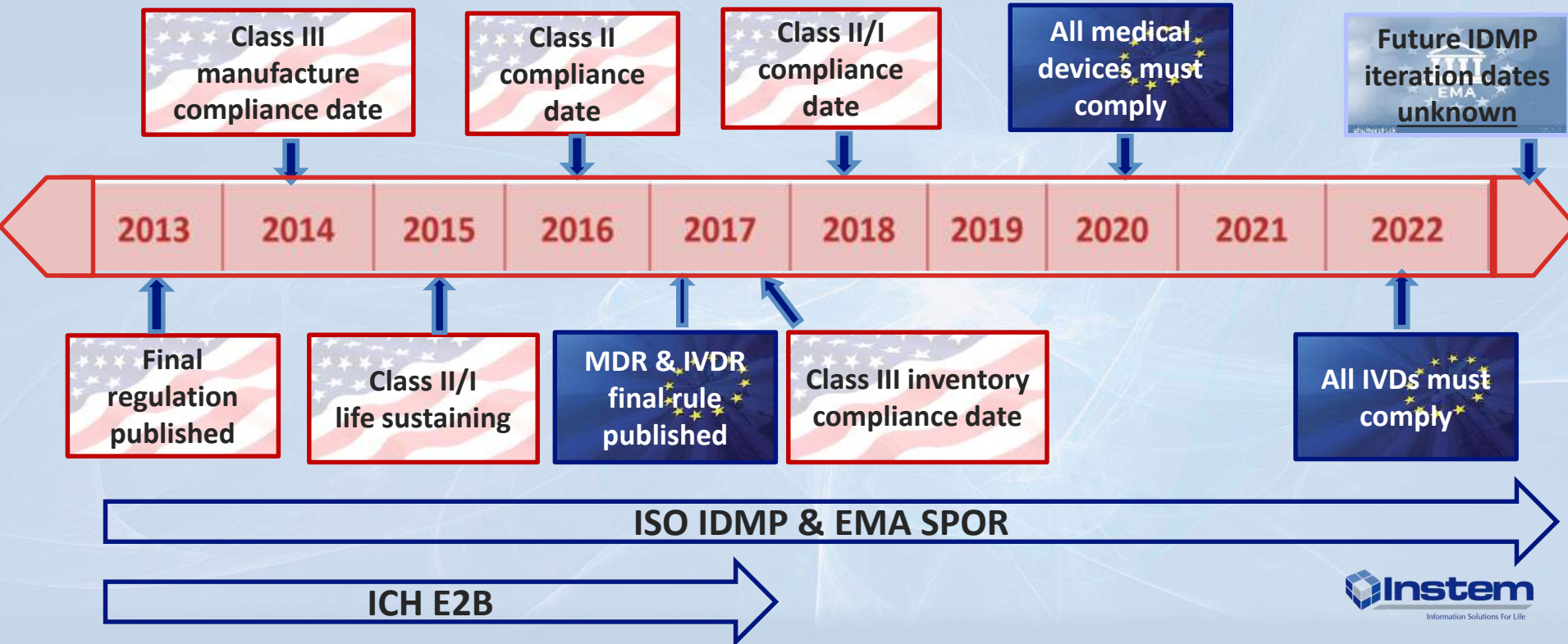
Questions & Answers

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	

“Change is the only constant”

- Heraclitus, Greek Philosopher



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?

- › 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



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

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

Device Details: TNREAR001

Close Copy Save Delete K < > < > > >

Device Details | Regional Information | Facilities | UDI Details | Document Details | FEO / IFE Details | Logs

Send To FDA

Set Id

Primary Issuing Agency: GS1 UK (GS1UK)

Primary DI Number: TNR9020

DI Record Publish Date: 19 May 2017

Device Count: 1

Unit Of Use DI Number: 001

Catalog Number: TNREAR001

Device Description: Cerumol Ear drop Applicator

Version or Model Number: 2.5

Subject To Direct Marking but Exempt:

Direct Marking DI Number: 0001

Secondary DI Issuing Agency:

Secondary DI Number: 2301

Commercial Distribution End Date:

Contains HCTP:

Is Combination Product:

Lot or Batch Number On Label:

Serial Number On Label:

DIN On Label:

Manufacture Date On Label:

Expiration Date On Label:

Packaged As Fully Sterile:

Requires Full Sterilization:

Labeled As Containing Latex:

Labeled As Not Containing Latex:

What MRI safety information does the labeling contain?
MRI Safe

FDA Product Codes: 34TNR13 (Ear Dropper)

GMDN Numbers:

Registration Details
The UDI FDA registration is taken to be the latest approved US registration for this device.

UDI Packaging | UDI Size | UDI Storage And Handling | Message Details | Message History

Open Add New Refresh Print Copy

DI Number	Quantity	Package Contains	Type	Discontinue Date
0000023	1	(Base Package)	Carton	
0000024	1000	0000023, Carton, 1	Cardboard Box	
0000025	1	0000024, Cardboard Box, 1000	Crate	

3 Records Found

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

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	

Maintaining Compliance cont'd

Tasks

Open Add New Refresh Print Copy Generate Country Tasks

Task Type	Sequence	Task Details	Status
Registration Preparation	1	Prep for EU DD submission	Completed
Registration Preparation	2	Prep for US clinical trial (IDE) submission	Not yet started
Registration Preparation	3	Prep for GCP Japan	In progress
Renewal Decision	4	US PMA decision	Cancelled
Registration Preparation	5	Prep EEA template documentation	Completed

Status Key :- Tasks: Past due date ■ In progress ■ Completed ■ Cancelled ■

Document Details

Document in another system

Reference: MEDICAL DEVICE DOC.docx

Status: Approved

Title: MEDICAL DEVICE DOC

Date: 28 Feb 2017 Version: 0.1

Type: Medical Device Document

Template: [Dropdown]

Valid From: [Dropdown] Valid To: [Dropdown]

File Size (MB)
Document: 0.01
PDF: 0.03

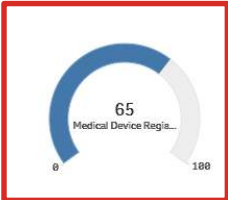
View Download

Notes PDF Shares Version History Log

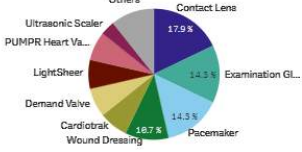
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- Manage & coordinate all team members globally
- Sync team tasks with product key dates
- Link, maintain and archive within a secure EDMS

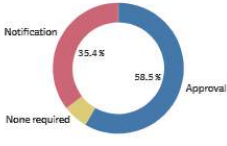
Maintaining Compliance



Family



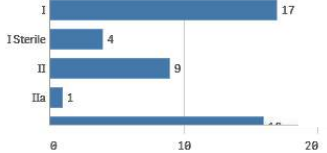
Process



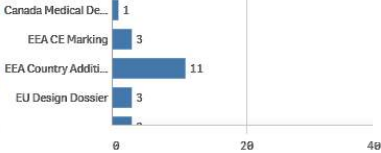
Distribution



Class



Type



Status



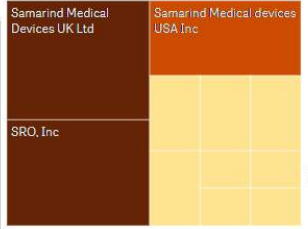
Device Registration Detail

Registered Name	Country	Approval	Code
	European Economic Area	-	23
Air Optix Aqua	Angola	-	46
Air Optix Aqua	European Economic Area	2016	38
Air Optix Aqua	Germany	-	39
Air Optix Aqua	Italy	-	40
	European Economic Area	2014	16

Device

- Air Optix Aqua
- BioRh Mark 3
- BOC Resuscitation demand valve
- Cardiotrak Cardiac monitor
- Cerumol Ear drop Applicator
- Dailies 123
- Dailies 123.1
- Dailies 123.2
- Dailies Total1 Mark 1
- Exhalation Valve

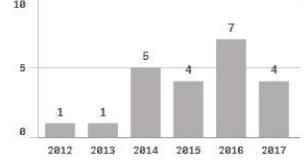
Registration Holder



Legal Manufacturer



Approval



Expiry



Determine the impact of the standard

Maintaining Compliance

MDR Country
Brazil

Family

Medical Device Regs... 3

Process

Notification 33.3%
None required 66.7%

Distribution

Country: Brazil

Class

Unclassified 2

Type

General Internatio... 1
None Required 2

Status

Approved 2
Pending 1

Device

- Dallies Total1 Mark 1
- Hypo Gloves Basic
- Hypo Gloves Lined 2012
- Hypo Gloves Lined 2014
- Ultrawave Piezo Ultrasonic Scaler

Registration Holder

- Samarind Medical Devices UK Ltd
- Samarind Medical devices USA Inc

Approval

Expiry

Note Expiry Dates
First=
Last=

Device Registration Detail

Registered Name	Country	Approval	Code
Dallies Total1 Mark 1	Brazil	-	36
Hypo Gloves	Brazil	-	14
Ultrawave Piezo Ultrasonic Scaler	Brazil	-	31

Legal Manufacturer

- Samarind Medical Devices UK Ltd
- Samarind Medical Devices UK Ltd (SAMMD)
- Samarind Medical devices USA Inc (SMUSA)

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



Medical Devices

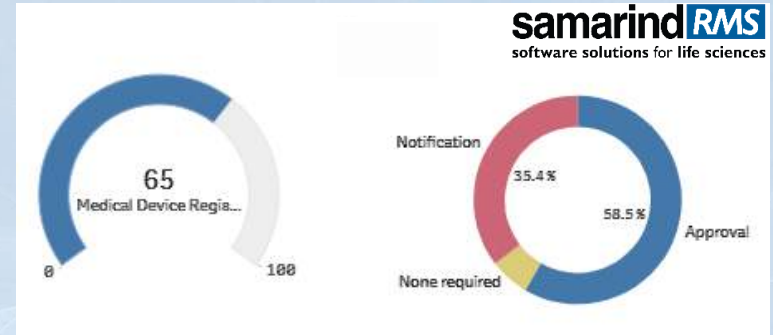
Medical Device Company

Local Authority

UDI Issuing Agency ▼

Requires Import Export Compliance

CE Number



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

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!



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