Unique Device Identification | Aligning to a Single Approach

Presented by:

Mark Agostino
Managing Director, QARA Biomed

Agenda

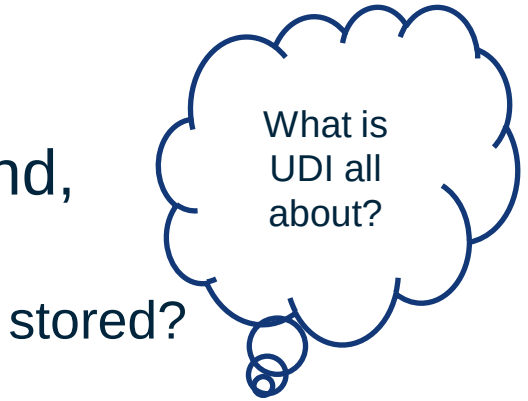
- High Level Overview of Unique Device Identification
- Basics Of Unique Device Identifier (UDI)
- Integration of UDI into QMS
- UDI Compliance Dates
- Challenges for company QMS
- Key Takeaways

High Level Overview of Unique Device Identification

- Essentially, it is/will be enforced as a requirement for all medical devices distributed worldwide
  - Some countries are further in the process than others

- There are constant challenges for manufacturers to understand,
  - When is a UDI needed on the device? On the packaging?
  - What is the data to be submitted? Where to submit? How should it be stored?

- UDI will impact multiple functional areas within an organization



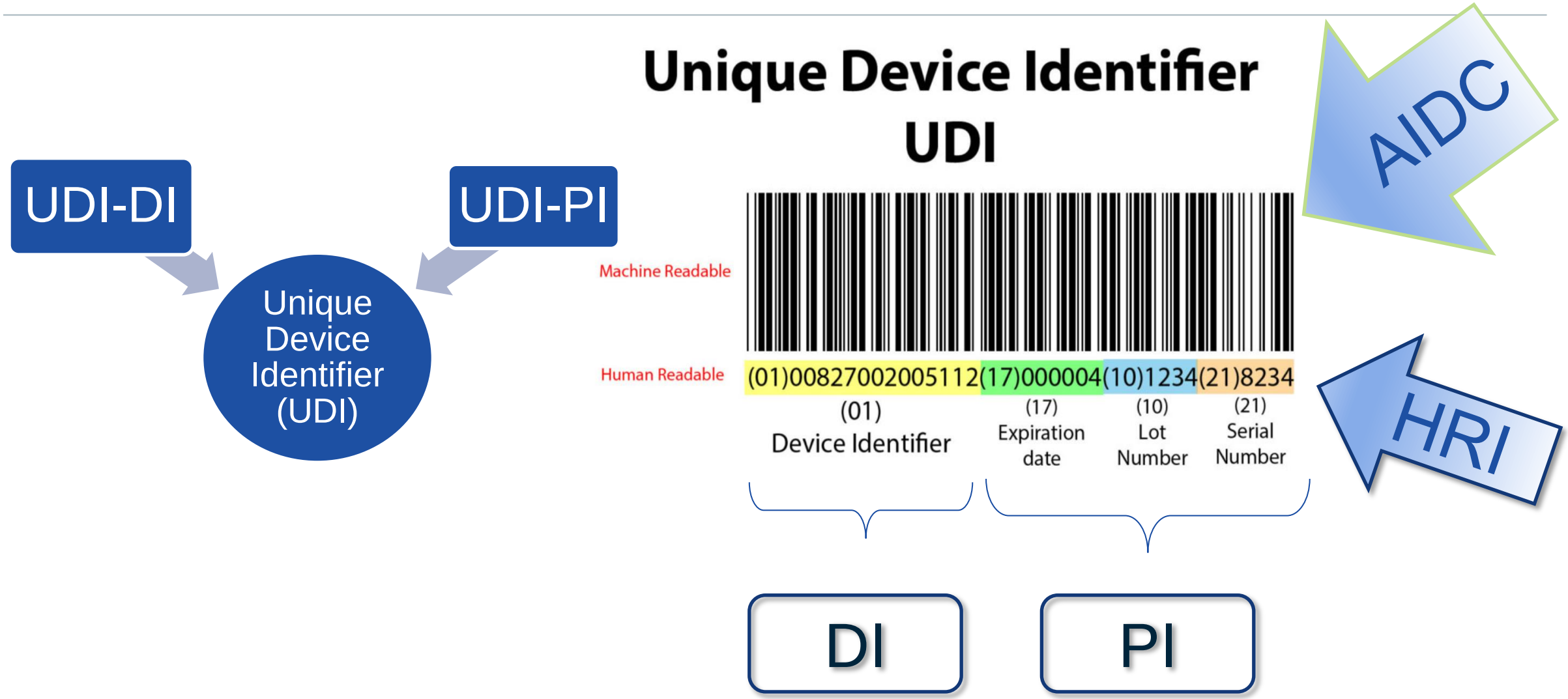
Basics of UDI

Unique Device Identifier (UDI)

Composed of two parts, UDI-DI and UDI-PI

- **Device identifier (DI)**, a mandatory, fixed portion of a UDI that identifies the labeler and the specific version or model of a device.
- **Production identifier (PI)**, a conditional, variable portion of a UDI that identifies one or more of the following when included on the label of a device:
  - Lot or batch number
  - Serial number
  - Expiration date
  - Date a specific device was manufactured;
- The device labeler must provide the UDI in **two forms** on labels and packages for the UDI Carrier:
  - Easily readable plain-text
  - Machine-readable form that uses automatic identification and data capture (AIDC) technology.

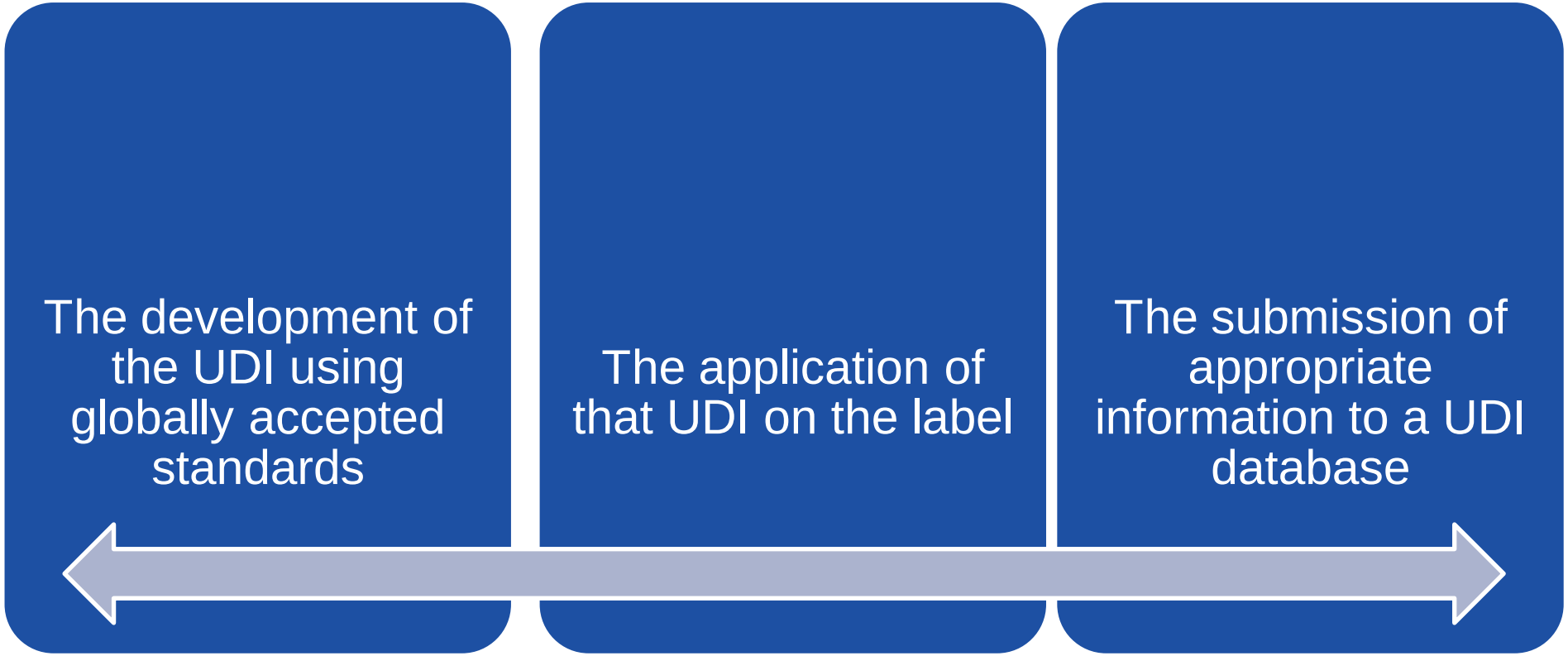
UDI vs. UDI Carrier



Aspects of a Unique Device Identification System

IMDRF/UDI WG/N7FINAL:2013 UDI Guidance Unique Device Identification (UDI) of Medical Devices

- Guidance for Harmonized Approach to UDI across countries



Fundamental Concepts of a Globally Harmonized UDI System

- The UDI and UDI Carrier are based on standards,
- UDI applied to a medical device anywhere in the world should be able to be used globally and to meet the UDI requirements of its regulatory authority,
- National or local identification numbers should NOT be a substitute for UDI,
- Regulatory authorities should not specify the procedure for modifying these UDI standards
- The UDI database (UDID) core elements should not be modified,
- Every medical device needs to be identified by a UDI, unless it is exempted

Benefits of UDI

- Traceability of medical devices
- Adequate identification of medical devices through distribution and use,
- Identification of medical devices in adverse events, field safety corrective actions,
- Reduction of medical errors,
- Documenting and capture of data on medical devices.

Why the need for a Unique Device Identification System?

- US FDA:

  The FDA established the unique device identification system to adequately identify medical devices sold in the United States from manufacturing through distribution to patient use.

  When fully implemented, the label of most devices will include a unique device identifier (UDI) in human- and machine-readable form, which will ultimately improve ***patient safety, modernize device postmarket surveillance, and facilitate medical device innovation***.

- EU Medical Device Regulation (MDR)

  The traceability of devices by means of a Unique Device Identification system (UDI system) based on international guidance should significantly enhance the effectiveness of the ***post-market safety-related activities for devices, which is owing to improved incident reporting, targeted field safety corrective actions and better monitoring by competent authorities***. It should also help to reduce medical errors and to fight against falsified devices.

GUDID and EUDAMED Databases

- What is Global Unique Device Identification Database (GUDID)?
  - A database administered by the US FDA that will serve as a reference catalog for every device with a unique device identifier (UDI).
  - GUDID contains ONLY the device identifier (DI) portion of the UDI.
- What UDI data is needed for EUDAMED?
  - The manufacturer should ensure that the information referred to in **Part A and Part B of Annex VI MDR/IVDR** relevant to the device in question is correctly submitted and transferred to the UDI database in EUDAMED.
  - UDI Module of EUDAMED is active as of October 2021

Prepare for GUDID and EUDAMED submissions

GUDID

- Review UDI guidance documents and resources to create an internal action plan/timetable for preparing data for the GUDID.
- Work with FDA-accredited issuing agencies to assign and maintain UDIs. Establish processes for physical labeling.
- Establish standard operating procedures for records management.
- Gather data required for GUDID DI records based on the GUDID Data Elements Reference Table (April 27, 2020).

https://www.fda.gov/medical-devices/global-unique-device-identification-database-gudid/prepare-gudid

EUDAMED

- Refer to UDI User Guide, https://ec.europa.eu/health/system/files/2021-11/md_eudamed_udi-devices-user-guide_en_0.pdf

Integration of UDI into the QMS

Holistic Plan for Implementing UDI into the QMS

QMS sections for consideration for implementing UDI

- *Design and Development*
- *Production*
- *Postmarket Surveillance*
- *Responsibilities of Economic Operators*
- *Supply Chain*
- *Documentation and Records*

UDI Implementation Plan

MDCG 2021-19 Guidance note integration of the UDI within an organization's quality management system

- Analysis of expectations and needs of different stakeholders such as economic operators, healthcare institutions/professionals, patients/users, insurance providers;
- Analysis of the relevant issuing entities' standards;
- Choice of a designated issuing entity;
- Definition of internal responsibilities for the implementation and subsequent management of the plan;
- Description of methods and use cases to verify the continuous compliance of UDI-related QMS processes.

Design and Development

- Create an UDI in compliance with the rules of the issuing entities,
- Assign to the device and, if applicable, to all higher levels of packaging,
- Development of UDI-DIs prior to placing a device on the market or submitting the Technical Documentation for regulatory clearance/approval,
- In addition to traceability, the appropriate level of product serialization should be assessed by proper risk management (i.e. active implants),
- Understand the impact of any potential changes to DI and the necessary reporting to regulatory authorities

UDI Issuing Agencies

- US FDA and EU MDR have 3 shared accredited issuing agencies, GS1 (http://www.gs1.org/) , HIBCC (http://www.hibcc.org) , and ICCBBA (http://www.iccbba.org)

- Each of the issuing agencies have their own standards and requirements for identification

	GS1	HIBCC	ICCBBA
Device Identifier (UDI-DI)	GTIN (Global Trade Item Number)	HIBC-LIC (Labeler Identification Code)	ISBT-28 PPIC (Processor Product Identification Code)
Production Identifier (UDI-PI)	Application Identifier (PI)	HIBC UDI format for PI	ISBT UDI format for PI

GS1® Issuing Agency[1]

Issuing Agency	Data Delimiters	Identifier	Data type	Human Readable Field Size	Database Field Size
GS1	(01)	Device Identifier (DI)	Numeric	16	14
GS1	(11)	Manufacturing/ Production Date	numeric [YYMMDD]	8	6
GS1	(17)	Expiration Date	numeric [YYMMDD]	8	6
GS1	(10)	Batch/Lot Number	alphanumeric	22	20
GS1	(21)	Serial Number	alphanumeric	22	20
GS1		***Maximum Base UDI***	***alphanumeric***	***76***	***66***
Example of GS1 easily readable plain-text UDI: (01)51022222233336(11)141231(17)150707(10)A213B1(21)1234					

QMS Challenge with Issuing Agencies

- The challenge is not only what works within a company QMS but also what is recognized in various countries

Country/ Region	USA	EU	Australia	Japan	Saudi Arabia	Taiwan	South Korea	Brazil	China
Accredited/ Recognized issuing agencies	GS1	GS1	GS1	GS1	GS1	GS1	GS1	GS1	GS1
	HIBCC	HIBCC	HIBCC		HIBCC	HIBCC	HIBCC	HIBCC	
	ICCBBA	ICCBBA	ICCBBA		ICCBBA	ICCBBA	ICCBBA		
		IFA GmbH							ZIIOT
									Ali Health
									M. Platform

Production

- The manufacturer should decide when, where, and how the UDI carrier should be applied
- For US FDA, all device risk classes ,except for certain Class I devices, are expected to have a UDI marking existing on the device ,if applicable, and all appropriate levels of packaging at the time of a regulatory submission
- Incorporate UDI labeling requirements into device master records (DMR)
- Include inspection and verification of UDI into device history records (DHR)
- Identify owners to manage the PI data for the UDI
- An important aspect of the UDI process is labeling:
  - Manufacturers should ensure that the label printing process is verified and validated.
  - Changes to validated processes need to be assessed for impact on device labeling.
  - The software used in implementing the UDI system should remain in a validated state.
  - Establish UDI labeling requirements

FDA 483 Observations related to UDI

- The FDA has taken notice of importance of UDI in a company`s QMS
- Observations related to UDI cover many different functional areas
- List of some types of 483 Observations from 2014 to Present:
  - The device history record does not include or refer to a location of an UDI
  - Complaint investigation records do not include UDI
  - Illegible UDI label
  - UDI not carried throughout distribution
  - No UDI labeling specifications
  - No UDI process validation
  - Failure to maintain UDI records

Postmarket Surveillance Activities

- Similar to the US FDA, according to EU MDR 2017/745 and EU IVDR 2017/746, the following require documentation of UDI information:
  - Postmarket surveillance and vigilance reports
  - Serious incident reports
  - Field safety corrective actions
  - Customer complaints

- Benefits of UDI for Postmarket Surveillance:
  - Traceability
  - Response time to adverse events; containment
  - Response time to address recalls and field safety corrective actions

Responsibilities for Economic Operators

- Manufacturers shall be responsible
  - for the UDI assignment and placement of the UDI carrier,
  - the initial submission and updates of the identifying information and other device data elements in the Eudamed database,
  - update the relevant database record within 30 days of a change being made to an element, which does not require a new UDI-DI.
- Responsibilities of other Economic Operators
  - Distributors and importers shall verify that a UDI has been assigned by the manufacturer.
  - All economic operators and health institutions shall store and keep preferably by electronic means the UDI of the devices,

Supply Chain

- Understanding the role and responsibilities in the management and reporting of UDI is critical
  - Ensuring UDI is managed throughout the supply chain
  - Documentation in support of UDI is maintained
  - All appropriate levels of packaging have a UDI

Manufacturing

Distributor

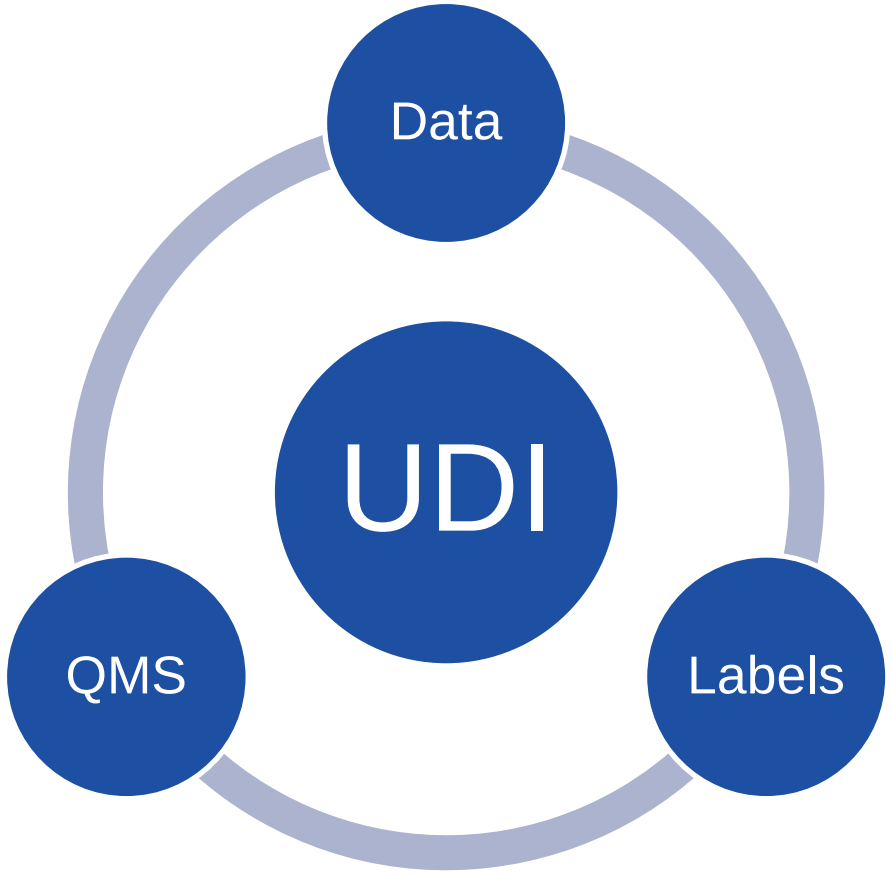
Importer

Clinical Setting/Home Use

Patient

Documentation and Records

- The management of UDI is a culmination of three key aspects



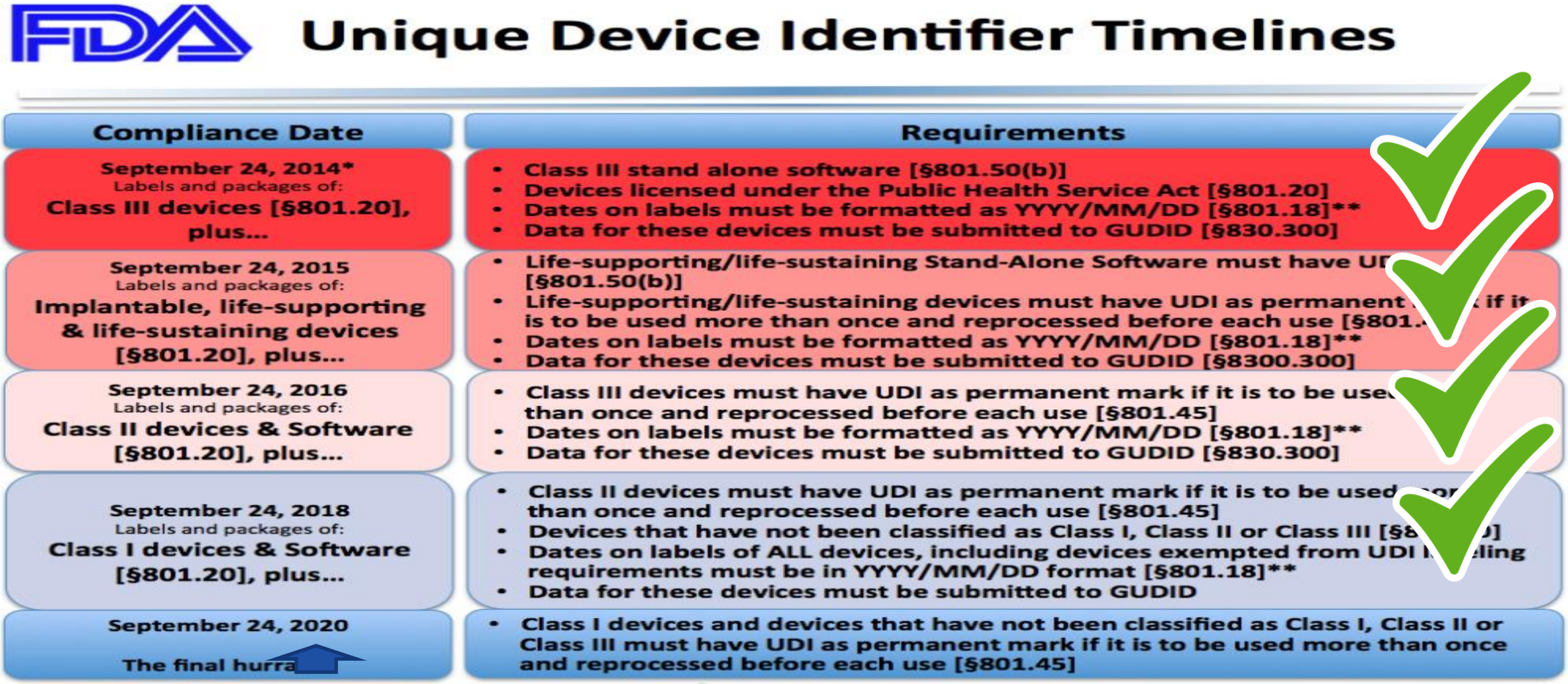
Data – The information that is contained in the records to designate the correct UDI and is communicated to the appropriate UDI databases

Labels – The physical assignment of the UDI. The information that is read to accurately represent the device when necessary

QMS – The processes and procedures that exist to support the necessary actions for the UDI system

UDI Compliance Dates

FDA UDI Compliance Dates



Now September 2022

EU MDR/IVDR UDI Compliance Dates

Device as per Regulation (EU) 2017/745 (MDR)	Implantable devices and Class III devices	Class IIa and Class IIb devices	Class I devices
Placing UDI-carriers on the labels of devices MDR Article 123(3)(f), Article 27(4)	26 May 2021	26 May 2023	26 May 2025
Direct marking of the reusable devices MDR Article 123(3)(g), Article 27(4)	26 May 2023	26 May 2025	26 May 2027

Device as per Regulation (EU) 2017/746 (IVDR)	Class D IVDs	Class C and B IVDs	Class A IVDs
Placing UDI-carriers on the labels of devices IVDR Article 113(3)(e), Article 24(4)	26 May 2023	26 May 2025	26 May 2027

Challenges for company QMS

Challenges for QMS: Timelines for Enforcement

- Timelines for Enforcement of UDI on the device vary significantly from country to country
- US and EU further advanced than other countries; QMS will have to remain agile for marketing devices in multiple countries/regions

Country/Region	Medical Device/IVD
China	January 2021 UDI Data and Label Required June 2022 Remaining Class III, IVD
Saudi Arabia	August 2021 Class D (High risk) February 2022 Class B & C (Medium risk) February 2023 Class A (Low risk)
Brazil	2 years from publication of 1051/2021; targeted for 2022 2024 – Class IV (Highest risk) 2025 – Class III (High risk) 2026 – Class II (Medium risk) 2027 – Class I (Low risk)
Australia	May 2021 – Class III and Implantable (High risk) May 2023 – Class IIa and IIb (Medium risk) May 2025 – Class I (Low risk)

Challenges for QMS: Device Nomenclature

- European Medical Device Nomenclature (EMDN Code) is the nomenclature that will be of use to the manufacturers when registering their Medical Devices in the EUDAMED database.
- The Global Medical Device Nomenclature (GMDN) is a list of generic names used to identify all medical device products. US FDA uses GMDN.
- Depending on the country, there are four (4) options for medical device nomenclature, EMDN, GMDN, National specific system, or none at all.
- The challenge is in the reporting of data to a country UDI database will be potentially different in its nomenclature.
- In addition, the data elements from country to country may be different in assessing a database for postmarket information

Key Takeaways

- Develop a QMS that is agile for managing UDI throughout the device product lifecycle
- Promote awareness in understanding the differences from country to country where you intend to market
- Understand that the regulatory landscape for medical devices worldwide for UDI is constantly evolving
- Create regulatory and production strategies to effectively react to the different requirements and enforcement timelines for the countries where you are intending to market

Thank you for your attention!