UDI - Experiences, Challenges and Keys to Success

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Statutes and Regulation

- FDA Amendments Act, 2007
- FDA Safety and Innovation Act, 2012
- UDI Rule, September 24, 2013

Link: UDI Final Rule

Objectives of the UDI Program

Establish a system to adequately identify devices through distribution and use

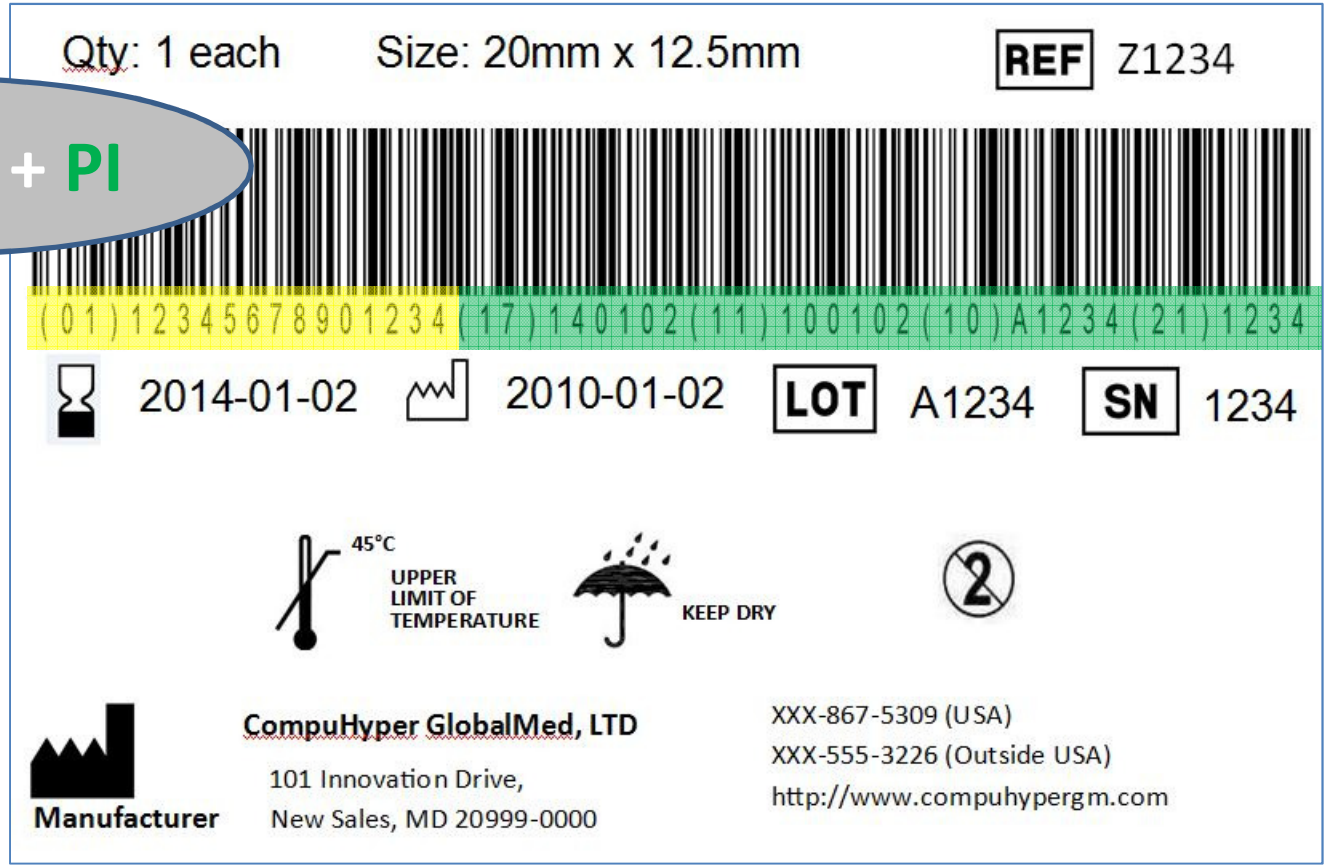
- Facilitate the rapid and accurate identification of a device
- Enable access to important information concerning the device
- Provide a standard and clear way to document device use in electronic health records, clinical information systems, and registries

What is a UDI?

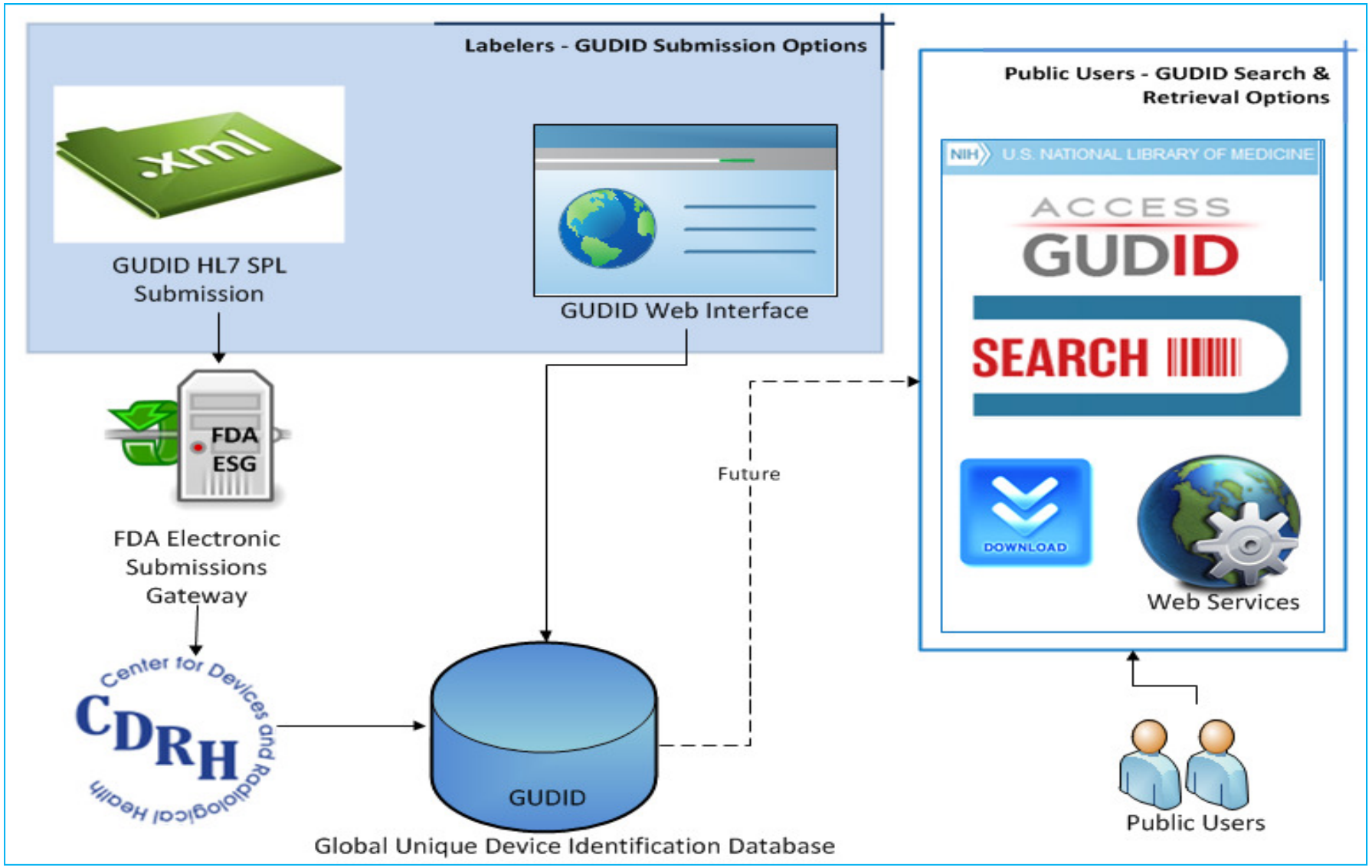
Found on the device label, packaging or, in some cases, on the device itself

Both in plain text and machine readable format (AIDC)

UDI = DI + PI



GUDID Overview



Compliance Dates for UDI Requirements

Device	Label/GUDID/Date Format	Direct Mark (When Required)
Class III (including class III LS/LS)[1] **Devices licensed under the PHS Act**	September 24, 2014	Class III LS/LS devices must bear a permanent UDI by September 24, 2015 All other class III devices must bear a permanent UDI by September 24, 2016
Implantable (class II, class I & unclassified)	September 24, 2015	N/A
LS/LS[1] (class II, class I & unclassified)	September 24, 2015	September 24, 2015
Class II (other than I/LS/LS)	September 24, 2016	September 24, 2018
Class I or unclassified (other than I/LS/LS)	September 24, 2018	September 24, 2020

Link: Details on Compliance Dates

Record Counts to Date

GUDID Records

- Almost 34,000 on September 24, 2014
- Over 49,000 as of today

Helpdesk Cases

- Almost 4,000 on September 24, 2014 with a 90% closure rate
- Over 6,000 as of today with a 95% closure rate

Solving Challenges

Versions and models of devices	• Very general definition of version or model • Helps to see the data
Heterogeneity of devices	• Wide variety of characteristics • Implantables, instruments, orthopedic trays, software, etc.
Education and outreach	• Need to understand the landscape • Helps to tailor the message to the audience

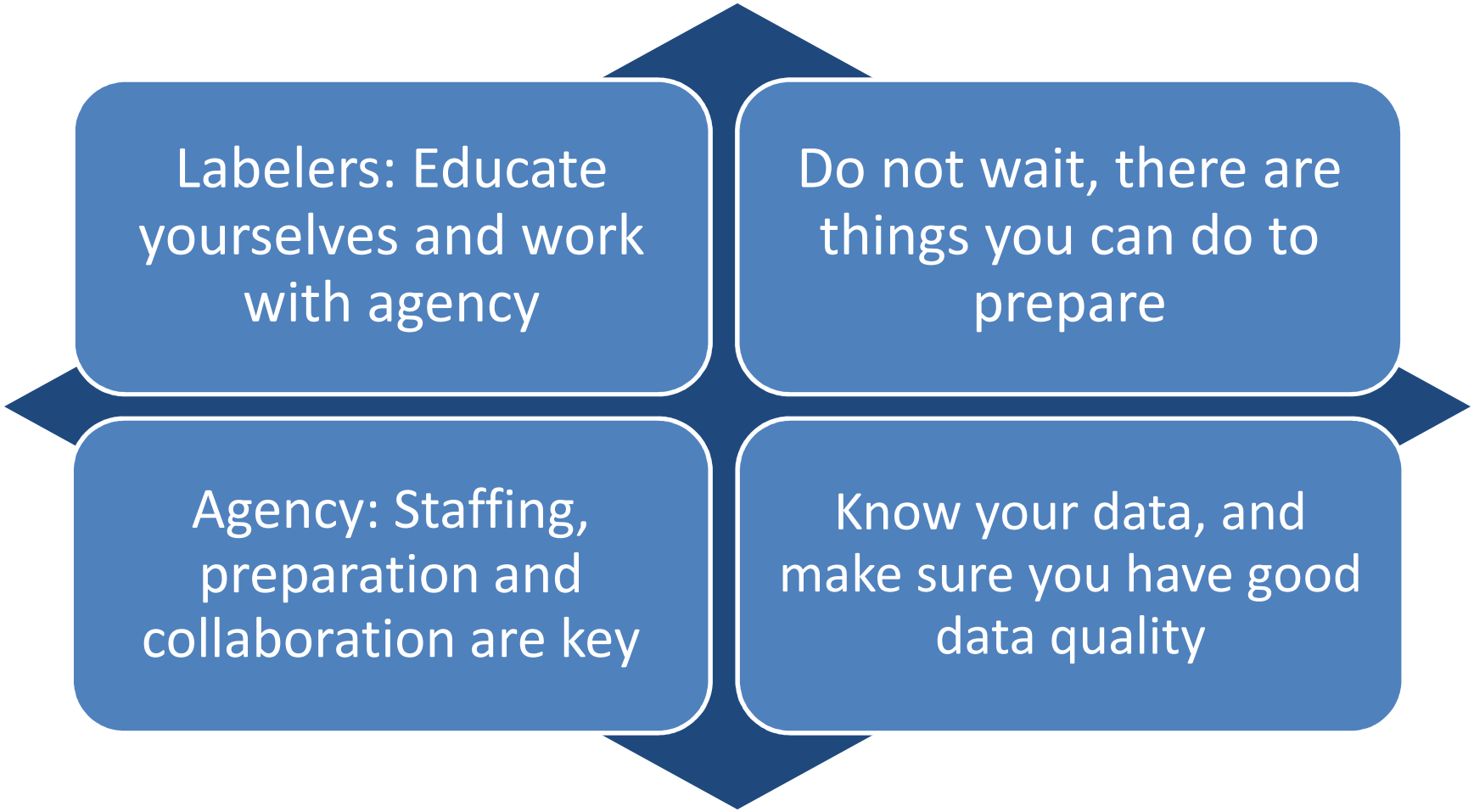
Link: UDI Website

Questions?

FDA UDI Website:
www.fda.gov/udi

Slide Presentations, Transcripts and Webinar Recordings are available at:
www.fda.gov/CDRHWebinar
Under Heading: Unique Device Identification (UDI) System

General Advice



What's next?

- AccessGUDID public release of GUDID data
- Convenience Kit Guidance
- Direct Mark Guidance
- Frequently Asked Questions, Volume 2
- Upcoming compliance dates

Key Benefits of UDI

Improve Patient Safety

More Accurate Understanding of Device Benefit-Risk Profile

Facilitate Device Innovation and Patient Access

Strengthening our National System for Medical Device Postmarket Surveillance
http://www.fda.gov/downloads/MedicalDevices/Safety/CDRHPostmarketSurveillance/UCM348845.pdf