Agenda

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2018 UDI Conference Agenda (as of April 11, 2018 – subject to change)

Click here to learn more about our speakers.

April 23, 2018

3:00pm — 6:00pm
UDI Conference Registration Open

1:00pm — 5:00pm
Co-located Program – GS1 Standards: UDI Workshop

(Co-located program delivered by GS1 US. Separate registration required.)

This 4-hour workshop is an abbreviated version of the GS1 Standards: UDI Certificate Course. It introduces you to the GS1 System and focuses on the GS1 Standards used within the context of the U.S. FDA Rule for Unique Device Identification (UDI).

Attendees will be introduced to the basics of the FDA UDI rule and to those GS1 Standards that can be used to address each aspect of the requirements for product identification, product labeling and submission of information to the Global Unique Device Identification Database (GUDID). In addition, we will discuss the importance of data quality as a component of UDI implementation and you will also be introduced to the concepts of the GS1 US National Data Quality program and how it pertains to healthcare.

Click Here for more details and to register

April 24, 2018

8:00am — 5:00pm
Registration Open

IMPORTANT NOTE
You may choose from two concurrent tracks for your morning topics: *"UDI Basics"* or *"Global UDI-Related Activity"*

9:00am — 9:45am
***UDI Basics*: FDA UDI Regulatory Basics**

Speaker: **Christopher Diamant**, Program Analyst, U.S. Food & Drug Administration

This session will serve as an introduction to the UDI system from a regulatory perspective. FDA representatives will provide an overview of the regulatory requirements for UDI labelers. The presentation will be geared towards new labelers, and will discuss examples and answer questions for people who are engaging with UDI for the first time.

Christopher DiamantU.S. Food & Drug Administration*Program Analyst*

Global UDI-Related Activity: **Global Harmonization and IMDRF**

Speaker: **Terrie Reed**, Senior Advisor for UDI Adoption, U.S. Food & Drug Administration

This session will provide a summary snapshot of the global UDI-related activities being harmonized in a new IMDRF UDI Application Guide Work Item. Regulatory participants in this work item include: US, European Union, South Korea, Australia, Brazil, Canada, Japan, Russian Federation, and Singapore. Other members include: World Health Organization (WHO), Global industry associations GMTA and DITTA.The current progress and latest activities will be shared.

Terrie ReedU.S. Food & Drug Administration*Senior Advisor for UDI Adoption*

9:50am — 10:35am
UDI Basics: **UDI Submission Basics: ABC's of GUDID Submissions**

Speakers: **Varsha Thakar**, Technical/HL7 Specialist and **Jay Jacobs**, IT Project Manager, U.S. Food & Drug Administration

FDA representatives will provide an overview of the GUDID data submission requirements for UDI labelers. You will be guided through the different types of GUDID submissions – the web submissions and the HL7 SPL submissions.

Varsha ThakarU.S. Food & Drug Administration*Technical/HL7 Specialist*
Jay JacobsU.S. Food & Drug Administration*IT Project Manager*

Global UDI-Related Activity: **Update on EU UDI System**

The EU UDI System specifically (and prospectively) incorporates UDI into various new company and product registration systems and processes. The new regulations also impose obligations for the verification and use of UDI by importers, distributors, authorized representatives and, for certain device types, healthcare providers.

The EU UDI System, though similar to the US UDI System, has some significant differences – and will face many of the same implementation issues as have occurred in the US. At the same time, there are new "commercial" or "payor" UDI-like requirements, such as those from the UK National Health System (NHS), that are beginning to develop.

Jay CrowleyUSDM Life Sciences*VP UDI*
10:35am — 10:45am
Coffee Break

10:45am — 11:30am
UDI Basics: **UDI Support, Resources and Helpdesk**

Speakers: **Christopher Diamant**, Program Analyst, and **Jay Jacobs**, IT Project Manager, U.S. Food & Drug Administration

You will be informed about UDI resources and the account request process including how to effectively work with the UDI Helpdesk.

Christopher DiamantU.S. Food & Drug Administration*Program Analyst*
Jay JacobsU.S. Food & Drug Administration*IT Project Manager*

Global UDI-Related Activity: **The EU MDR & IVDR Regulations: Effective Tactics & Strategies for Implementation**

The timeline for manufacturers that want to continue to sell their devices in Europe has been defined by the EU MDR & IVDR Regulations. This session will provide critical information and guidance to help you prepare to meet the timelines, expose you to a philosophical and strategic approach to efficiently manage your devices from a global vantage point, provide tactics you must consider to stay in regulatory and commercial compliance, and provide details on the technical components.

Jay CrowleyUSDM Life Sciences*VP UDI*
11:40am — 12:10pm
Opening Keynote Address: The Conversations Driving the UDI Community Expansion

Ms. Sigg will share the progress, the conversations, and the evolution of the UDI initiative that is perpetuating the growth of the UDI Community. The FDA will share all that they have heard and learned along the way, how they have responded and how the UDI Community and the many stakeholders now engaged are making significant impacts to the expansion of UDI medical device information in real world applications.

Linda A. SiggU.S. Food and Drug Administration*Associate Director for Informatics*
12:10pm — 2:00pm
Luncheon & Exhibits

2:00pm — 2:45pm
Edit DI Process

Speaker: **Indira Konduri**, GUDID Program Manager, U.S. Food & Drug Administration

This session will highlight ways labelers can efficiently maintain high quality data in GUDID. FDA will share details of GUDID enhancements that will enable labelers to quickly and easily make corrections/edits to device records in order to maintain complete and accurate data in GUDID. FDA will present other GUDID enhancements that include newly added data elements to be released to AccessGUDID so end users can better manage updates and versions of device records.

Indira KonduriU.S. Food and Drug Administration*Program Manager for the Global Unique Device Identification Database*
2:45pm — 3:30pm
Access GUDID Updates

Speakers: **Heather Valadez**, Computer Scientist, and **Grace Kim**, Data Quality Specialist, U.S. Food & Drug Administration

This session highlights the latest AccessGUDID tools and enhancements and offers a look into the AccessGUDID data. You will see some interesting trends and discuss ways data submitters are making their device records useful for the people who need to use them.

Heather ValadezU.S. Food and Drug Administration*Computer Scientist*
Grace KimU.S. Food and Drug Administration*Data Quality Specialist*
3:30pm — 4:00pm
Exhibits & Stretch Break

4:00pm — 5:00pm
Data Quality: Compliant vs. Valuable

Speakers: **Mike Schiller**, Senior Director Supply Chain, AHRMM; **Behnaz Minaei**, Data Quality Lead, U.S. Food and Drug Administration; **John Terwilliger**, GS1 Senior Consultant, Global Standards and Serialization Office (GSSO), Abbott Laboratories

AHRMM will share real-world challenges they are hearing from the healthcare community and the Learning UDI Data Quality work group members, and the cause and effect impacts inconsistent data is having on Provider adoption of the UDI. Understand why it is critical for GUDID data to be more than just compliant – it needs to be valuable! as well as the importance of engaging with your customers who are incorporating this data into their clinical and operational processes and health IT systems.

Michael SchillerAHRMM*Senior Director Supply Chain*
Behnaz MinaeiU.S. Food & Drug Administration*Data Quality Lead*
John Terwilliger Abbott Laboratories*GS1 Senior Consultant, Global Standards and Serialization Office (GSSO)*
6:00pm — 7:30pm
Networking Gathering in Watertable Restaurant Bar (Cash Bar)

April 25, 2018
8:00am — 5:15pm
Registration Open

8:15am — 9:30am
Exhibits, Networking & Coffee – Make the most of your time by visiting with the UDI Exhibitors and networking! Exhibit Hall open 8:15am – 2:15pm

9:30am — 10:30am
It Does Take a Village: Collaborative Communities

Panel: **Karen Conway,** Past Chair of the Board, AHRMM and Vice President, Healthcare Value, GHX; **Linda Rouse O'Neill**, Vice President Government Affairs, Health Industry Distributors Association (HIDA); **Denise Downing**, The Association of periOperative Registered Nurses (AORN); **Ellenmary Martin**, Chief Strategy Officer at DUKAL Corporation, and a board member of the Healthcare Manufacturers Management Council (HMMC); **Terrie Reed**, Senior Advisor for UDI Adoption, U.S. Food & Drug Administration

This session will highlight the role FDA plays in UDI adoption and the commitment by cross-stakeholder groups to ensure that expected UDI benefits are achieved. You will hear what industry organizations are teaching and learning about UDI adoption, and programs being implementation through their member constituents representing the healthcare providers, medical device manufacturers, and distributor organizations. Gain an understanding of the strategic UDI priorities creating the collaborative communities both here in the United States as well as other countries for the benefit of global trade and device evaluation.

Karen ConwayGHX*Past Chair of the Board, AHRMM and Vice President*
Linda Rouse O'NeillHIDA*Vice President of Government Affairs*
Denise Downing The Association of periOperative Registered Nurses (AORN)*Perioperative Informatics Nurse Specialist*
Ellenmary Martin Chief Strategy Officer at DUKAL Corporation*Board Member - Healthcare Manufacturers Management Council (HMMC)*
Terrie ReedU.S. Food & Drug Administration*Senior Advisor for UDI Adoption*
10:30am — 11:15am
Kits and the GUDID Entries That Describe Them

Speakers: **Loretta Chi,** Senior Regulatory Counsel and **Christina Savisaar**, Regulatory Policy Analyst, U.S. Food and Drug Administration

On September 6, 2016, Agency extended the compliance date for most collections of two or more different class II (or class II and class I) devices packaged together and repackaged class II single-use devices in which the individual devices in the packages are not labeled with a UDI. On September 24, 2018, the compliance date extension will expire. This session will be used to discuss FDA's current thinking on kits, and provide suggestions on how data relating to kits should be submitted to GUDID.

Loretta ChiU.S. Food & Drug Administration*Senior Regulatory Counsel*
Christina SavisaarU.S. Food & Drug Administration*Regulatory Policy Analyst,*
11:15am — 11:45am
Exhibits & Coffee Break

11:45am — 12:45pm
UDI LUM (Lowest Unit of Measure) Best Practices

Moderator: **Linda Rouse O'Neill**, Vice President Government Affairs, Health Industry Distributors Association (HIDA)

Panelists: **Loretta Chi,** Senior Regulatory Counsel, U.S. Food and Drug Administration; **Christina Savisaar,** Regulatory Policy Analyst, U.S. Food and Drug Administration; **Dennis Black**, Director of eBusiness, BD; **Mike Marchlik**, Vice President Global Quality & Regulatory Compliance, Owens & Minor

HIDA and its supply chain partners have finalized a set of unique device identifier (UDI) best practices regarding lowest unit of measure (LUM) programs. These guidelines can help distributors and their trading partners comply with the Food and Drug Administration's (FDA) UDI requirements while ensuring patient safety.

Though UDI implementation presents a challenge for all parties involved, distributors and manufacturers have an opportunity to help each other and their customers. By initiating conversations around programs like low-unit-of-measure and just-in-time, distributors can offer manufacturers insight into how providers purchase, store, and use their products so appropriate solutions can be implemented.

This session will cover: Key information on the requirements of UDI regulation; discussion on the impact of LUM programs; steps for coordination between supply chain partners on UDI and LUM; and potential outcomes to the conversations between trading partners.

Linda Rouse O'NeillHIDA*Vice President of Government Affairs*
Loretta ChiU.S. Food & Drug Administration*Senior Regulatory Counsel*
Christina SavisaarU.S. Food & Drug Administration*Regulatory Policy Analyst,*
Dennis BlackBD*Director of eBusiness*
Mike Marchlik Vice President Global Quality & Regulatory Compliance*Owens & Minor*
12:45pm — 2:15pm
Exhibits & Luncheon/Networking

2:15pm — 3:45pm
Data Quality in the Real World: Ensuring Integrity across the Medical Device Lifecycle

Speakers: **Karen Conway,** Past Chair of the Board, AHRMM and Vice President, Healthcare Value, GHX; **Susan A. Morris,** Supply Chain Healthcare Executive, Cerner Corporation;

Steve Luxenberg, MD, Associate Director for Health Informatics, CDRH;**Robert Lynch**, former Supply Chain Process Improvement Analyst, Franciscan Missionaries of Our Lady Health System (FMOLHS), consultant, GHX; **Dennis Black**, Director of eBusiness, BD

Changing regulatory approval pathways for manufacturers and new value-based payment methodologies for providers are accelerating the demand for real world evidence on how medical devices perform in routine clinical practice. This, in turn, requires a new approach to how product data is managed by providers and suppliers. It begins with how manufacturers manage master data within their own organizations and how they publish data to regulatory databases, but it also demands consideration of how that data is disseminated downstream and how providers consume and manage product-related data for a multitude of purposes, from sourcing to patient level accounting. This end-to-end panel of industry experts explores how to ensure data integrity across the medical device lifecycle.

Karen ConwayGHX*Past Chair of the Board, AHRMM and Vice President*
Susan Morris Cerner Corporation*Supply Chain Healthcare Executive*
Steve Luxenberg, MDCDRH*Associate Director for Health Informatics*
Robert LynchGHX - *ConsultantFranciscan Missionaries of Our Lady Health System (FMOLHS) - former Supply Chain Process Improvement Analyst*
Dennis BlackBD*Director of eBusiness*
3:45pm — 4:00pm
Stretch Break

4:00pm — 5:00pm
Think Globally: Act Locally: UDI Compliance at the Global Level

Speakers: **Jay Crowley**, Vice President UDI,USDM Life Sciences; **Dawn Fowler**, Program Manager, UDI and Master Data, Massimo

For many manufacturers, UDI compliance in the U.S. was handled with a singular focus on meeting the regulatory requirements of the FDA regulation. Now that the European Commission has issued the Medical Device and IVD regulation, and other countries have issued their draft UDI regulations, global manufacturers need to develop sustainable systems and processes to meet multiple regulations across multiple markets. A panel of medical device manufacturers will share how their organizations are expanding their UDI compliance programs to coordinate cross-functional activities and scale best practices on a global level.

Jay CrowleyUSDM Life Sciences*VP UDI*
Dawn Fowler Massimo*Program Manager, UDI and Master Data*
5:00pm — 5:15pm
Conference Wrap-Up and Prize Give-Away (MUST be present to win).