Unit of Use Work Group Charter

WORK GROUP TOPIC: Unit of Use

WORK GROUP LEADERS:

Corwin Hee, Medtronic, MDM Business Process Program Director

Amy Kohl, HIDA, Senior Manager of Government Affairs

PARTICIPATING MEMBERS:

Name	Organization	Title
Darcy Aafedt	Banner Health	Cost Improvement Senior Manager
Billy Almon Jr	Claflin	
Paul Ashford	ICCBBA	
Becky Ashin	University of Tennessee Medical Center	Vice President Advanced Orthopaedic Center
Kim Bedwell	Owens & Minor	Director, Regulatory Compliance Administrator
Minaei Behnaz	FDA Informatics Team	
Carol Bickford, Ph.D	ANA	Senior Policy Advisor
Kathleen Blake	AMA	
Jim Booker	Stanford Health Care	Manager, Master Data Management
Denea Boyle	Novant Health	Manager for Data Integrity
David Brooks	Medtronic	
Greg Bylo	GS1	Vice President, Healthcare
Jeanett Calderon	Advocate Health	
Alex Caldwell	Claflin	Director of Sales and Marketing
Kevin Capatch	Geisinger	
Pete Casady	Champion Medical Technologies	CEO & Co-Founder
Loretta Chi	FDA Informatics Team	
Mark N. Cohen, MD	National Recall Alert Center	
Karen Conway	GHX	
David Coons	Zebra Technologies	Vice President, Advanced Markets & Technologies
Jeff Coughlin	HIMSS	
Jennifer Crowder	Novant Health	Manager, Contract Administration
Jay Crowley	USDM	VP and Practice Lead – UDI Services and Solutions
Karen Dean	Kaiser/HTG	
Sheri DeVinney	MDMA	

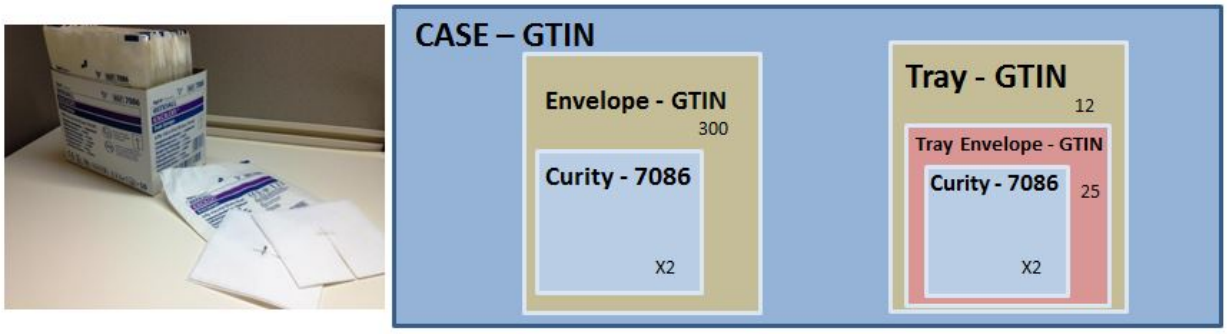
Christopher Diamant	FDA Informatics Team	
Pat Distler	ICCBBA	
Curtis Dudley	Mercy/HTG	
Todd Ebert	HSCA	
Hallissey Edward	FDA Informatics Team	
Steve Emrick	NIH/NLM	
Eli Fleet	HIMSS	
Cheryl Flury	Jump Technologies	VP, Marketing
Jennifer Gedney	CHA	
Beth Gibson	GS1	
Leslie Kelly Hall	Patient Advocacy	
Mohammed Harunani, MD	ADA	
Sandra Hayter	MedAssets	VP of Supply Chain Services
Michael Hudon	Philips	
Myoung Kim	J&J	Executive Director, Epidemiology, Medical Devices
Jodi King	Philips	
Indira Konduri	FDA Informatics Team	
Mark Leahy	MDMA	
Nancy LeMaster	BJC	
Joe Lewelling	AAMI	
Natalie Lind	IAHCSMM	
Keith Lohkamp	Workday	Director, Industry Strategy
John Lorenc	Reed Tech	
Denise Maxwell-Downing	AORN	
Lisa McGiffert	Consumer Union	
Allison Mehr	HIBCC	Communication Director
Matthew Mentel	Mercy/HTG	
Sandy Michel	FMOLHS	
Melissa Michurski	FDA Informatics Team	
Karen Morlan	Vanderbilt	Administrative Director, Supply Chain Operations
Alicia Morton	ONC	
Dennis Orthman	SMI	
Nancy Pakieser	Tecsys	Senior Director, Product Marketing & Business Development
Richard Perrin	Active Innovations	
Ron Prybella	Medegen Medical Products	Senior Director of Marketing
Erin Quencer	FDA Informatics Team	

Anita M. Rayner	FDA Informatics Team	
Dave Reed	Cook Medical	
Terrie Reed	FDA	
Zachary Rothstein	Advamed	
Christina Savisaar	FDA Informatics Team	
Michael Schiller	AHRMM	Senior Director
Jay Shawntae	FDA Informatics Team	
Cynthia Shumway	Intermountain/HTG	
Linda A. Sigg	FDA Informatics Team	
Rich Spano	BARD	
Leslie Steen	FDA Informatics Team	
Tom Stenger	BJC	
Robert Stephens	Sutterhealth	
Susan Stimpson	Novant Health	Director for Procurement and Business Systems
Barbara Strain	AHVAP – Value Analysis	
Liz Summy	ACHE	Executive Vice President/COO
Varsha Thakar	FDA Informatics Team	
Jerry Tischler	Specialty Surgical Products	
Jeffrey Toevs	Providence Health	
Joyce Trese	Roche Diabetes Care	
Heather Valadez	FDA Informatics Team	
Margaret Weiker	NCPDP	
Tom Werthwine	J&J	
Shanell Whitehead	FDA Informatics Team	
Chris Wiekert	Infor	Product Manager
Keith D. Williams	Campbell Clinic	
Natalia Wilson	BUILD	
Ricki Wilson	Vizient	
Marc R. Wine	VA	Lead Executive, Cooperative Research and Development Program
Karen Wolfe	Mayo/HTG	
Sandy Wolfskill	HFMA	
Zita Yurko	Philips	
Liz Wang	Antmed	Marketing assistant
Molly Chen	Antmed	Administrative Director

CHARTER:

FDA Global Unique Device Identification Database (GUDID) compliance currently requires manufacturers to provide unique device identifiers at the "Unit of Use" (UOU). Many products have multiple discrete items contained within the lowest packaging level. In those instances, the requirement is to provide unique device identification for items that are not intended to be labeled in the product. These identifiers will only be found in the GUDID itself.

UOU Package Example



7086 Level	ANSI UOM	GTIN	Qty Sponges	Units at Next packaging level	PI?
Single Sponge	-	UOU GTIN	1	-	No
Package	PK	**10101010101019**	2	-	No
Tray	TY	**20101010101016**	50	25	Yes
Case	CA	**30101010101013**	600	12	Yes

In the example listed above, the manufacturer is expected to provide another identifier to represent the individual sponge as there are two included in the lowest packaging level. The original intent of the rule was to provide a mechanism to track individual medical devices.

BACKGROUND:

The UOU concept is difficult to understand and complicated to execute precisely.

- There is a lack of clear guidance from the issuing agencies because the concept is not widely used in other industries.
- Without clear guidance, many manufacturers are not assigning these identifiers correctly to their products.
- Many manufacturers are incorrectly loading their data into the FDA GUDID. There are multiple examples of incorrect and/or erroneous data being entered into GUDID. These failures threaten to jeopardize the perceived integrity of the underlying database.
- The intended use of the UOU is unclear. While the intention was to use the UOU in electronic health records (EHR) and for other documentation purposes, there are no clear guidelines for this activity. Additionally, it is still unclear whether or not the clinicians and staff will be able to use the UOU as originally intended.
- The UOU is never intended to be labelled anywhere. Without any physical reference to the identifier, users will never be able to scan AIDC to obtain the identifier. They will have to intuitively know to search the GUDID, ensure that they have identified the correct product, select the correct UOU (assuming it has been loaded properly), and manually enter the identifier into their documentation.

AFFECTED STAKEHOLDERS:

Manufactuers, Regulators, Providers, Distributors, Standards Organizations, Health IT providers

DELIVERABLES:

- Convene a task force to identify issues with the existing UOU
- Develop recommendations for the proper disposition of UOU
- Develop recommendations for the use of UOU in GUDID
- Identify potential use cases that might require UOU
- Develop potential solutions for the use cases requiring UOU

COMMUNICATION PLAN

Develop a three-part webcast series that covers this topic starting at a high level and then drilling down into the details and potential use cases and solutions.