

MCKESSON

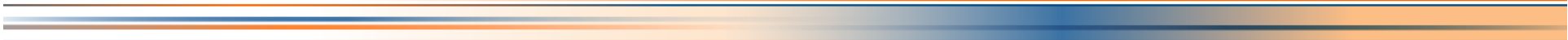
Empowering Healthcare

**A Wholesaler's Point of View on
UDI**

Welcome to San Francisco



PHOTO: JUSTIN SULLIVAN/GETTY IMAGES



Overview

- Advancing the healthcare industry for more than 180 years.
- Innovation, technology and process knowledge gives our customers and partners the power to succeed
- Pharmaceutical Distribution
- Medical Surgical
- Specialty Drugs
- Fortune 14 company, 3rd largest company in California with sales of \$123 Billion.



Jay's Memorable Quote

“ Current device identification is a mess. Different manufacturers use different standards in different ways if they use anything at all. Distributors apply their own. Hospitals apply their own. And we just sort of cascade into this series of events which means that we can't find devices.”

Jay Crowley, Senior Adviser for patient safety at the U.S. Food and Drug Administration's (FDA) Centers for Devices and Radiological Health (CDRH) at the FDA UDI Public Workshop on February 12, 2009.

Parallels with National Drug Code

1969- The Food and Drug administration(FDA) created a National Drug Code Directory

1970- the FDA required NDC numbers on pharmaceuticals to simplify out-of-hospital drug reimbursement for Medicare

1972- Drug Listing Act established

Commonality between NDC and UDI

- Each item is unambiguously identified
 - Eliminated the human error
 - Eliminates confusion of the product being ordered
 - Filling errors are virtually eliminated in the warehouse by using AIDC capture and verification
 - It led to the elimination of paper documents the warehouse
 - Recall management is done by Unique Identifier and Lot Number
 - Returns are processed by scanning the barcode for replenishment of saleable returns
 - Dramatically improved Inventory accuracy
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Benefits of a Unique Device Identifier

- Unique identification of an item
 - Ability to use AIDC to capture the information on the package
 - Ability to link to a database for additional information about the item
 - Improvement in service level
 - Reduction in inventory
 - Improved recall management
 - Improved returns processing
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FDA Looks for the Following UDI Benefits

Provide a standardized identifier that will allow manufacturers, distributors and healthcare to improve:

- ▶ ordering accuracy and fulfillment
- ▶ returns processing
- ▶ recall management

Allow more accurate reporting, reviewing and analyzing of adverse event reports so that problem devices can quickly and accurately withdrawn from the market

Provide a foundation for a global, secure distribution chain, helping to address counterfeiting and diversion and prepare for medical emergencies.

GS1 Expectations of UDI

Unique Device Identification is expected to improve patient safety and healthcare business processes. A single, global system of standards is fundamental to enable an efficient and effective implementation of UDI by all healthcare stakeholders worldwide.

Challenges

- The regulation takes 7 years to fully implement.
 - Variability is the enemy of Six Sigma process control in the warehouse environment
 - Industry will have to work together to determine the best placement of the barcodes for consistent accurate reads
 - Quality control of barcode printing
 - Variability of the size of the medical devices.
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AIDC and The “Patient Rights”

