



# Practical Aspects of UDI *(Unique Device Identification)*

Panel Discussion

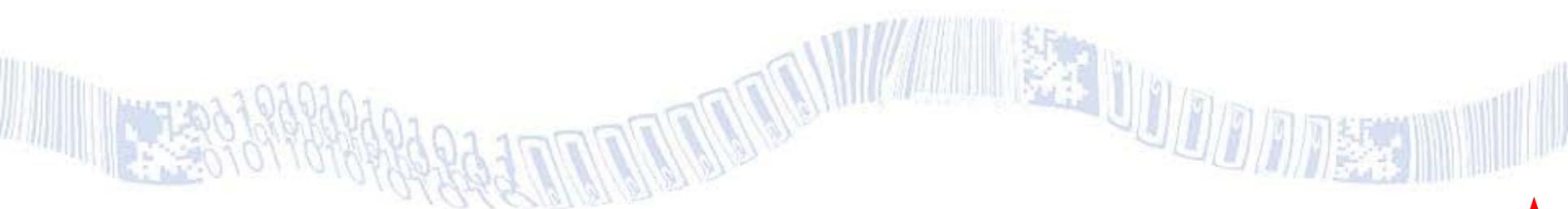
April 6, 2011





# GS1 Healthcare Topics

- Ground Rules
- UDI Defined
- Key Areas of UDI and How They Impact You
- Questions





# Healthcare Ground Rules

- This is an interactive session
- Define 'UDI' and some basics
- Then the panel will introduce specific topics
  - Opportunities
  - Costs
  - Questions
- Then it's your turn to ask questions, debate, and learn from each other
- You will get more out of this if you participate, so please speak up!

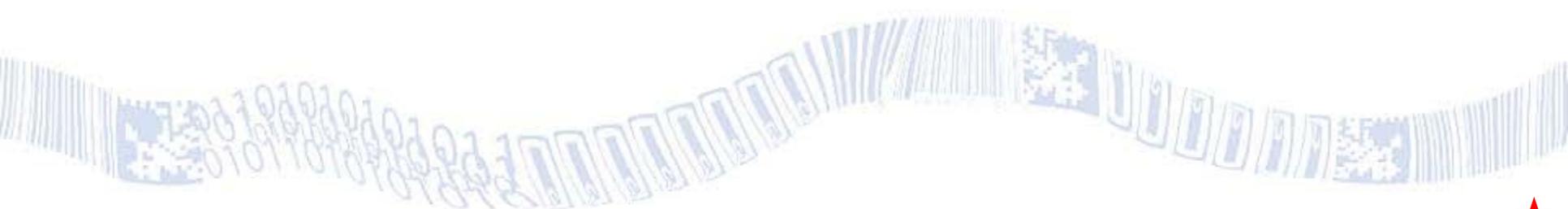




# GS1 Healthcare Preamble

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- Key Questions you need to ask...
  - How to implement?
  - What help and information is available?
  - How does the GS1 System help me?
  - How much is this going to cost?
  - How do I make the business case to senior managers?
  - Who do I contact for more information?





# **Healthcare Today's Panelists**

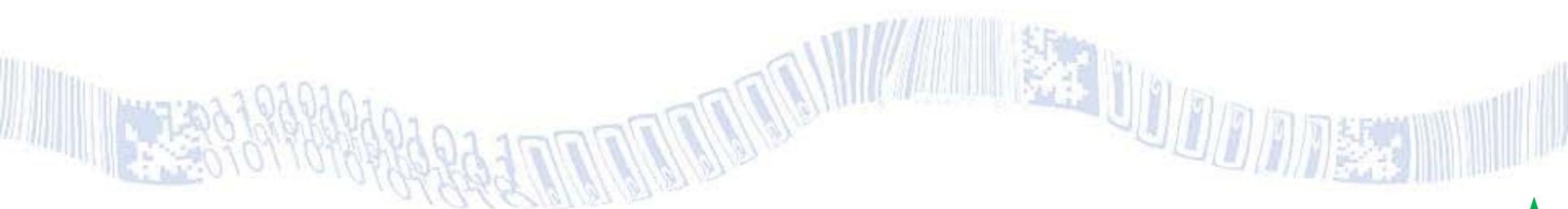
- Steve Capel – Moderator and Chief Cheerleader
- Rosalind Parkinson – Hospital / Patient View
- Clemens Haas – Supplier / Supply Chain View
- Chuck Biss – GS1 Global Office AIDC, and backup cheerleader





# Healthcare Why UDI?

- UDI can link product to episode of care
- UDI recognized in global economy
- UDI rides on global IT infrastructure
- UDI crosses business-clinical divide
- UDI cuts costs from healthcare



# GS1 Healthcare **Why UDI?**

- Medical devices from different suppliers may share the same product numbers, creating confusion and errors
- With UDI, everyone knows exactly \*which\* product is being transacted, used, or reported
- Using the GS1 System of Standards to address UDI drives additional benefits (eCom, AIDC, Traceability, GDSN, etc.)

Device Part Number	Manufacturer	Device Description
1006	Masimo Corp.	Patient Cable PC12
1006	Salter Labs	System, Skin Fixation, Tender Grip
1006	Alcon Labs, Inc.	Needle, Ocutome, Irrigating
1006	Chattanooga Corp	Pack, Moist Steam, Std., 10x12



# GS1 Healthcare UDI Defined

- UDI = Unique Device Identification
  - Globally-unique product identifier
  - Every device is assigned a UDI code
  - Most packaging levels marked with the appropriate UDI
    - UDI differs by packaging level
    - So, need to develop a “UDI Reference” solution
  - Database of all UDI’s with additional product details

UDI +  
Variable Data

ENDOPATH®  
**dextrus**  
Finger-Mounted Locking Forceps

REF FMF02 LOT 1Q34

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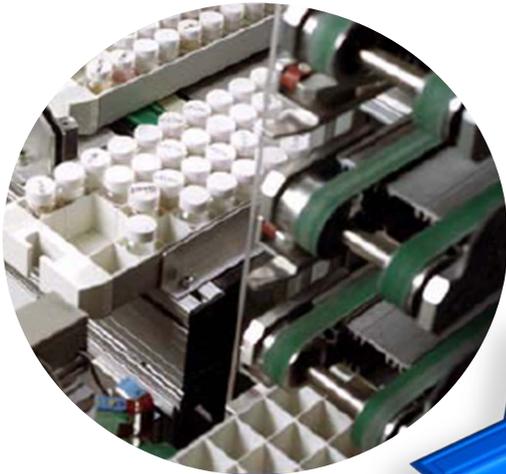
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# Healthcare It's a Regulation, but...

...we're also building a new "ecosystem of opportunities", if you're clever and willing to make some investments...



**Manufacturer**



**Healthcare provider**



**Distributor, Wholesaler, GPO...**



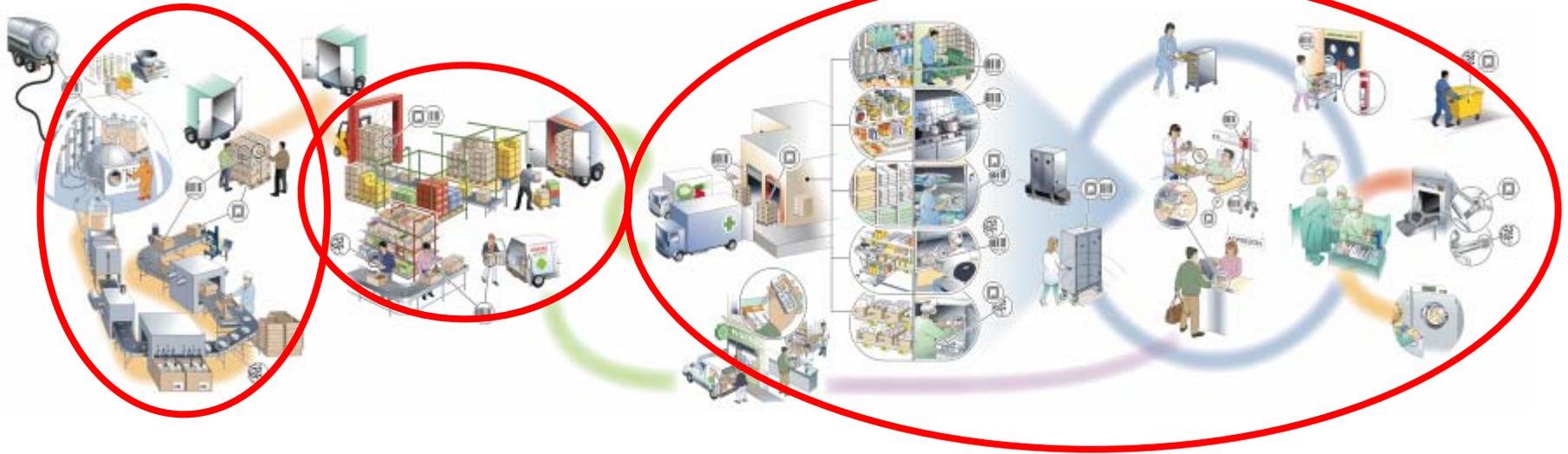
**Patient**





# Healthcare UDI Lifecycle in Healthcare

- UDI in Manufacturing
- UDI in Distribution



- UDI in healthcare facilities





# Healthcare UDI in Manufacturing

- Opportunities
  - Meet regulatory requirements
  - Foundation for downstream improvements
- Costs and Challenges
  - High-speed printing of variable information
    - Lot, Expiry
    - Serial Number (for currently-serialized products)
  - Equipment and systems needed for
    - Printing and verifying the UDI and variable data
    - Assigning, storing, tracking variable data
    - Communicating this information down the supply chain



# GS1 Healthcare UDI in Distribution / Fulfillment

- Opportunities
  - Automate ordering, billing, replenishment
  - Automate physical processes by scanning
    - Receiving
    - Stocking and Inventory Management
    - Picking and Shipping
  - Reduce errors, returns, exchanges, administration
- Costs and Challenges
  - Equipment and systems needed
    - For scanning the UDI
    - For assigning, storing, tracking variable data





# Healthcare UDI in healthcare facilities

- Where?
  - Supply chain
  - Bedside
  - EHR
  - Comparative Effectiveness
  - Accountable Care Organization
- Opportunities
  - Reduce errors
  - Reduce holding costs
  - Cross the business-clinical divide
  - Facilitate healthcare reform (for example in the US)





# Healthcare UDI is the foundation

Leading to improved processes for...



**UDI enables transparency, improves processes, increases efficiency and makes isolated systems interoperable**





Healthcare

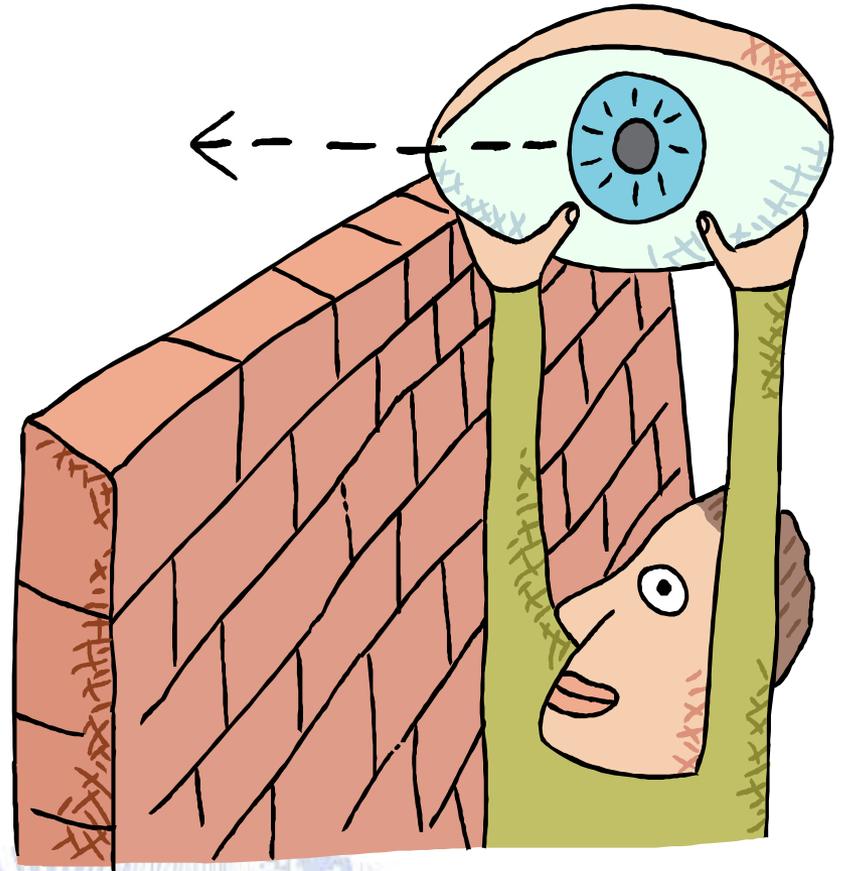
# Vision: UDI in Hospital Information Systems

- UDI used in...
  - Procurement systems
  - Inventory management
  - Payment
  - Clinical information (EHR)
  - Billing systems



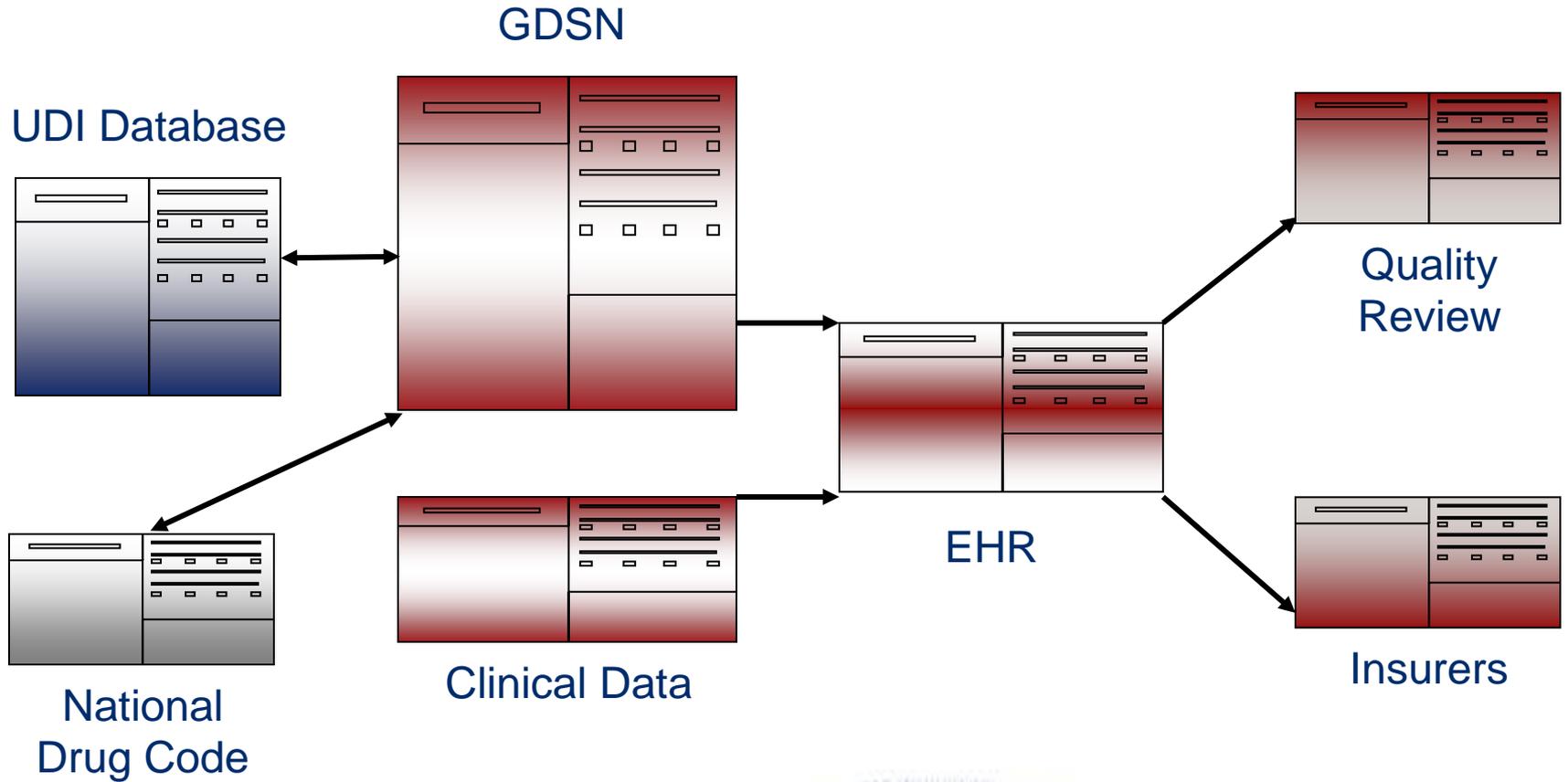
# It's all about Visibility and Value

- Order and Price Accuracy
- Inventory Optimization
- Patient Safety
  - Right Product/Right Patient
  - Recall Management
- Regulatory Compliance
- Claims Development





# Vision for System Integration



## **Institute of Medicine Top 100 Initial Research Priorities (June 2009)**

### **Examples:**

- **The Rule:** Compare the effectiveness of treatment strategies for atrial fibrillation including surgery, catheter ablation, and pharmacologic treatment
- **The Exception:** Compare the effectiveness of formulary management practices and usual practices in controlling hospital expenditures for products other than drugs, including medical devices.

### **Private Sector Examples:**

Sisters of Mercy ROI proposal: Drug eluting vs. bare metal stents



# ACOs Increase Complexity and Need for Standards

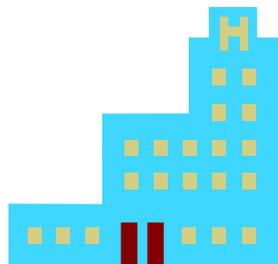
UDI can be a key enabler to meet these new requirements...

## Accountable Care Organization

Primary Care



Hospital



Specialists



**Other Possible Components:**

Home Health

Mental Health

Rehab Facilities





# GS1 Healthcare Summary

- Key Questions you need to ask...
  - How to implement?
  - What help and information is available?
  - How does the GS1 System help me?
  - How much is this going to cost?
  - How do I make the business case to senior managers?
  - Who do I contact for more information?
- Takeaways...
  - We are all in this together
  - The standards are ready for >90% of medical devices
  - There are numerous groups working on solutions





# Contact Details

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