Resource Booklet: UDIs for Medical Devices

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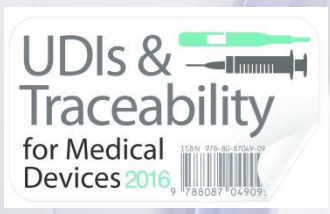

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Foreword

By Craig Karagitz, UDI Expert

It's hard to believe that it has been a little over five years since I first started learning about the GS1 Standard and the seeming tidal wave on the horizon at that time called Unique Device Identification or UDI. To try to get educated on this subject that I knew absolutely nothing about, I went to a conference called "U Connect", which eventually became the GS1 Connect conference held annually in the United States. And from there, I never looked back. I went to every conference, workgroup forum, group discussion, etc., I could find related to either GS1 or UDI and supposedly became a "subject matter expert".

But what did that really mean? Well, basically, it meant that as I led my company through this huge effort, we had encountered more pitfalls and fell into them faster than at least some of the other people in the industry. And of course people want to hear about your trials and tribulations, so I started getting asked to speak at conferences, conferences like the UDI & Traceability for Medical Devices conference held the last two years in Munich, Germany.

Fast forward to present day, and as we all know, the US FDA's UDI regulation has been "live" since September 2013 and Medical Device companies have been actively facing the challenges of re-mapping their processes, revising and upgrading their printing and labelling technologies, and gathering data from all corners of their little worlds so that they can upload it to the Global Unique Device Identification Database or GUDID. We also should all now be aware that the UD FDA is just the first of an expected many more regulatory bodies to enact some form of UDI regulation, including of course, the European Commission.

Foreword

By Craig Karagitz, UDI Expert

In response to these challenges, Pharma IQ has compiled this resource booklet containing presentations held at the 2015 Medical Device UDIs and Traceability conference on the following subjects:

- GUDID – The Data Gathering and Maintenance Challenges
- Re-thinking Your Labelling Processes and Getting the Buy-in from All Stakeholders
- Evaluating and Determining the Key Components, Planning and Execution of a UDI Project

These presentations drill down and examine each of the above challenges in great detail and assess the strategies that can address them.

So what does all this mean to you? Well, even though it may seem like an insurmountable task looming on the horizon, you can avoid disaster by getting started now (if you haven't already), and by studying this eBook, and by attending as many conferences as you can to learn what you need to learn, as well as to help shape the upcoming regulations as they are proposed. Don't let the wave come crashing over and capsize you, turn into it and face it head on!

Cheers and good luck!

Craig Karagitz, UDI Project Manager at USDM Life Sciences.

GUDID – The Data Gathering and Maintenance Challenges

By Inge Ornhoj Senior Process Improvement Manager, Coloplast & Bianca Maria Gravenhorst Greve Senior Regulatory Affairs Manager,Global Operations, Coloplast

This slideshow explores data challenges in regards to UDIs, master data governance, controlling data maintenance and handling submissions to GUDID.

GUDID - The Data Gathering and Maintenance Challenges

UDIs & Traceability for Medical Devices 2015

Inge Ørnhøj, Sr. Process Improvement Manager & Bianca M. Gravenhorst Greve, Sr. RA Manager

Agenda

- The data challenge in regards to UDI
- Master Data Governance
- How to control data maintenance
- GUDID account
- Handling submissions to GUDID

This is the four business areas of Coloplast

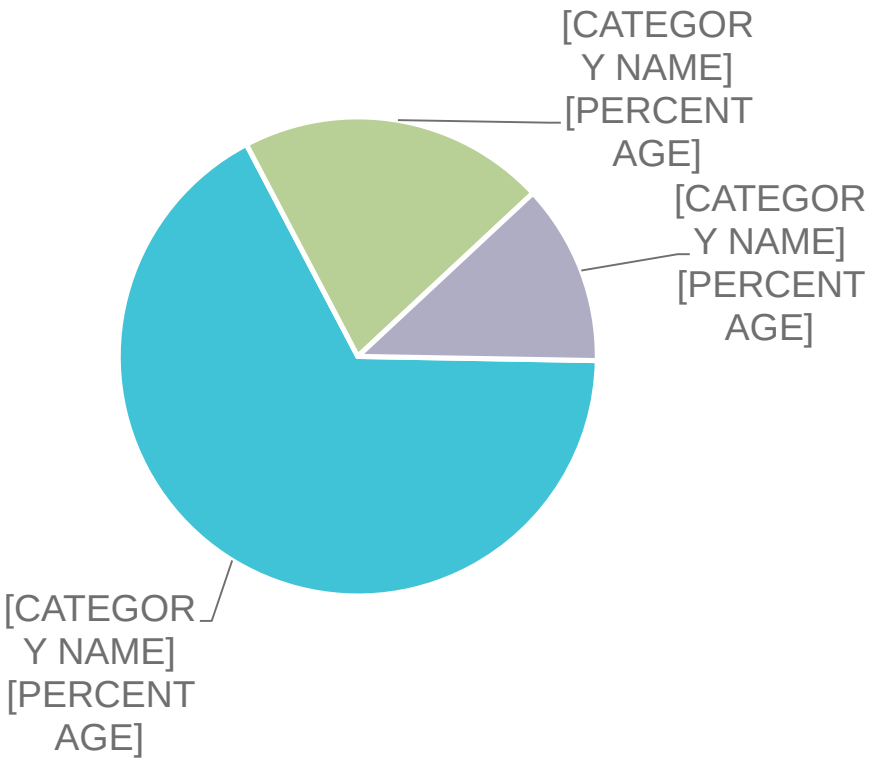
Ostomy Care

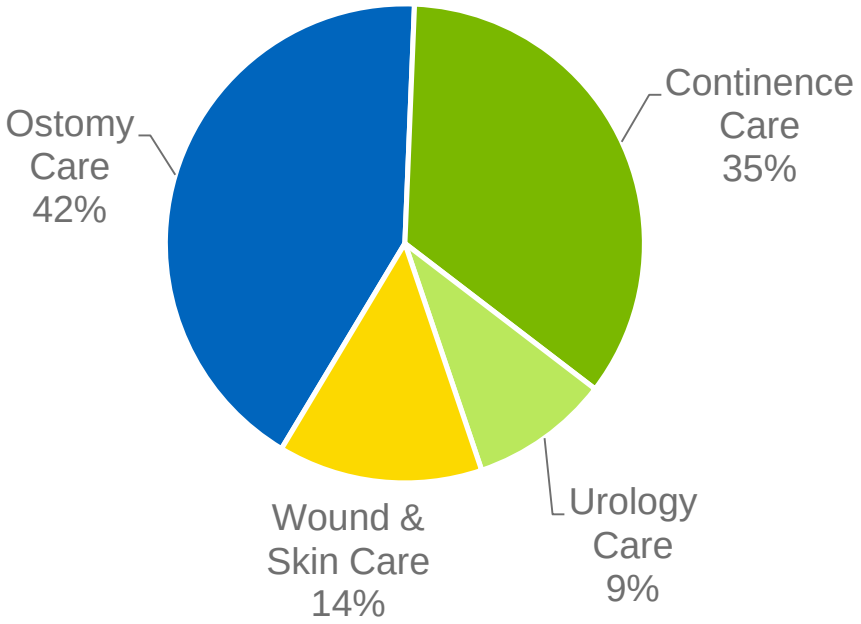
Urology Care

Continence Care

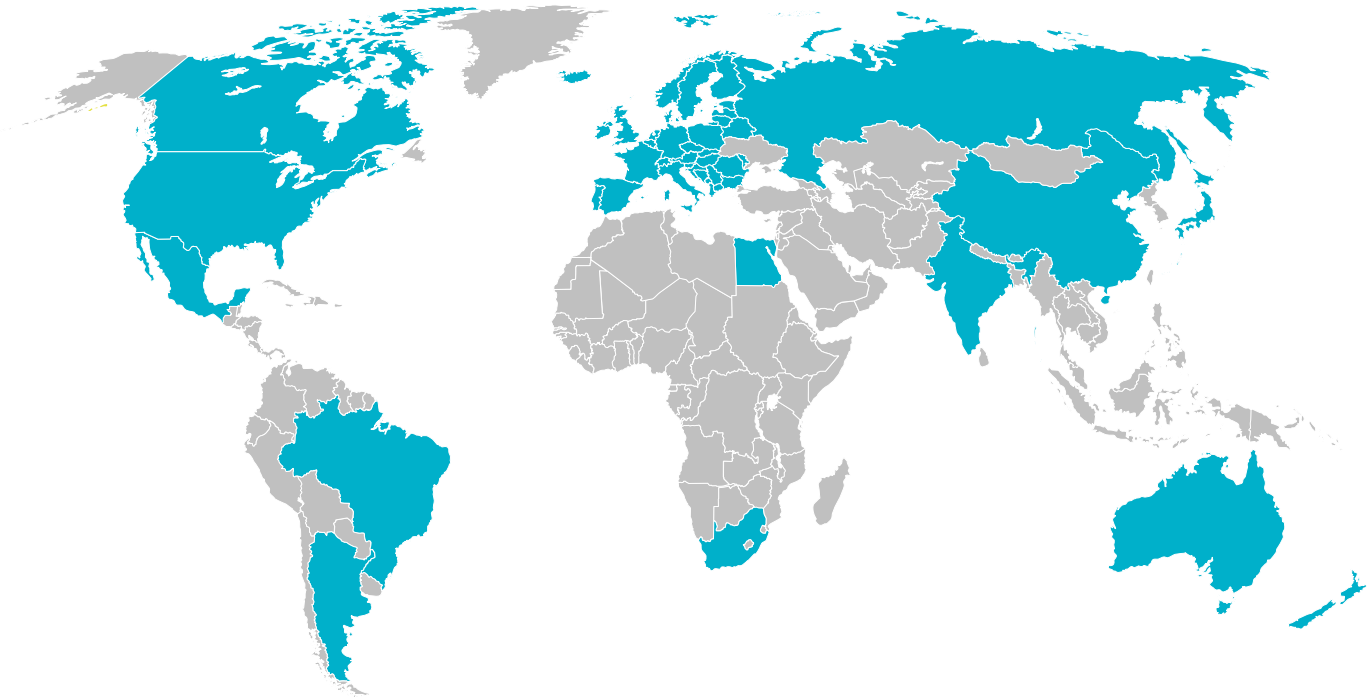
Wound & Skin Care

Coloplast has a strong global position



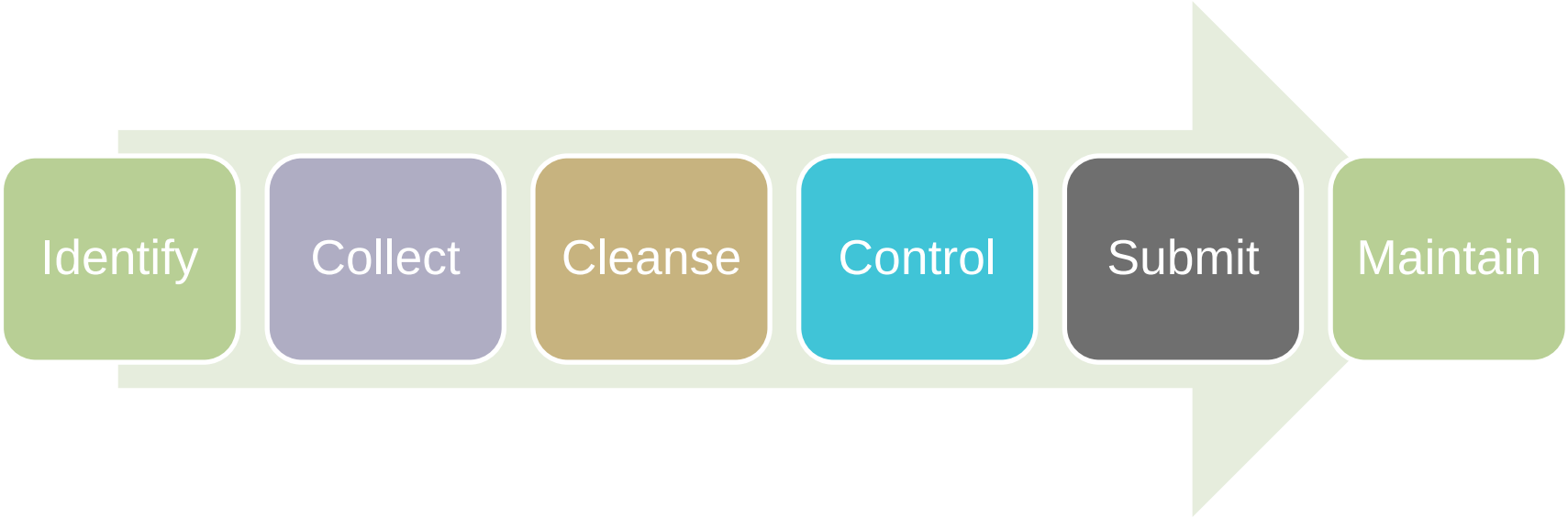


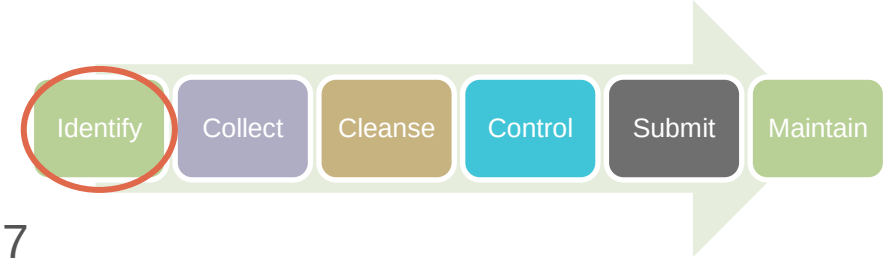
Sales offices all over the world and headquarter in Denmark



The quality of your data is key

The data challenge



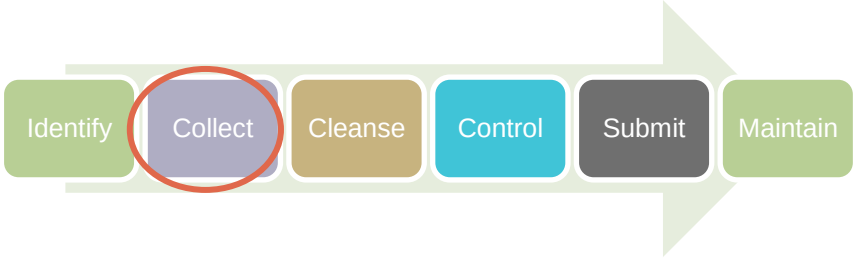


Identify

- Data needed for each data element (55 + 7 auto populated)
- Translate each data element to your company “language”
- Data sources and source systems
- Is data extractable in electronic form?
- Group into level of accessibility

Status	Count	Percentage
Completed / Known data source – better specification needed	24	39 %
Known data source – data clean-up or population needed	14	22 %
Potential data source identified – specification & data population needed	6	10 %
No electronic source	11	18 %
Auto populated	7	11 %
Total	**62**	**100 %**

Collect



- If data exist in multiple systems choose a unique source
- Establish electronic data sources where missing
- Make specification of data extract method per data element
- Collect data from source systems to one repository
  - Get IT resources to support the data collection
  - Establish a repository
  - Create interface to source systems

Status	Count	Percentage
Completed / Known data source – better specification needed	24	39 %
Known data source – data clean-up or population needed	14	22 %
Potential data source identified – specification & data population needed	6	10 %
No electronic source	11	18 %
Auto populated	7	11 %
Total	**62**	**100 %**

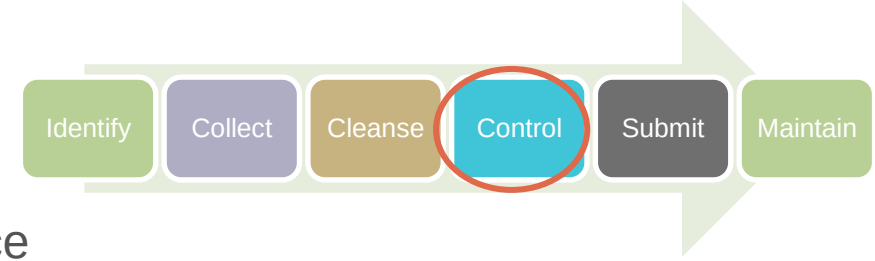
Cleanse

- Identify data accuracy
- Identify the correct value where multiple sources exist with different values
- Clean up redundant data
- Make sure your data still supports other areas of your daily business
- Establish data completeness where data is missing

Translated to GUDID format:

Size type	Size	Size UoM
Width	10	Centimetres
Height	10	Centimetres
Width	4	Inches
Height	4	Inches

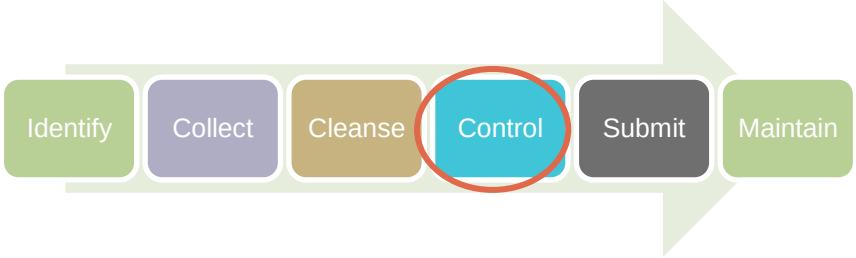
Control



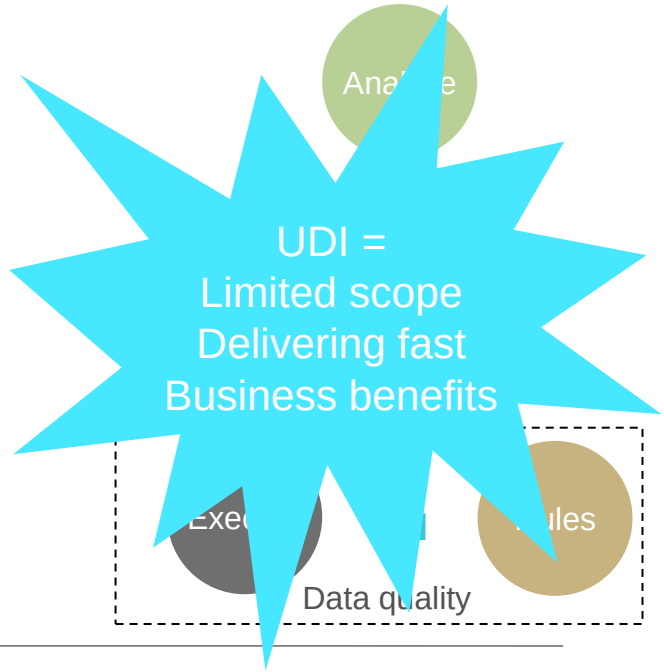
Control data by establishing data governance

- Identify owner of each data element
- Define rules for each data element
- Establish quality measurements
- Monitor that data is maintained in the right way
- Incorporate data control in daily operations
  - Quality control system
  - New product development procedures
  - Change control procedures
- Ensure knowledge in the organisation about UDI in general

Master Data Governance (MDG) - How can MDG help you?



- Establish one single source of truth
- Provide reliable regulatory framework
- Establish clear responsibilities
- Provide focus on correct data in the organisation
- Making data consistent
- Improving data quality
- Making data accurate & complete
- Maximising the use of data to make decisions
- Improving business planning
- Maximising profit of the company



Master Data Governance (MDG) – e.g. Catalogue number

Example

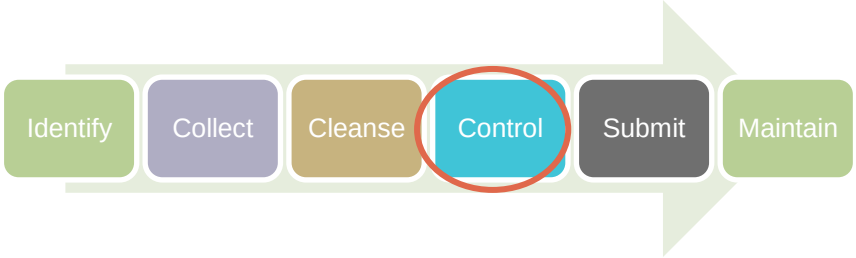
Created in:

- EC declarations of conformity
- Labelling system
- Specifications
- Design documentation
- ERP system
- Finance reporting system

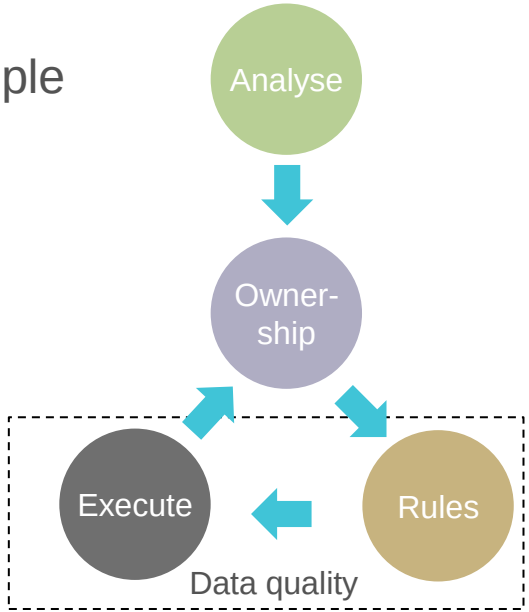
Used in:

- Price lists
- Catalogues
- Registration files
- Labels
- Invoices
- Certificates
- Change Requests
- Complaints
- Reporting
- Marketing materials
- Web shops
- Web sites
- Sales order entry

Master Data Governance (MDG) - What does it take?



- Manpower to set up the MDG organisation
- Change mind-set – impacts day-to-day work for many people
- Resources to work with ownership responsibilities
- Train people responsible for data entry
- Resources to analyse the data
- Resources for data cleansing
- Master data repository
- Changing processes



MDG & UDI roles

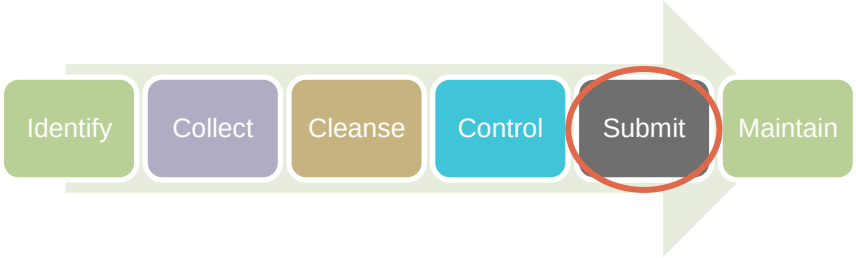
Regulatory Affairs

- Owner of regulatory data elements
- Develop procedures & work instructions
- Get UDI into the different operational systems & documents
- Training in UDI requirements & data maintenance
- Verify data before submission
- Submit data to GUDID

Supply Chain Management

- Owner of logistics data elements
- Develop procedures & work instructions
- Data cleansing
- Train users in data maintenance
- Establish tools to support data maintenance

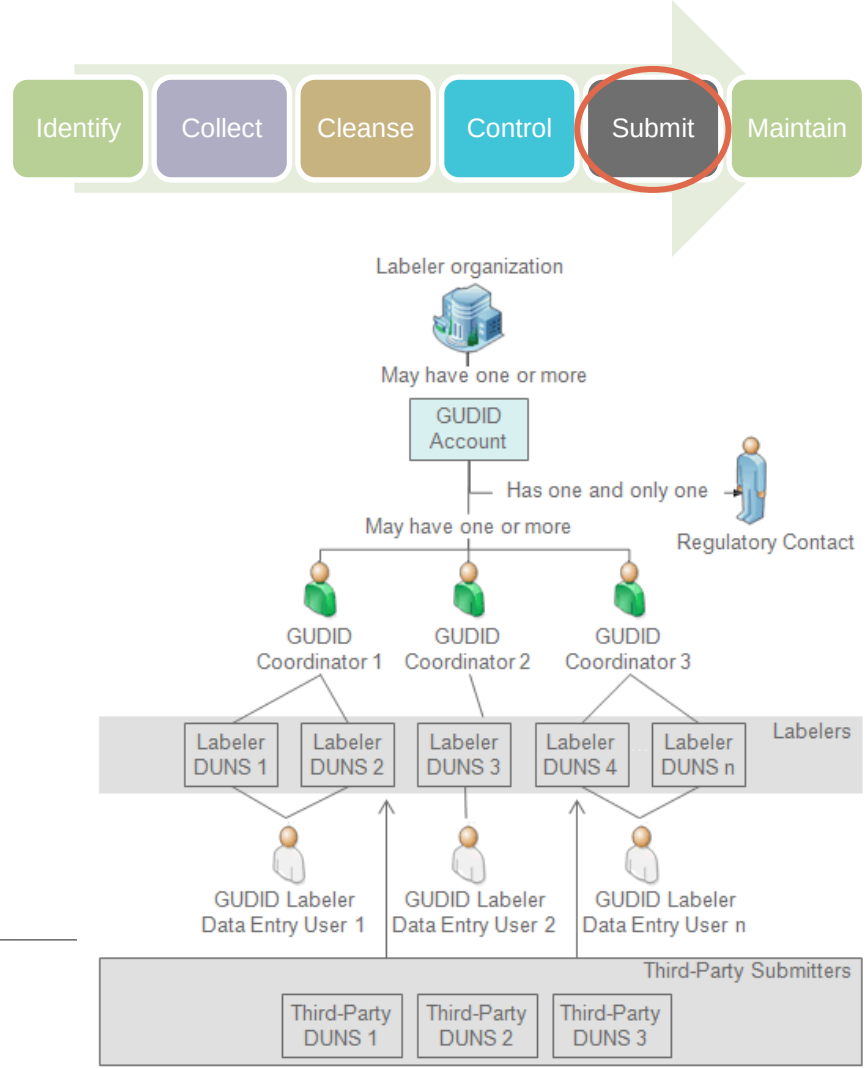
Submit



- Choose submission method
  - Web form
  - HL7 SPL
- For web form submission ensure manpower for data entry & validation
- For HL7 SPL submission select a supplier, ensure IT resources & integrate to the system

GUDID account – The roles

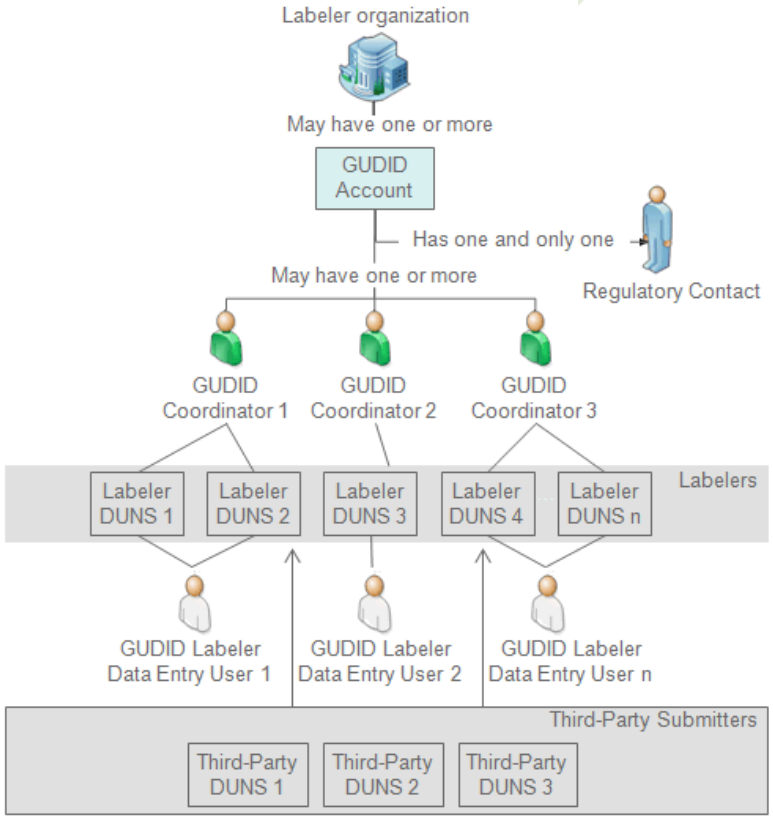
- Labeler organization
- Regulatory Contact
- GUDID Coordinator
- Data Entry Users
- Third-Party Submitters



GUDID account – Roles & responsibility

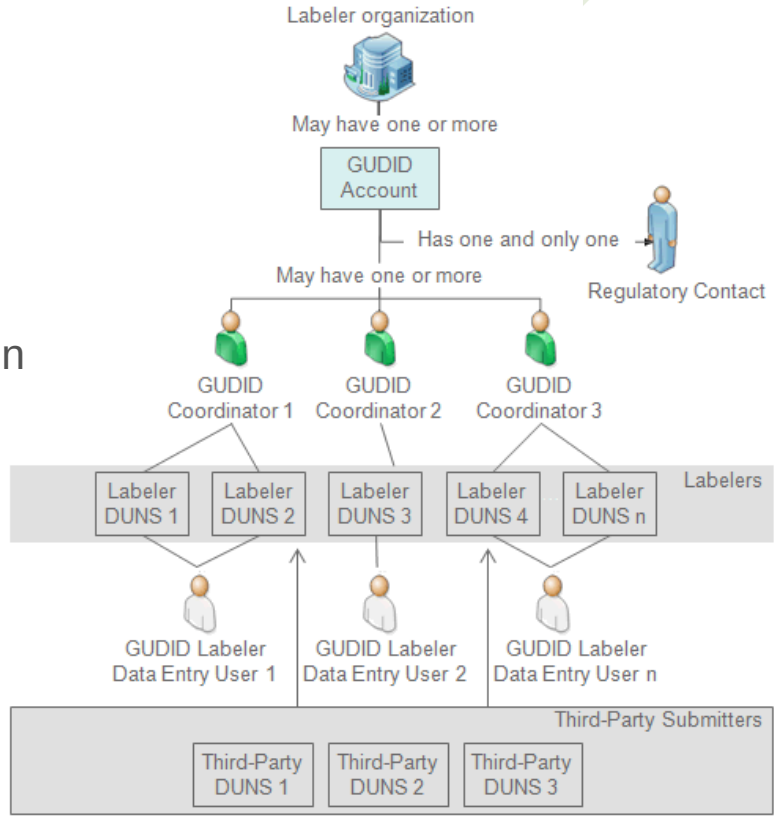
- Labeler organization
  - Represents the labellers view of the highest corporate level = head quarters' DUNS #
  - Name and address must be correct in the D&B DUNS database

- Regulatory Contact
  - Individual responsible for management of GUDID submission requirements for the labeller organisation
  - Will be contacted by FDA on matter pertaining to GUDID regulatory submission requirements

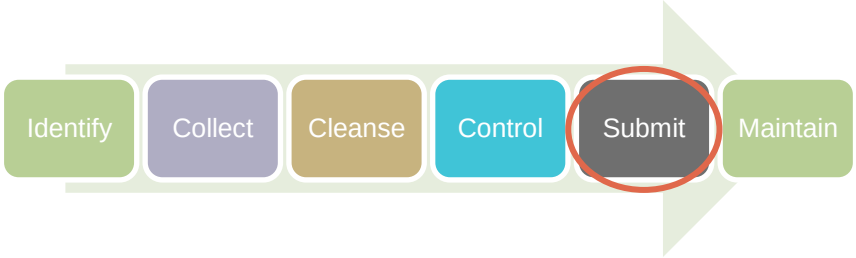


GUDID account – Roles & responsibility

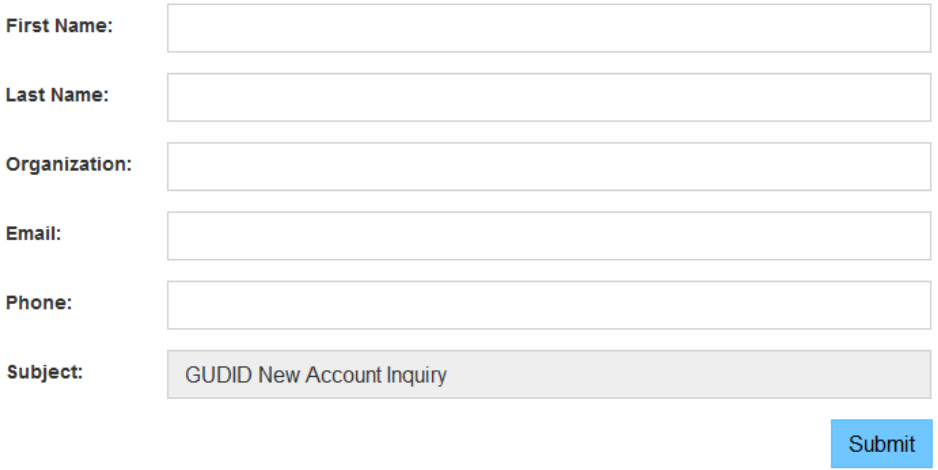
- GUDID Coordinator
  - Assigned one or more labellers DUNS #
  - Create Data Entry user accounts
- Data Entry Users
  - Responsible for data entry
  - Responsible for data submission
  - Responsible for management of device identification information
- Third-Party Submitters
  - Needed if submitting via external company



GUDID account – Setting up the account

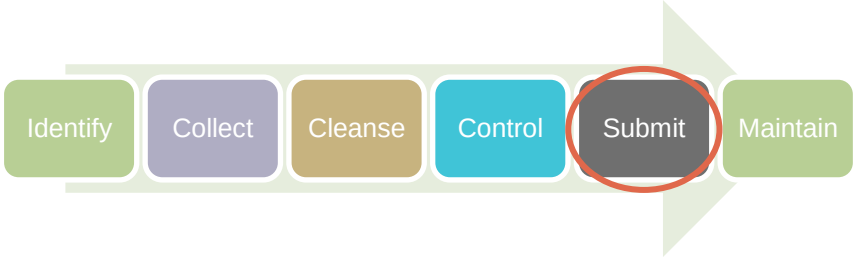


- Complete short form on FDA UDI site and submit
- Complete long form received from FDA
- Provide Device Listing # of one device
- Provide information about Regulatory Contact and GUDID Coordinator
- Provide Labeller DUNS #
- Submit via UDI helpdesk



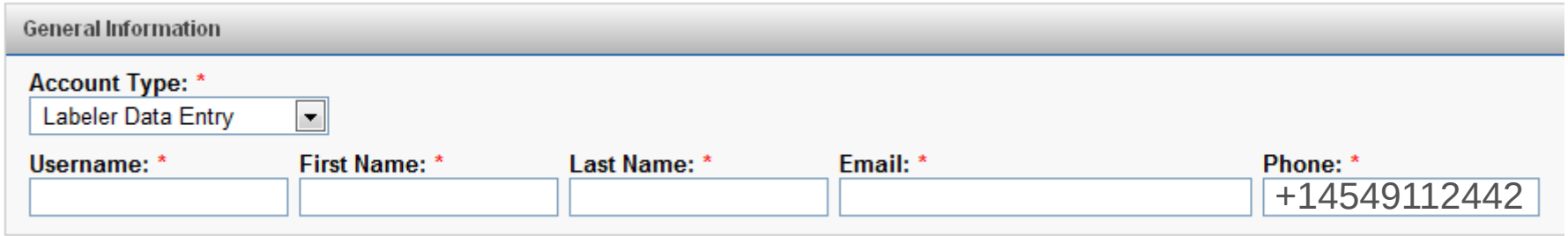
Link to application form:
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/GlobalUDIDatabaseGUDID/ucm416113.htm

GUDID account
- Setting up Data Entry Users

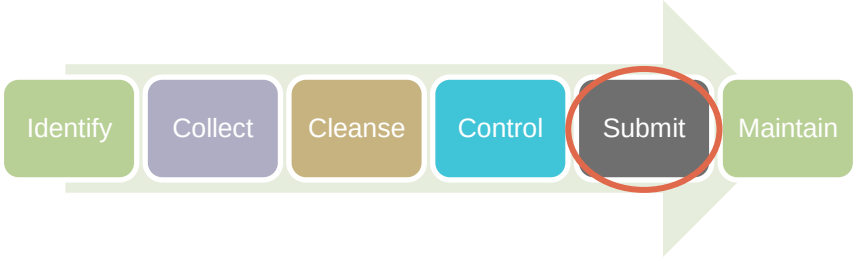


- Log on as GUDID Coordinator
- Choose Manage Accounts

- Choose Username
- Complete form and save
- E-mail automatically sent to user with log-on details



Handling submission to GUDID

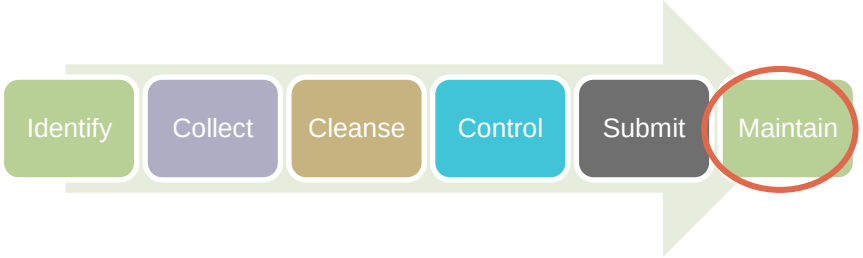


- Class III devices – submitted via web form (59 products → 2 man weeks)
- Implantable + LS/LS – will be submitted via Excel template + submission tool
- Class II devices – will be submitted via master data repository + submission tool

- We have chosen Reed Tech for submission as they have:
  - A proven record of submission
  - 24/7 support
  - A user friendly system

Deadline	Scope	Products impacted
24-Sep-2014	Class III	2 %
24-Sep-2015	Implants + LS/LS	6 %
24-Sep-2016	Class II	26 %
24-Sep-2018	Class I	66 %

Maintain



- Overview of data element changes that triggers a new DI, e.g.
  - Brand name
  - Packing size
- Ensure knowledge in the organisation about DI triggers
- Incorporate data maintenance in daily operations
  - Quality control system
  - New product development procedures
  - Change control procedures
- Ensure re-submission when required

The quality of your data is key

Our mission

Making life easier for people
with intimate healthcare needs

Our values

Closeness... to better understand

Passion... to make a difference

Respect and responsibility... to guide us

Our vision

Setting the global standard
for listening and responding

Update: 2016

When asked about the progress made since the conference, Inge Ørnhøj clarified:

" All data sources have been identified. However, we are still working on making data extractable in electronic form.

Data cleansing and data population is well underway.

Owners of all data attributes have been defined and data governance for the various attributes is being established.

We have gained experience with the use of HL7 SPL as we used this submission method for Life sustaining / Life supporting devices."

Re-thinking Your Labelling Processes and Getting the Buy-in from All Stakeholders

By Dawn Fowler Senior Manager, Labeling & Documentation, Endologix

This presentation discusses the route to obtaining buy-in from senior figures as well how to fully locate and illustrate where the return on investment lies within UDIs.

UDI Project Buy-In & Potential ROI

Dawn Fowler

You have to implement UDI….
So, what's next?

Senior Management Buy-in……..

"Before I make my decision, I'd like to see those meaningless statistics again."

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Steps To Buy-in (Senior Leaders & Stakeholders…..)

- Prosci's ADKAR® Model - Awareness, Desire, Knowledge, Ability & Reinforcement
- In order for a change to be made successfully, an individual must have strong:
  - Awareness of the need for change
  - Desire to participate and support the change
  - Knowledge on how to change
  - Ability to implement required skills and behaviors
  - Reinforcement to sustain the change

Steps To Buy-in …..

- Develop awareness and recognition of need to support this change – use facts & statistics
  - "XXX" has developed regulations for industry to comply.
  - Without doing this, we cannot sell product in "XXX"….
- Become familiar with industry best practices
  - Comparable size competitors in industry executed using "XXX" plan/approach/tools
- Communicate a clear vision & goals
  - Our goal is to have all our products UDI compliant by XXX date

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Steps To Buy-in…

- Build & present your business case
  - Develop a solid business case for the project
    - Phased approach - Assessment, Strategy, Planning
    - Benefit Realization
    - Risk Mitigation
    - Return on Investment (ROI)
    - Certainty of return
    - Be ready to educate on the true bottom line benefit -
      - Product compliance = product sales

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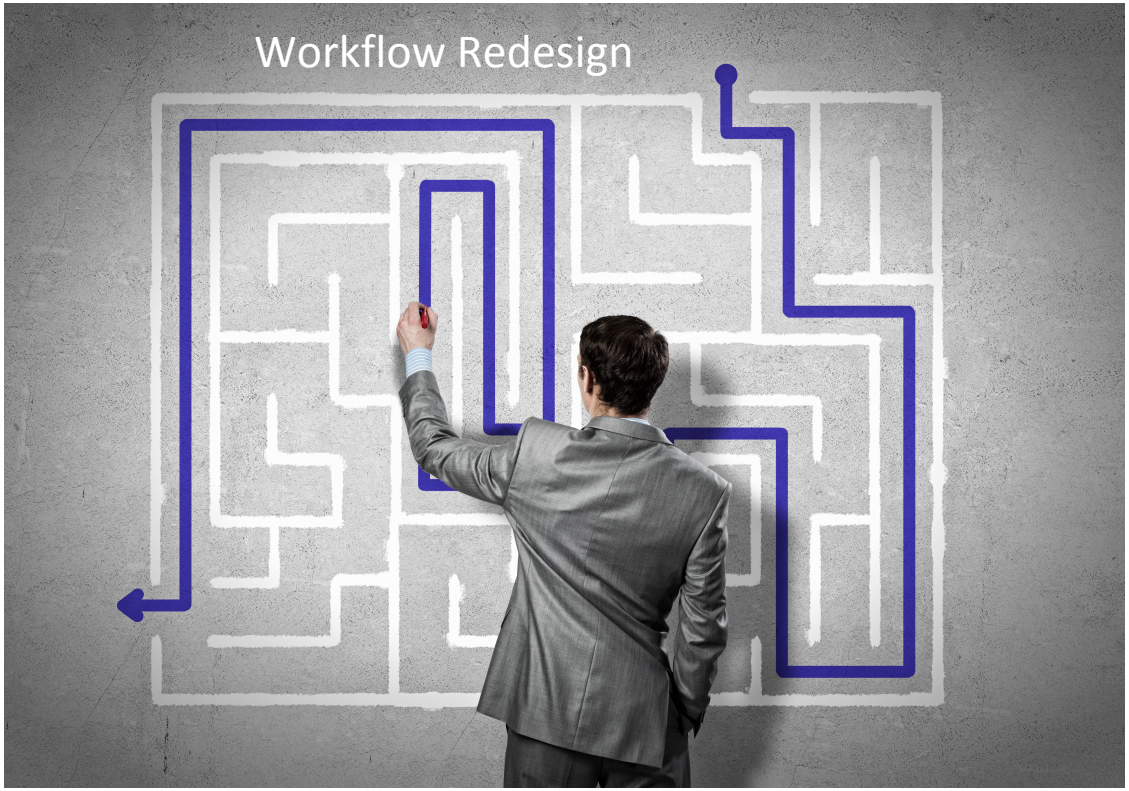
- Don’t present this as an example of your planning process…..



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More Steps To Buy-in…

- Present multiple options for implementation
- Be assertive - approach with certainty
  - Boldly move forward with ideas, answers & solutions

"This really is an innovative approach, but I am afraid we can't consider it, it's never been done before."

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More Steps To Buy-in…

- Identify Sponsor(s) & Champion(s)
  - Identify & engage with influential person(s) or department to champion your project.
- Bring in Experts
  - If you need support of outside experts - bring them in!
  - They have the independence to challenge traditional thinking & breakdown paradigms like - "But, we have always done it that way……"

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More Steps To Buy-in…

- Risk Mitigation
  - Take on risk, but don't gamble
  - All projects involve risk, just don't rely on luck
- Establish trust by following through
  - Present plan to keep senior management, sponsors & champions "in the loop" with communication on deliverable progress, accomplishments and challenges

How Can You Realize Benefit from UDI – it's a Compliance Project!

Is There Truly a ROI with UDI?

- ROI – Return on Investment
  - A performance measure used to evaluate the efficiency of an investment or to compare the efficiency of a number of different investments.

- Your Finance people see:

$$ROI = \frac{(\text{Gain from Investment} - \text{Cost of Investment})}{\text{Cost of Investment}}$$

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ROI with UDI?

- But, this is a compliance effort….
- Most companies are consumed with implementation.
- Not enough time to look downstream at possible benefits of UDI
- If you present potential ROI when getting buy-in it will be a surprise!

Where is Potential ROI?

- UDI creates a more secure global distribution chain to address issues such as:
  - Counterfeiting
  - Diversion of product
  - Tracking - provides standardized identifiers to better track devices & manage device recalls/adverse events
    - "Currently, I can locate a jar of peanut butter in the supply chain easier than a catheter"

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Efficiencies Where Are They Gained?

- Customer Order:
  - Reduce manual data entry time, cost & errors
  - Improved data accuracy realizing a reduction in order errors

    "**Get it right the first time….**"

  - Utilization of data pools and electronic transactions (EDI)

- Payment :
  - Ensures accuracy with data for AP and simplifies contract administration

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Where is Potential ROI?

- Supply Chain/Distribution Efficiencies:
  - Improves customer fulfillment times
  - Makes JIT possible, resulting in lower inventory carrying costs
  - Inventory more accurate as manufacturer and distributors can ship the right amount of product
  - Accurate product identification and tracking along the supply chain
  - Use in distribution/warehouses to decrease logistics expenses
  - Faster re-labeling of returned/damaged goods

Where is Potential ROI?

- Faster re-labeling of returned/damaged goods
- Enables Deferment /Postponement

  Also known as "Late Stage Labeling"
  - Performed in multiple places
    - Additional labeling operation in separate environment in production
    - Warehouse – either company owned or third party logistics site (known as 3PL)
    - Local site labeling operation
- Enables easier e-labeling

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Resource Example…..

- "The Perfect Order: Lessons Learned from BD and Mercy/ROi from Karen Conway/GHX
  - By implementing UDI and partnering with end users, BD & Mercy/ROi have achieved:
    - 73% reduction in discrepancies
    - 30% reduction in days payable outstanding
    - Greater process efficiencies
    - Significantly improved data quality, enabling information exchange supply chain efficiency

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Questions?

Contact Information:
Dawn Fowler
dfowler@endologix.com

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Update: 2016

"Having completed the UDI & GUDID implementations, we are still working to uncover additional systems/processes benefits to expand our use of UDI internally.

" I am working with other companies to understand how they are internally leveraging UDI to benefit as well. We are also partnering with our customers and other providers to help them understand and utilize the UDI information present on our products to gain efficiencies and improved traceability." – Dawn Fowler

UDIs & Traceability for Medical Devices 2016

Presentation

Pharma iQ a division of IQPC

Evaluating and Determining the Key Components, Planning and Execution of a UDI Project

By Craig Karagitz UDI expert, previously of Terumo

This presentation covers an overview to UDIs, how to frame a project, necessary questions to ask within implementation alongside key takeaways.

Implementing UDI Workshop

26 May 2015
Terumo Cardiovascular Group
Craig Karagitz

Agenda

- UDI – An Overview
- Framing Your Project
- Questions You Need to Ask
- Lessons Learned

UDI Overview

UDI Compliance Dates…

UDI COMPLIANCE DATES		
CLASS 1	Labeling Requirements Data Submission Requirements Date Format Requirements	**September 24, 2018** *(5 years after publication date)*
	Direct Marking Requirements	**September 24, 2020** *(7 years after publication date)*
CLASS 2	Labeling Requirements Data Submission Requirements Date Format Requirements	**September 24, 2016** *(3 years after publication date)*
	Direct Marking Requirements	**September 24, 2018** *(5 years after publication date)*
CLASS 3	Labeling Requirements Data Submission Requirements Date Format Requirements	**September 24, 2014** *(1 year after publication date)*
	Direct Marking Requirements	**September 24, 2016** *(3 years after publication date)*
DEVICES LICENSED UNDER THE PUBLIC HEALTH SERVICE ACT	Labeling Requirements Data Submission Requirements Date Format Requirements	**September 24, 2014** *(1 year after publication date)*
	Direct Marking Requirements	**September 24, 2016** *(3 years after publication date)*
IMPLANTABLE, LIFE-SUPPORTING OR LIFE-SUSTAINING DEVICES	Labeling Requirements Data Submission Requirements Date Format Requirements	**September 24, 2015** *(2 years after publication date)*
	Direct Marking Requirements	**September 24, 2015** *(2 years after publication date)*
DEVICES NOT CLASSIFIED AS CLASS 1, CLASS 2 OR CLASS 3	Labeling Requirements Data Submission Requirements Date Format Requirements	**September 24, 2018** *(5 years after publication date)*
	Direct Marking Requirements	**September 24, 2020** *(7 years after publication date)*

UDI – Learning the Terms…

FDA UDI	GS1 STANDARDS
FDA UDI Unique Device Identification	**GS1 Standards** Product Identification
Labeler	**Brand Owner**
DI FDA Device Identifier (DI)	**GTIN** GS1 Global Trade Item Number® (GTIN®)
Dynamic Data (PI) FDA Production Identifier (PI) *(if applicable)*	**Dynamic Data (AI)** GS1 Application Identifier (AI) • Batch/Lot Number: AI(10) • Production Date: AI(11) • Expiration Date: AI(17) • Serial Number: AI(21)
DI + PI = FDA UDI	**GS1 GTIN** or **GTIN + AI = UDI**

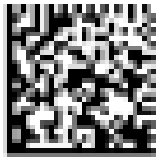
UDI – Dynamic Data…

GTIN with Lot Number
encoded in a GS1-128 Barcode

GTIN

Lot/Batch

GTIN with Expiry and Serial Number
encoded in a GS1 DataMatrix

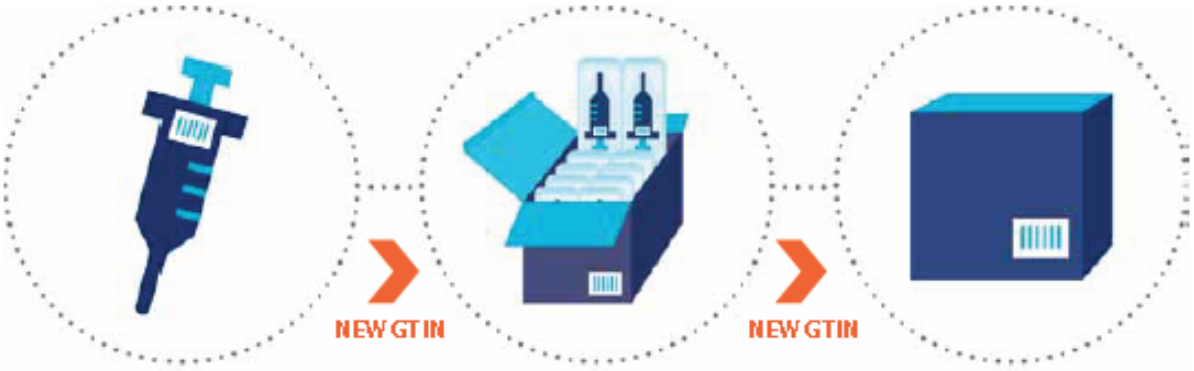


(01) 00614141007349
(17) 121231
(21) ABC6S1123456789

UDI – Packaging Levels…

MEDICAL PACKAGING LEVELS

There should be a UDI at every level of packaging, except at the logistics unit level.

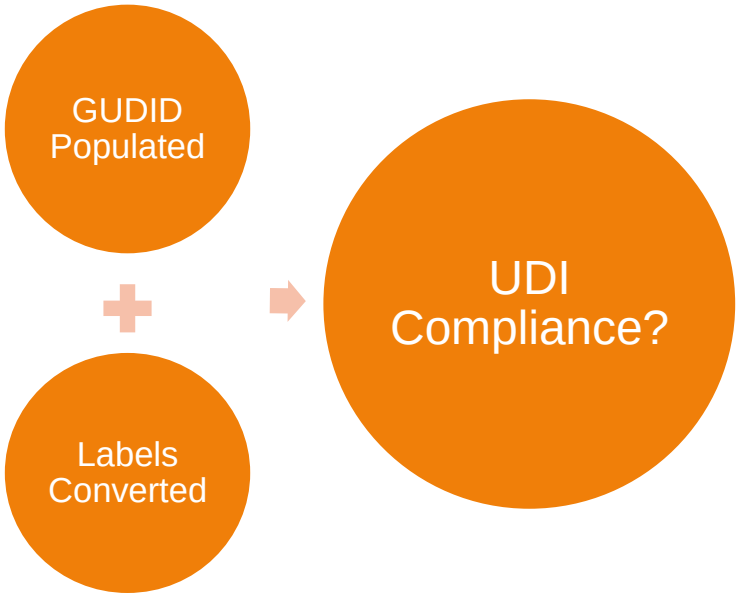


NOTE: GTINs below for illustration only

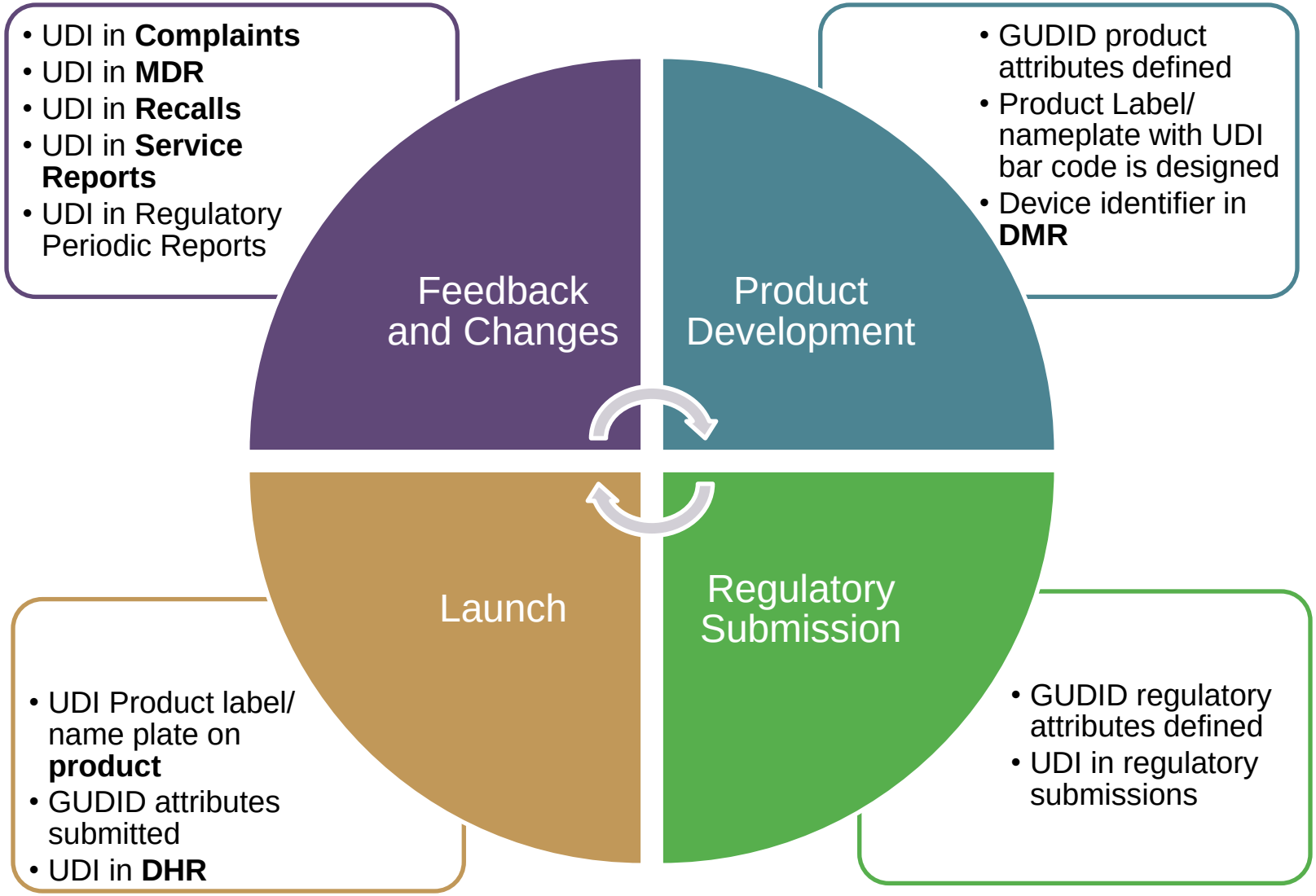
Single Unit Package	Multiple Unit Package	Case
GTIN A	GTIN B	GTIN C
00857674002010	10857674002017	40857674002018

Conforming Amendments

- Part 803 – Medical Device Reporting
- Part 806 – Reports of Corrections and Removals
- Part 810 – Medical Device Recall Authority
- Part 814 – Premarket Approvals
- Part 820 – Quality System Regulation
- Part 821 – Medical Device Tracking Requirements
- Part 822 – Postmarket Surveillance



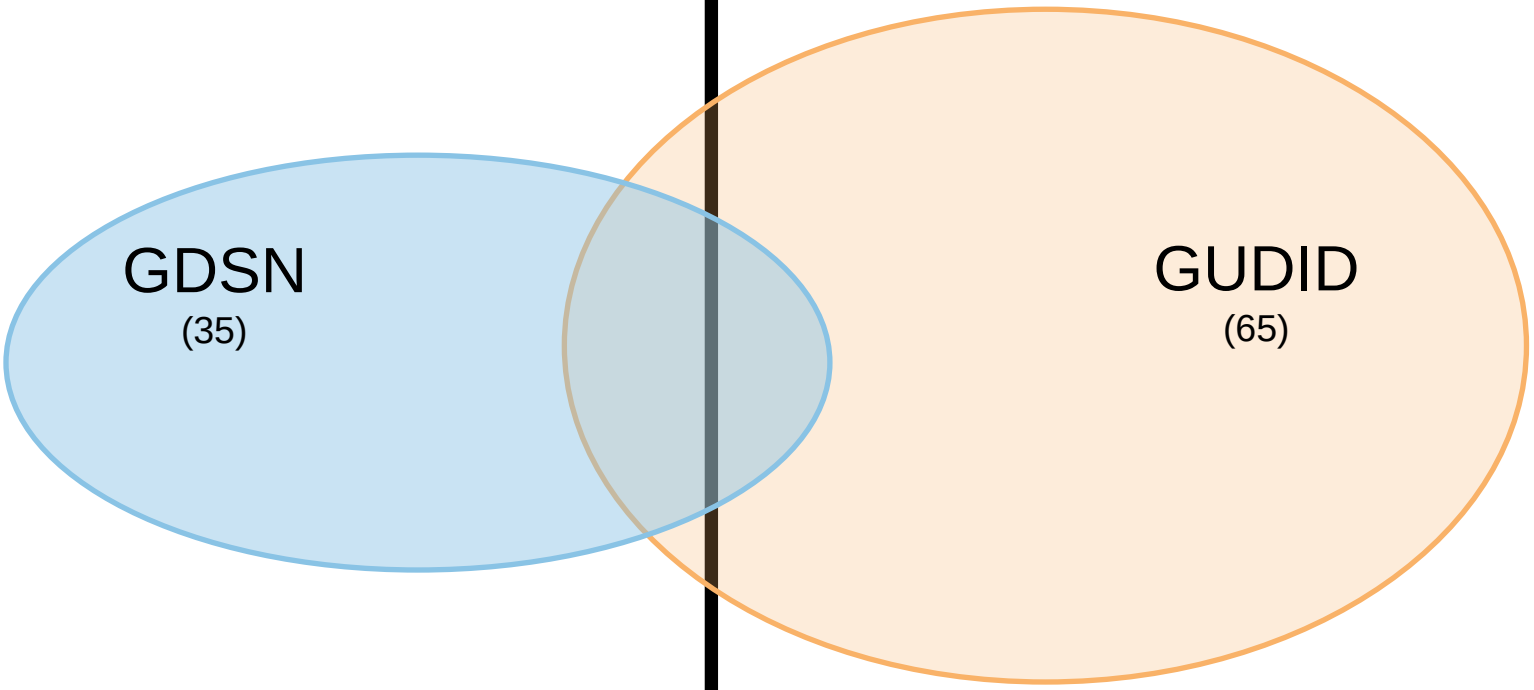
UDI - Upstream and Downstream Processes Impacted



The Two Things That Drive Us…

– *Supply Chain* (GS1)

Regulatory (FDA)



TERUMO

Framing Your Project

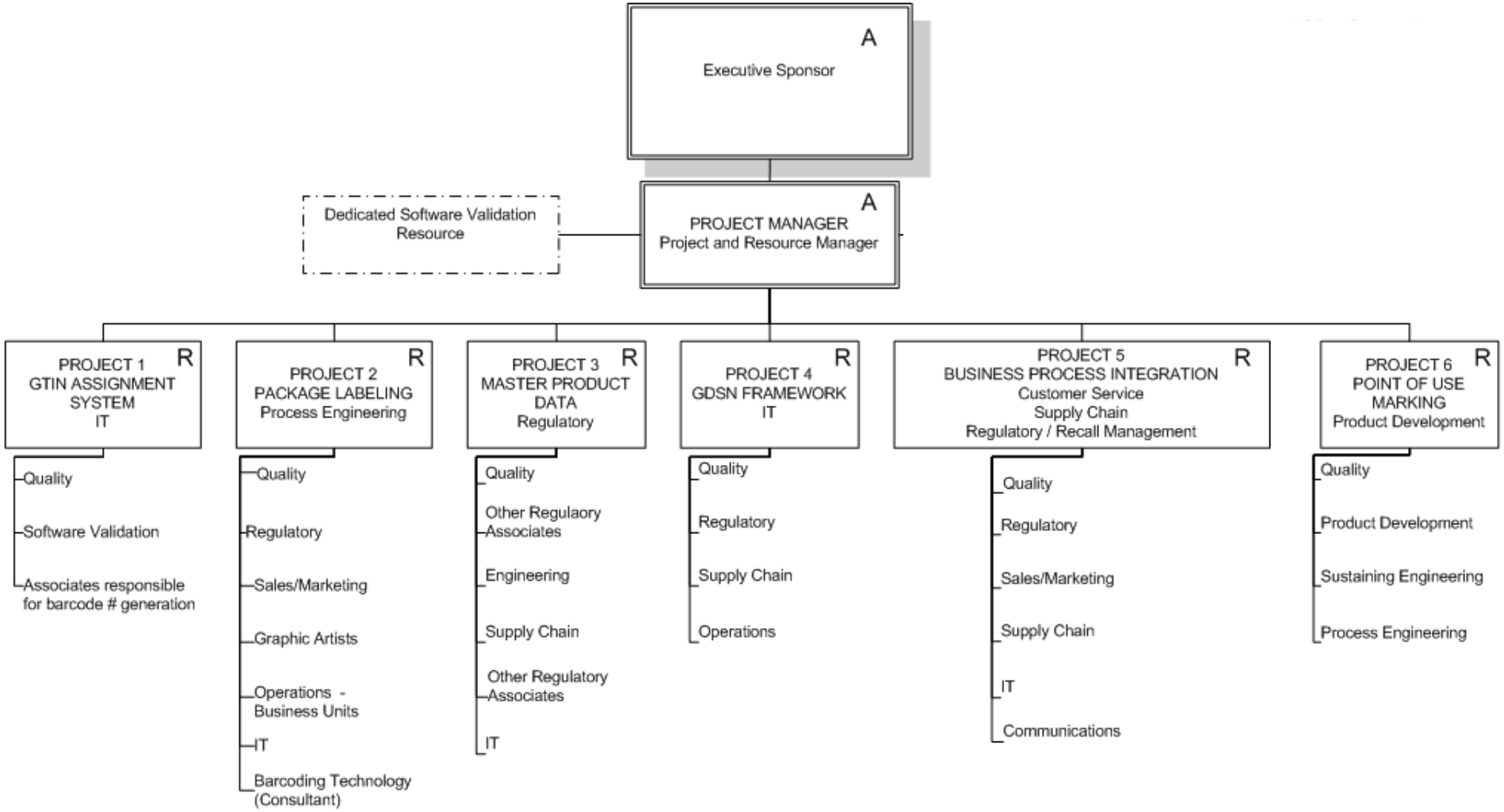
What It's Not…

- Just put some barcodes on labels

UDI Project at a High Level

- "The List"
- Procedures
  - New overall UDI
  - Complaints
  - MDR
  - Recalls
  - Service
- Labeling
  - Shipping
  - Nameplate
- Data
  - Format
  - Gathering
  - Storage
  - Uploading

Project Organizational Chart



Key Questions to Ask

Basic Questions
…with Seemingly Ever Changing Answers

PROJECT ORGANIZATION

- What is your charter?
- Who are your stakeholders?
- What is your true deadline?
- What are your costs?
- How do *you* define success?
- What does being *finished* look like?

Basic Questions
…with Seemingly Ever Changing Answers

RESOURCES

- How do we identify the resources?
- Do we have enough internal resources?
- How do we secure them?
- How do we educate them?

Basic Questions
…with Seemingly Ever Changing Answers

DATA

- What do we need?
- Who has it/owns it?
- What format is it in?
- How do we convert it?
- How/where will we store it?
- Can we trust it?

Some Additional Questions to Ask…

- Is my company already using a data pool to share product data commercially?
- What is my company's IT expertise in the UDI requirements? GS1 Standards?
- How will my company respond to sharing data with third parties? (legal, purchasing, regulatory, quality, commercial, IT)
- Who will the FDA call at my company if our data does not show up in the GUDID on time?

Lessons Learned

Lessons Learned

- *Takes longer than you expect*
  - Start as soon as you can even if all you have is Class I devices
  - Need to get your strategy and approach defined up front…but break it into manageable chunks and get going!
  - All data attributes will not be in your ERP
  - Resource constraints / competing initiatives

- *Building internal awareness is key*
  - A variety of functional areas are involved
  - Participation is key to repeatable, accurate processes

- *Not simply assigning a unique number*
  - Systems, customers, publishing considerations
  - Bar code / labeling requirements
  - Corporate or global SOP development

Lessons Learned

- *UDI isn't just a "project"*
  - Cross functional business process
  - Ongoing business requirement

- *A clear owner is not always evident*
  - Senior leadership must own the initiative
  - Sponsorship and management are required

- *Automate as much as you can*
  - UDI generation
  - Pulling info electronically for label printing

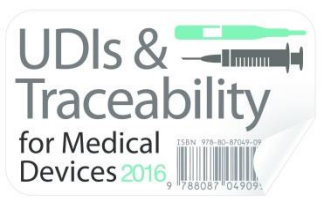
Final thought...

- “What we now want most is closer contact and better understanding between individuals and communities all over the earth and the elimination of that fanatic devotion to exalted ideals of national egoism and pride, which is always prone to plunge the world into primeval barbarism and strife.”
  — Nikola Tesla

Update: 2016

"Well, it's been a little over half a year since I gave this presentation. Another UDI compliance date has come and gone (FDASIA) and the next one (Class II) is almost exactly nine months away. As I continue to talk with people regarding their projects and what roadblocks they've encountered, it's my belief that most companies are meeting their deadlines and have even used this requirement as an opportunity to ask some tough questions about their current business processes and whether they need to change. I think the most important thing is to get a plan in place and then get going on executing it.

"But be ready to adjust the plan. This effort is a very complex effort that reaches into almost every aspect of your world, from engineering and labeling, to regulatory, quality, manufacturing, and distribution. Anything that all-encompassing is going to require a few iterations along the way, so expect them and embrace them as an opportunity to end up with an even better, more robust system in the end." – Craig Karagitz



UDIs & Traceability for Medical Devices 2016

Pharma iQ
a division of IQPC

The 2016 European UDIs & Traceability for Medical Devices Forum will bring together regulatory experts from public and regulatory bodies, healthcare organisations and device manufacturers to discuss how best to prepare and react to the European regulatory changes with regards to UDIs.

3 Reasons to Attend

- **European regulatory changes:** Understand what they mean for UDIs, and what you should be doing now!
- **FDA UDI deadlines:** Last chance to improve your Class II processes before the deadline, and looking ahead to Direct Product Marking and Class III regulations
- **Practical case studies:** The only opportunity in Europe to get both regulatory updates and practical manufacturer case studies to learn from – all dedicated to UDIs!

Call: +44 (0) 0207 036 1300
Visit: www.udisandtraceability.com
Email: enquire@iqpc.co.uk

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