The Long and Winding Road of Unique Device Identifier (UDI) Implementation: A Small Company Perspective

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About Me

- ***Daniel Simpson, RAC (US,CAN), ASQ CBA.*** Mr. Simpson is currently the Senior Director of Quality and Regulatory Affairs at Corgenix Inc. which produces In Vitro Diagnostic (IVD) products for the clinical laboratory market. Mr. Simpson has a combined 24 years of experience in the human and veterinary diagnostic industry. After many years of working in the lab developing new diagnostic medical devices, he received his RAC certifications in 2008 and 2009. For the last eight years in his current role, Mr. Simpson has been in charge of Quality System Management, Regulatory Compliance, and new product submissions at Corgenix, Inc. Currently Mr. Simpson has been in charge of ensuring UDI compliance for the 28 FDA regulated products marketed by Corgenix.

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Company Overview

- Founded in 1990; publicly traded since 1998
- Headquarters in Broomfield, Colorado, USA
- Employees approximately 50 FTEs
- Developer, Manufacturer, and Marketer of ClassII In Vitro Diagnostic Medical Devices
- Registration and Quality Management System: FDA Registered Facility, 21 CFR Part 820 QSR (GMP), ISO13485:2003, IVDD (CE), Canada CMDCAS, Japanese MHW, CFDA
- Product focus
  - cardiovascular disease risk
  - immunology/autoimmunity
  - liver fibrosis
  - emerging pathogens and infectious diseases
  - Contract Manufacturing
  - Companion Diagnostic Partnership with Pharma Companies

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Agenda

- Review current Final Rule and UDI requirements
- Discuss Global Unique Device Identification Database (GUDID Database)
- Some Corgenix experiences/challenges in implementation
- Q and A / discussion

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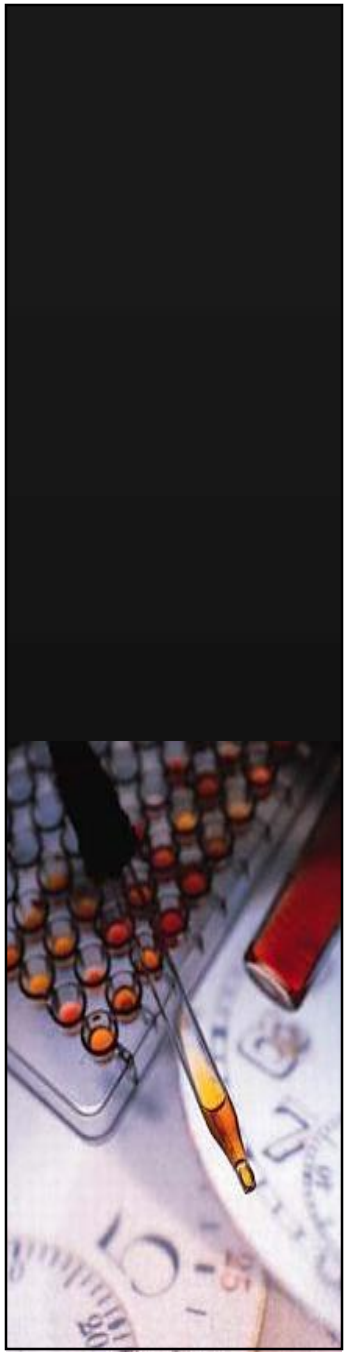

What is UDI?

- FDA is establishing a unique device identification system to adequately identify medical devices through their distribution and use. When fully implemented, the label of most devices will include a unique device identifier (UDI) in human and machine-readable form. Device labelers must also submit certain information about each device to FDA's Global Unique Device Identification Database (GUDID).
- Benefits identified by FDA:
  - Reduce Medical Errors
  - Simplify Integration of Device Use Information into Data Systems
  - More rapid identification during Adverse Events
  - Aid in Recall Resolution
  - Other Benefits

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Regulatory Foundation

- FDA Amendments Act, 2007
- FDA Safety and Innovation Act, 2012
- UDI Rule, September 24, 2013
  - 21 CFR part 830 (Unique Device Identification)

Regulations affected by UDI Final Rule.

21 CFR part 803 (Medical Device Reporting)

21 CFR part 806 (Medical Devices; Reports of Corrections and Removals),

21 CFR part 814 (Premarket Approval of Medical Devices),
21 CFR part 820 (Quality System Regulation)

21 CFR part 821 (Medical Device Tracking Requirements)

21 CFR part 822 (Postmarket Surveillance).

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UDI Compliance Dates

Compliance Date	Device Type
September 24, 2014 (One year past Final Rule)	• Class III devices, including class III stand-alone software • Devices licensed under the PHS Act
September 24, 2015 (Two years past Final Rule)	• Implantable, life supporting and life sustaining (I/LS/LS) devices, including stand-alone software • Direct Marking for I/LS/LS devices, for certain intended uses
September 24, 2016 (Three years past Final Rule)	• Class II Devices • Direct Marking for class III devices and devices licensed under the PHS act, for certain intended uses
September 24, 2018 (Five years past Final Rule)	• Class I devices and devices not classified as class I, II, or III • Direct Marking of class II devices for certain intended uses
September 24, 2020 (Seven years past Final Rule)	• Direct Marking of class I devices and devices not classified into class I, II, or III, for certain intended Uses

For details, reference:
www.fda.gov/medicaldevices/deviceregulationandguidance/uniquedeviceidentification/compliancedatesforudirequirements/default.htm

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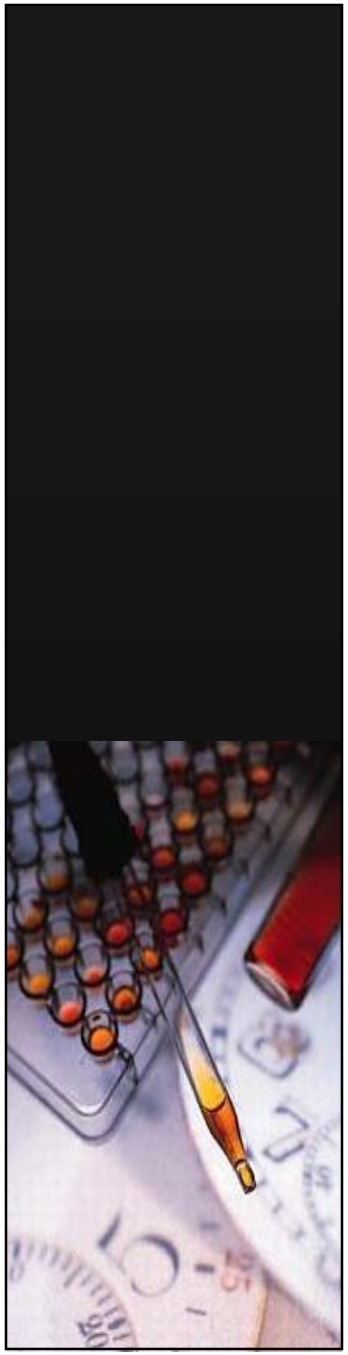

Exemptions to UDI

- Key General Exceptions to UDI rule. (Full list: 21 CFR 801.30)
  - Class I cGMP exempted devices
  - Individual single-use devices sold and stored in a single package
  - IDEs or devices used solely for nonclinical use (Research Use Only, etc.)
  - Devices intended solely for export from the US
  - Individual devices in convenience kits
- FDA may grant an exception or alternative on its own initiative or in response to a request.
- FDA will post decisions on FDA UDI website

UDI Basics

- Basic Requirements:
  - Device Label and Packaging must bear a UDI

  - Key data must be submitted to GUDID

ACCESS GUDID
IDENTIFY YOUR MEDICAL DEVICE

  - Dates on label must conform to specified format

YYYY-MM-DD

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UDI Basics

- The UDI consists of DI + PI
  - Device Identifier- (DI)

    mandatory, fixed portion of a UDI that identifies the labeler and the specific version or model of a device, and
  - a Production Identifier (PI),

    a conditional, variable portion of a UDI that identifies one or more of the following when included on the label of a device:
    - the lot or batch number within which a device was manufactured;
    - the serial number of a specific device;
    - the expiration date of a specific device;
    - the date a specific device was manufactured;

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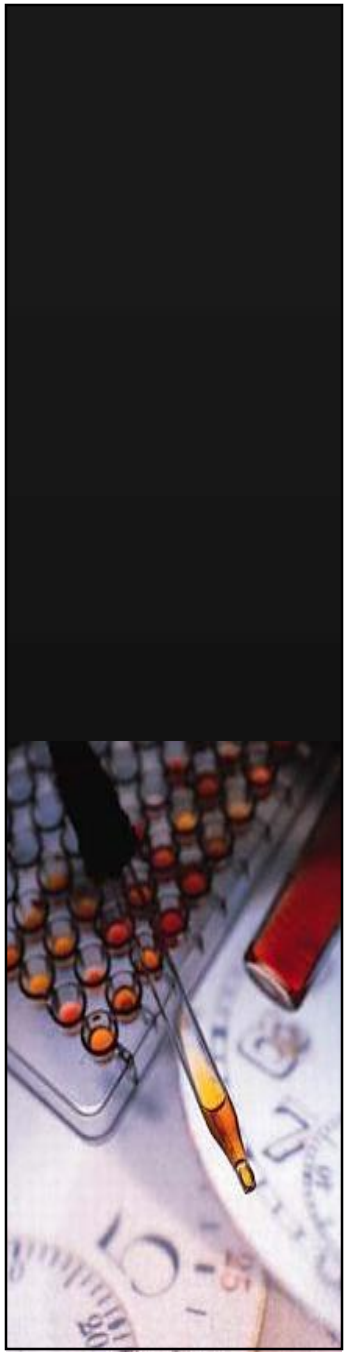

UDI issuers

- FDA has accredited the below institutions as DI issuers
- GS1
- HIBCC
- ICCBBA

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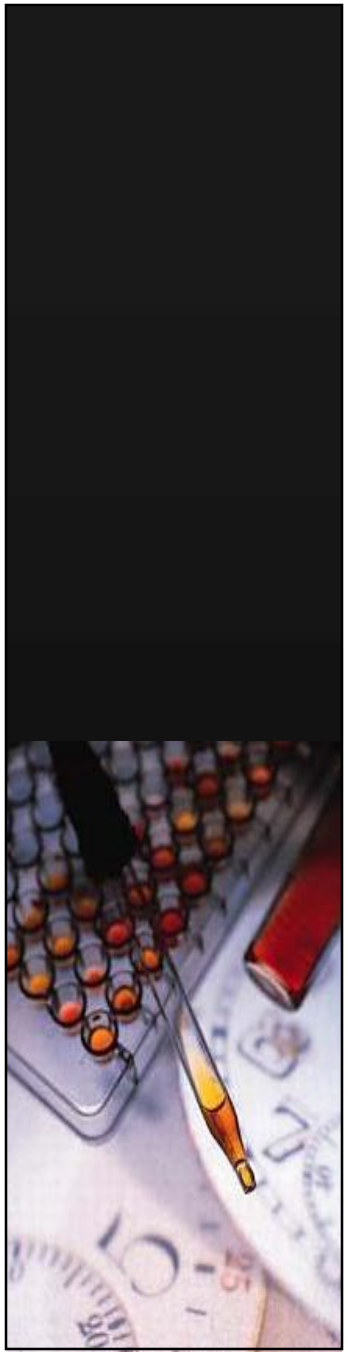
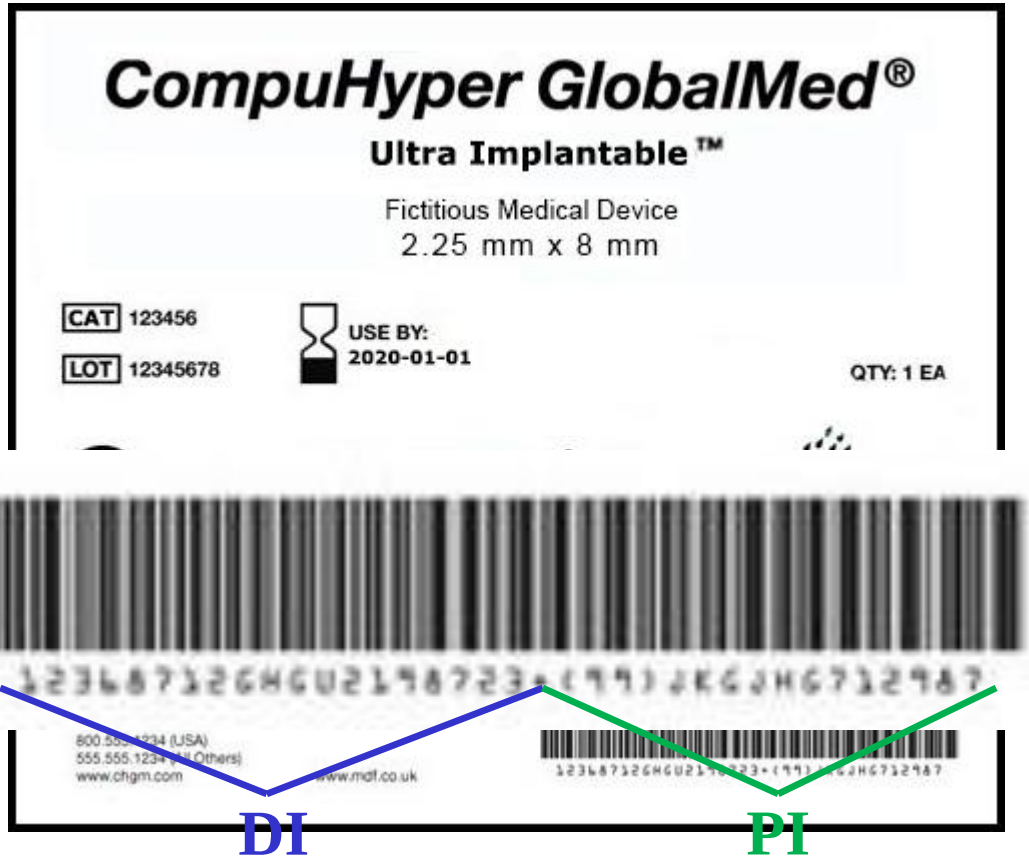


UDI Example



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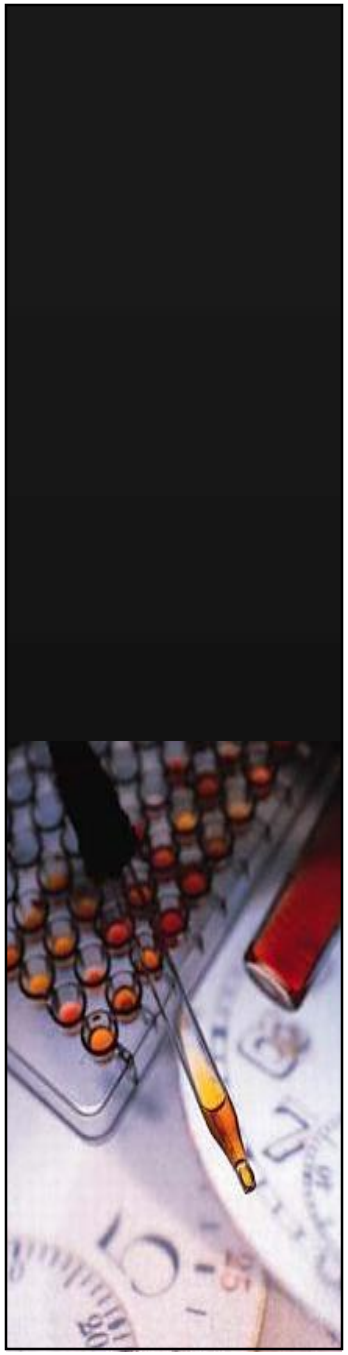

Packaging Requirements and UDI

- Each Complete Device Package is required to have a UDI.
- A device package is defined as being a package that contains a fixed quantity of devices for sale.
- Each level a packaging requires a different UDI (pack of 1, Pack of 100, pack of 1000).
- Shipping containers are not considered “packaging” and therefore do not require a UDI.
- Finished devices that are “kits” such as IVDs only require a UDI on the final kit label. Kit components do not require a UDI.
- “Convenience Kits”: a combination of two of more devices sold together require its own UDI. Individual devices within “convenience kit” do not require own UDI.

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GUDID

ACCESS GUDID
IDENTIFY YOUR MEDICAL DEVICE

- Repository of key device information
- Contains only DIs; PIs are not submitted or stored in the GUDID
- Contains only PI flags to indicate which PIs are on the device (for example: lot number and expiration date)

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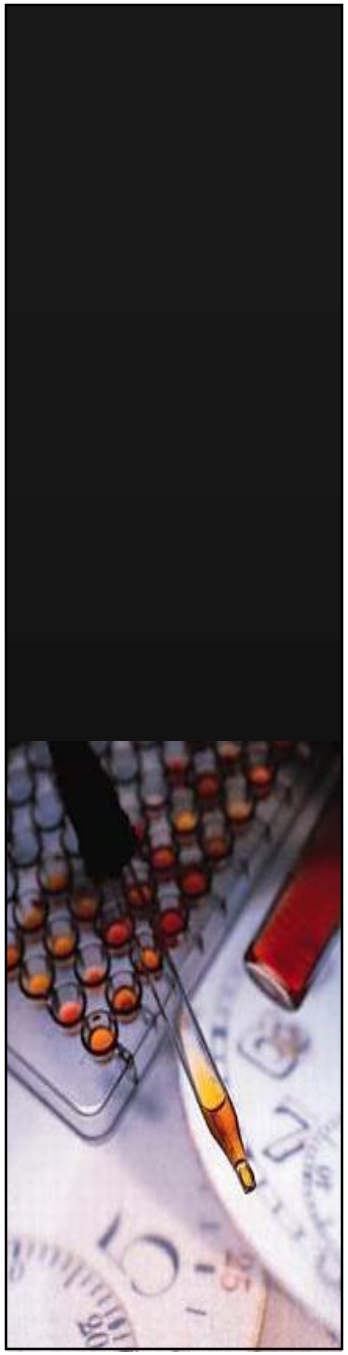

GUDID Access

- For Labelers to input information there are two routes available
  - Web interface: Manual entry for low volume submitters.
  - Heath Level 7 (HL7 SPL): Automated submission ideal for companies with large amounts of data. This pathway must be executed through the FDA Electronic Systems Gateway. User needs to register for the gateway and perform a “pre-production” test prior to entering information.
- For device users:
  - Free and public access to the device information in GUDID via public search (Access GUDID); download capability is planned for the future.

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Some GUDID Data Elements

- Issuing agency
- Primary DI
- Device Count
- Labeler DUNS number
- Flags for PI that already appear on device label (exp. Date, lot number, serial number, date of manufacture)
- Company Address
- Version or model number
- Device Description (including intended use)
- For full list of GUDID data elements see:http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/GlobalUDIDatabaseGUDID/UCM396592.xls

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Preparing for GUDID

- Review UDI guidance documents and resources
- Work with FDA-accredited issuing agencies to assign and maintain UDIs.
- Establish processes for physical labeling.
- Establish standard operating procedures for records management.
- Gather data required for GUDID DI records based on the GUDID Data Elements Reference Table.
- Understand the GUDID account structure and user roles as shown in the GUDID Guidance.
  - Identify individuals for the GUDID user roles and ensure that they understand GUDID functionality and responsibility for their user roles
- Identify/obtain appropriate Dun and Bradstreet (DUNS) numbers
- Determine GUDID submission option

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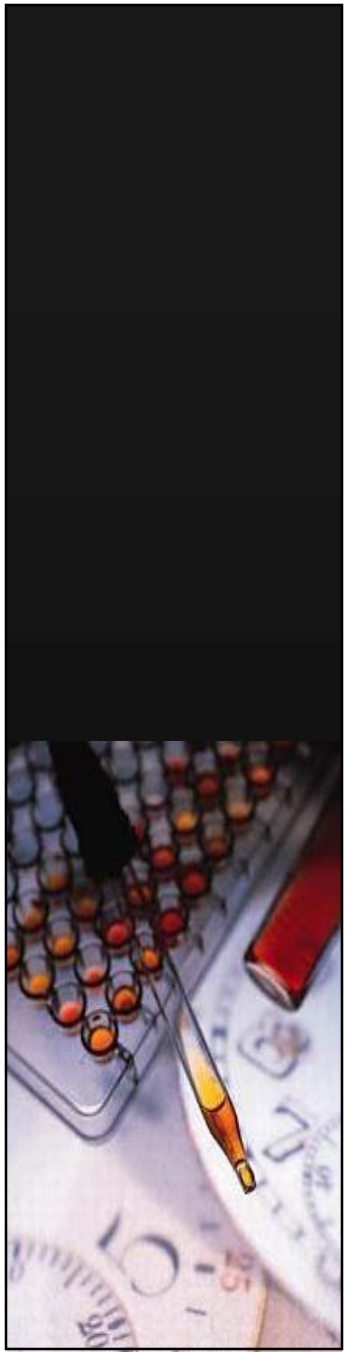

Corgenix Implementation

- Task team implemented in April of 2015.
- UDI has been identified as Management Objective by Management Review Committee
- Task Team Members (cross functional): Operations, Production, Quality Control, Marketing, RD (exec. Management), Quality Assurance, and Regulatory Affairs.
  - Operations/Production: Label logistics, equipment and resources
  - Quality Control: How to implement UDI testing in production
  - Marketing: How the UDI will be perceived by customer, etc
  - QA/RA: How to incorporate into Quality System and ensure regulatory requirements are met

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Initial Tasks

- Identify products with UDI September 24th requirement
  - All Class II 510(K) cleared products marketed
  - 28 products where Corgenix is “labeler”
  - 12 Products that Corgenix labels for another party (Contract Manufacturer, OEM Products)
  - 5 products for export only (CE, RUO). Put into voluntary UDI category
- GS1 chosen as issuer. Best choice for low volume company.
- Unique 14 digit GTIN numbers assigned for each mandatory device. GTIN number=Device Identifier
- Standard barcode initially chosen over Q-code

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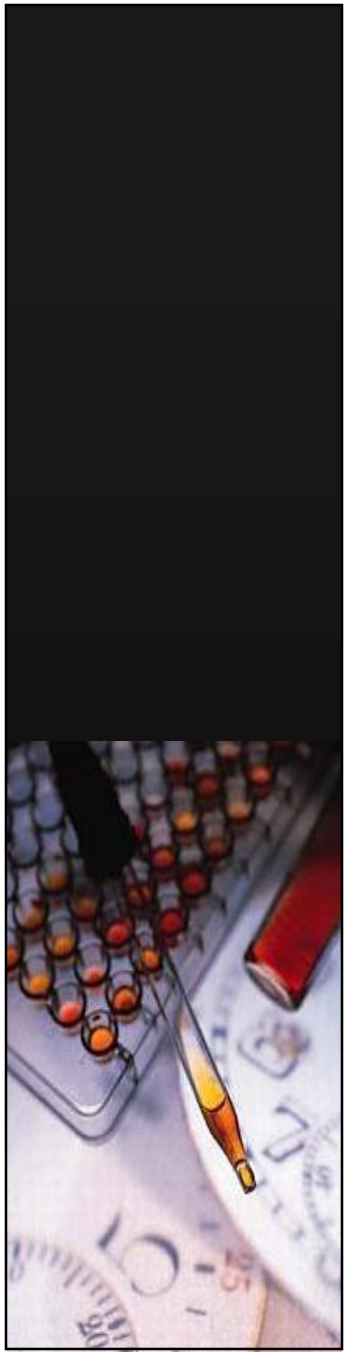
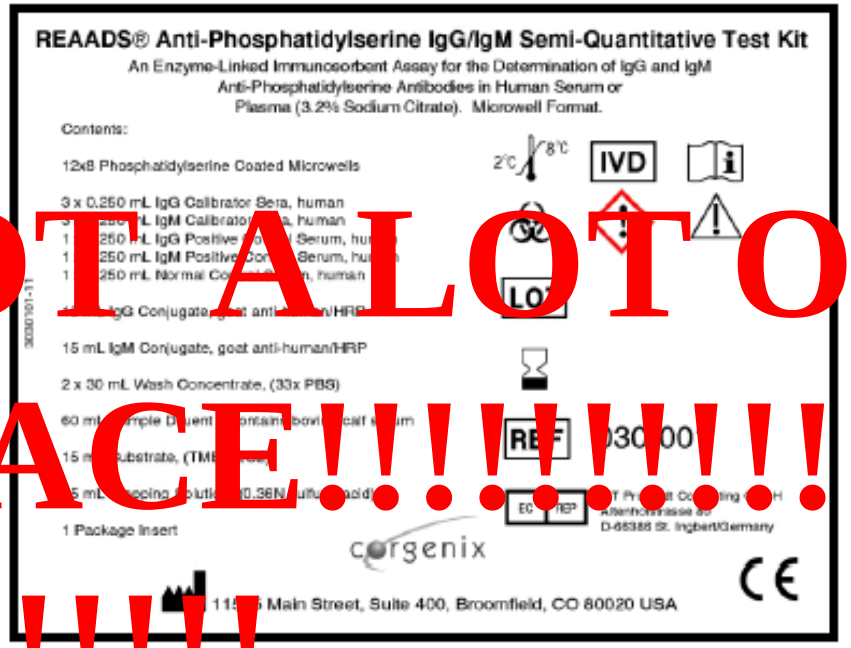


Labeling challenges



NOT A LOT OF SPACE!!!!!!!!!!!!!!!!!!!!

Also, current printers produce "fuzzy" barcodes

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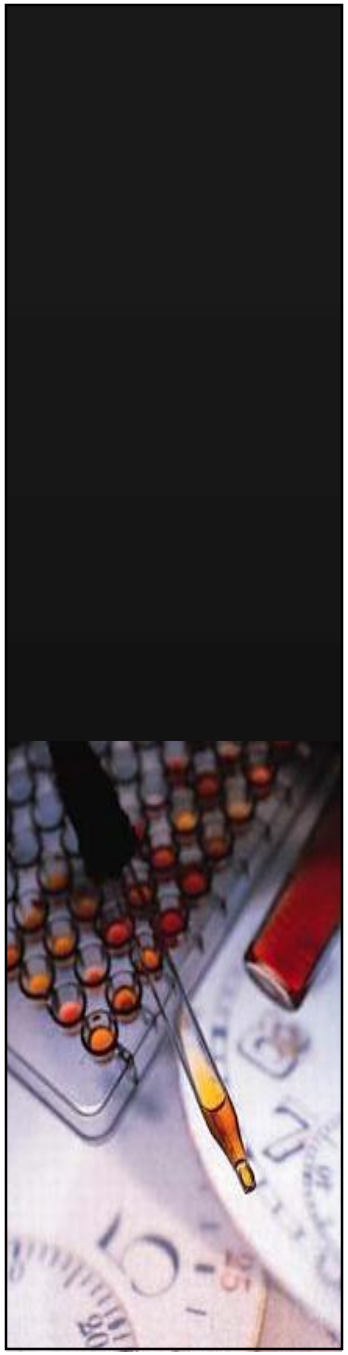
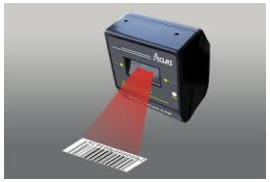


New Equipment

- New Printer(s)- Feasibility testing proved better for barcodes

- Barcode Scanners-



- To what level/degree do we inspect UDI's in-process?
- All new equipment entered into metrology program which includes receiving, ES documentation, validation, maintenance and calibration.

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Documentation/ Records!!!

- Initial review of Quality Management System documentation revealed approximately 70 documents that needed review for revision or creation.
- Standard Operating Procedures:
  - Regulatory overview procedure
  - Device History Record
  - Field Corrective Action
  - NCRs/Complaints/Adverse Events
  - Format and content of labels
  - Design Control
- Kit Assembly Documents/Labels
- New Equipment Specification Documents

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Contract Manufacturing

- Device “Labeler” is responsible for UDI requirements.
- 21 CFR Part 830.3
  - Any person who causes a label to be applied to a device with the intent that the device will be commercially distributed
  - Any person who causes the label of a device to be replaced or modified with the intent that the device will be commercially distributed
- For Contract Manufacturing/OEM Partners- Partner is considered labeler as they are causing device to be labeled (through Corgenix).
- Have had to work with partners: they create DI, CGX creates PI at time of manufacture.

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FDA Help

- UDI Resources: (Guidance Documents, Proposed Rule, Training)

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/ChangesbetweenUDIProposedandFinalRules/default.htm

- UDI Help Desk: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/ucm368904.htm

- www.FDA.gov: Search “UDI”

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Thank You

Any questions or comments:

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