The Global Language of Business

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Medtronic

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UNIQUE DEVICE IDENTIFICATION:
Experiences with implementation of the U.S. FDA UDI Rule

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OUR MISSION, TENET #3:

To strive without reserve for the greatest possible ***reliability and quality*** in our products and to be the unsurpassed standard of comparison. To be recognized as a company of ***dedication, honesty, integrity and service.***

UDI…WHERE TO START?

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UNDERSTAND THE RULE, UNDERSTAND THE IMPACT

The **objective** of UDI is to **establish a system to adequately identify devices through distribution and use.** The **purpose** is to **rapidly and definitively identify a device** and it is intended to lead to more **accurate reporting** of adverse events by **making it easier to identify the device** prior to submitting a report.

UNDERSTAND THE RULE

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U.S. FDA UDI BASICS

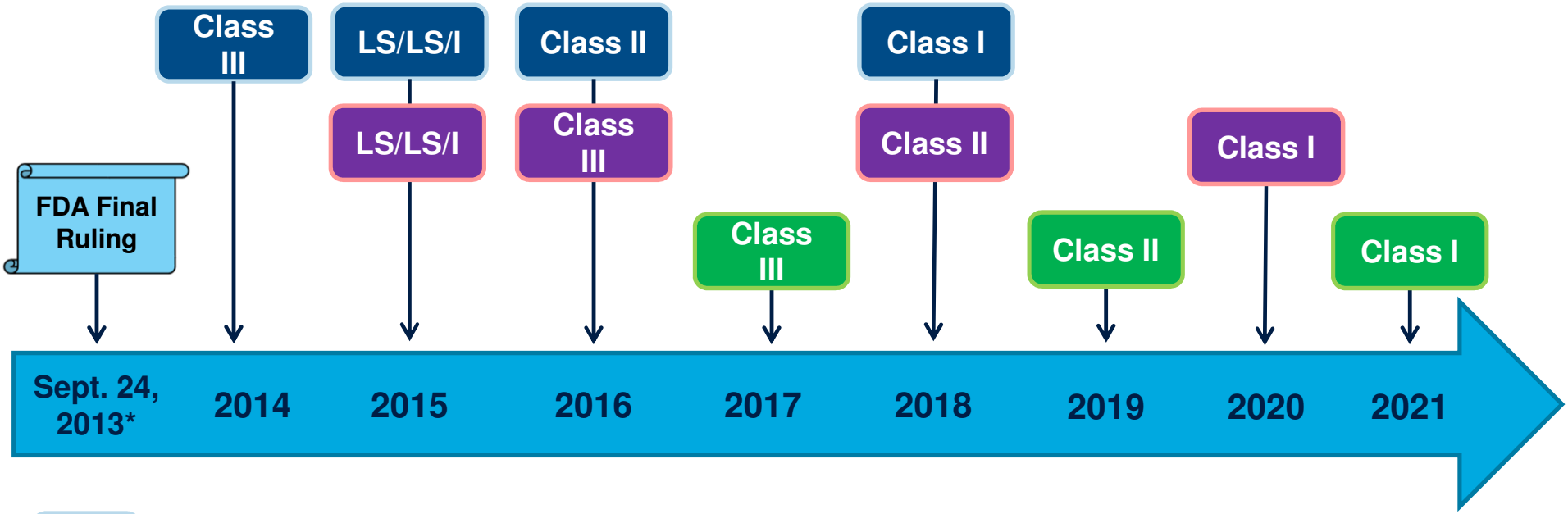
Basics

- In general, **every label of every medical device will carry a UDI** composed of a device identifier and production identifier(s). However, there are certain exceptions.
- Devices which are **multi-patient** use and are reprocessed in between uses will require a **UDI to be marked directly on the device**. If not technically feasible or would cause patient safety concerns, a detailed rationale for not directly marking the device must be documented in the design history file.
- Certain **data is required to be submitted** to the U.S. FDA's Global UDI Database **(GUDID)** for all medical devices.

Regulation

- 21 CFR 801: Labeling Requirements
- 21 CFR 830: UDI
  - Identification of Issuing Agencies
  - GUDID Submission Requirements
  - Maintenance of Records
- Conforming Amendments: includes the use of UDI throughout various requirements
  - 21 CFR 803: Medical Device Reporting
  - 21 CFR 806: Reports of Corrections and Removals
  - 21 CFR 810: Medical Device Recall Authority
  - 21 CFR 814: Premarket Approvals
  - 21 CFR 820: Quality System Regulation
  - 21 CFR 821: Medical Device Tracking Requirements
  - 21 CFR 822: Postmarket Surveillance

U.S. FDA COMPLIANCE TIMELINES



- UDI compliant label in production.
- Data submitted to GUDID.

- Devices requiring direct marking must bear a UDI on the device itself or have exemption documented in design history file.

- Devices in inventory require must bear UDI compliant labeling.

*All compliance dates occur on September 24th of the year indicated.

UNDERSTAND THE IMPACT

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THE UDI IMPLEMENTATION JOURNEY

- Philosophy and Approach
- Planning
- Assessment & Impacts
  - Labels, Printing, Verification
  - Data
- Lessons Learned & Best Practices

PHILOSOPHY & APPROACH

Mission

Deliver a Medtronic process and technology solution to fulfill UDI requirements of Regulatory Authorities across the world. UDI will leverage the Regulatory Information Management (RIM) strategy to develop common processes and data management practices across BUs and Geographies.

UDI Unique Device Identification

1) **Develop** standardized system of unique device identifiers (UDI)
2) **Label:** Place UDI (human readable & AutoID) on label, device or both
3) **Publish:** Develop process and technology platform required to submit UDI data elements to FDA

RIM Regulatory Information Management

Effective and efficient collection, creation, storage, retrieval and communication of Regulatory Information.

- Master Data Management
- Harmonized Processes
- Enterprise Solutions

Global Policy Updates

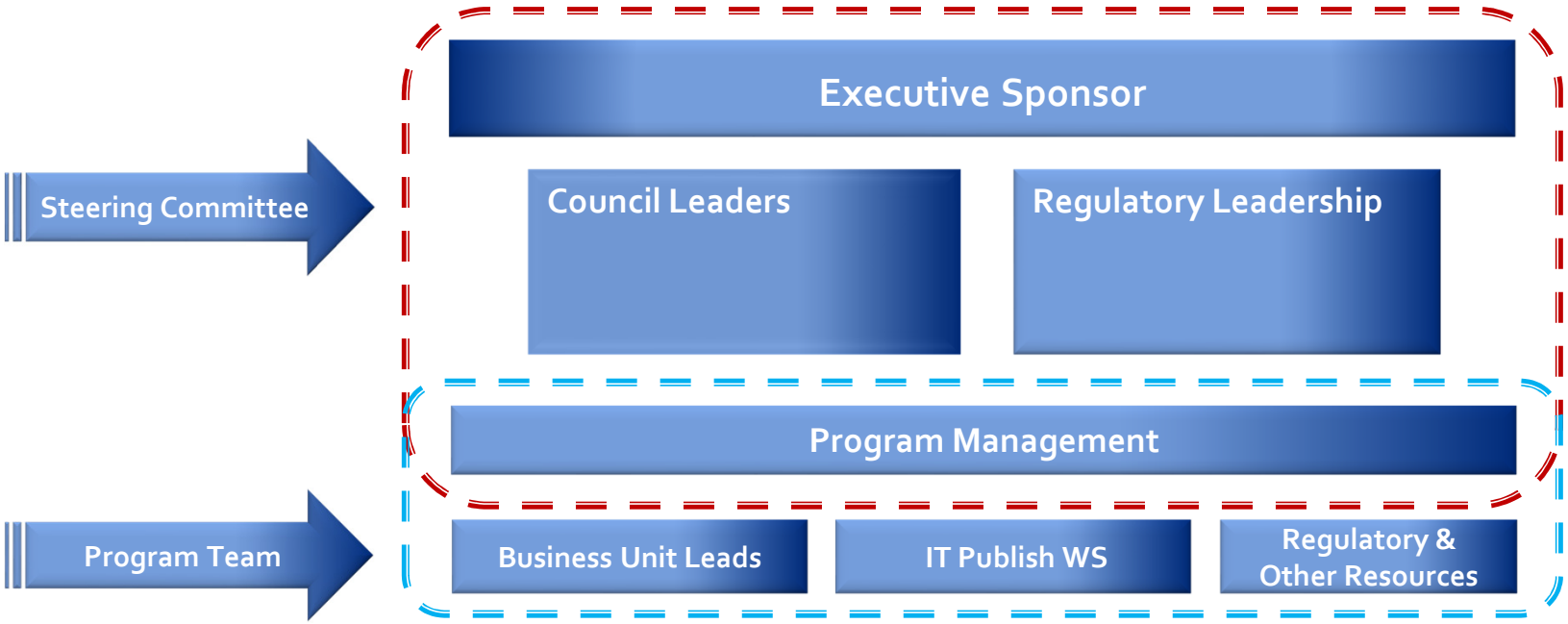
Corporate Regulatory, Corporate Quality, and Business Units

- Policy and procedures updates to align with new UDI requirements

Advocacy

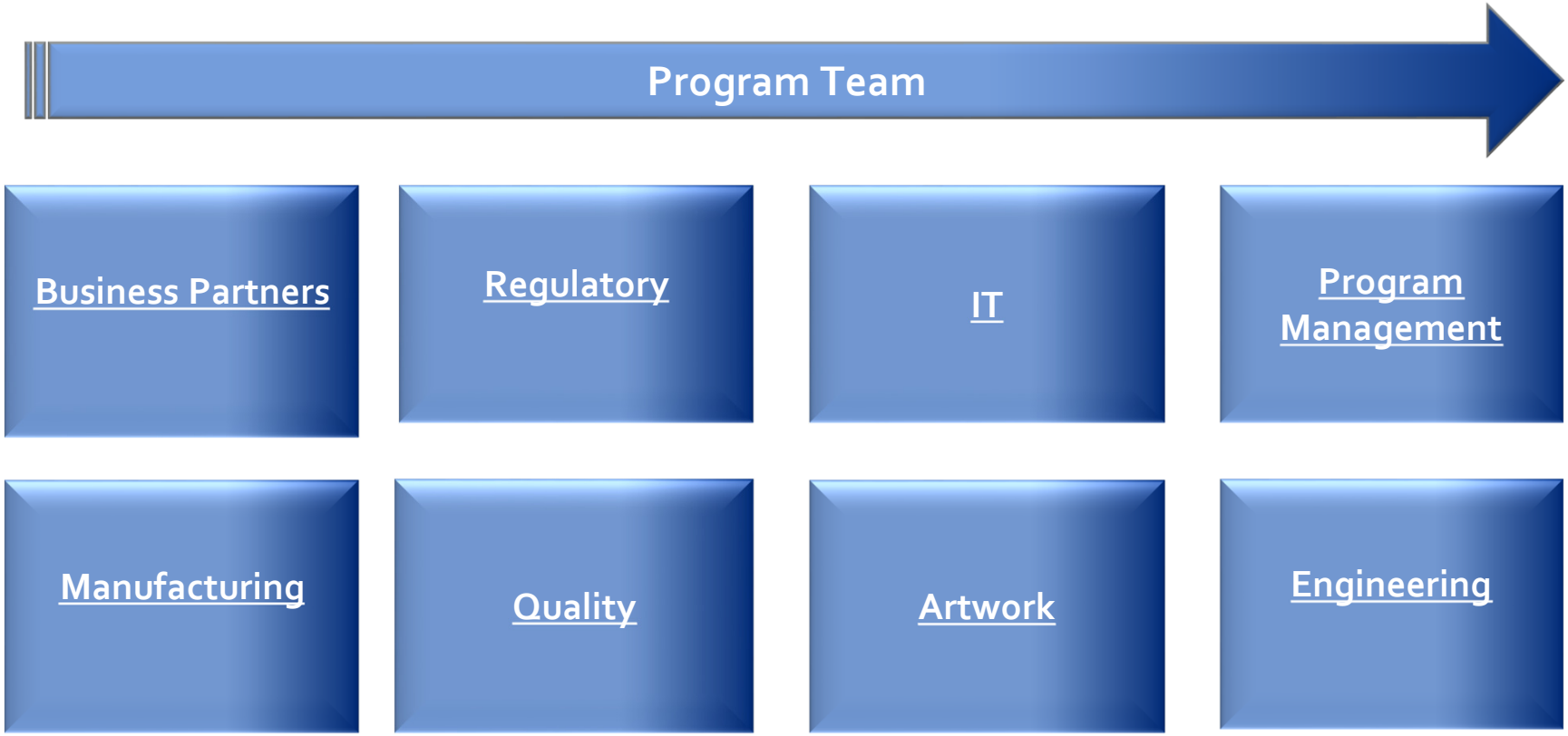
Medtronic Global Regulatory Affairs is advocating for harmonization of UDI requirements across the globe .

PLANNING: WHO IS ON YOUR TEAM?



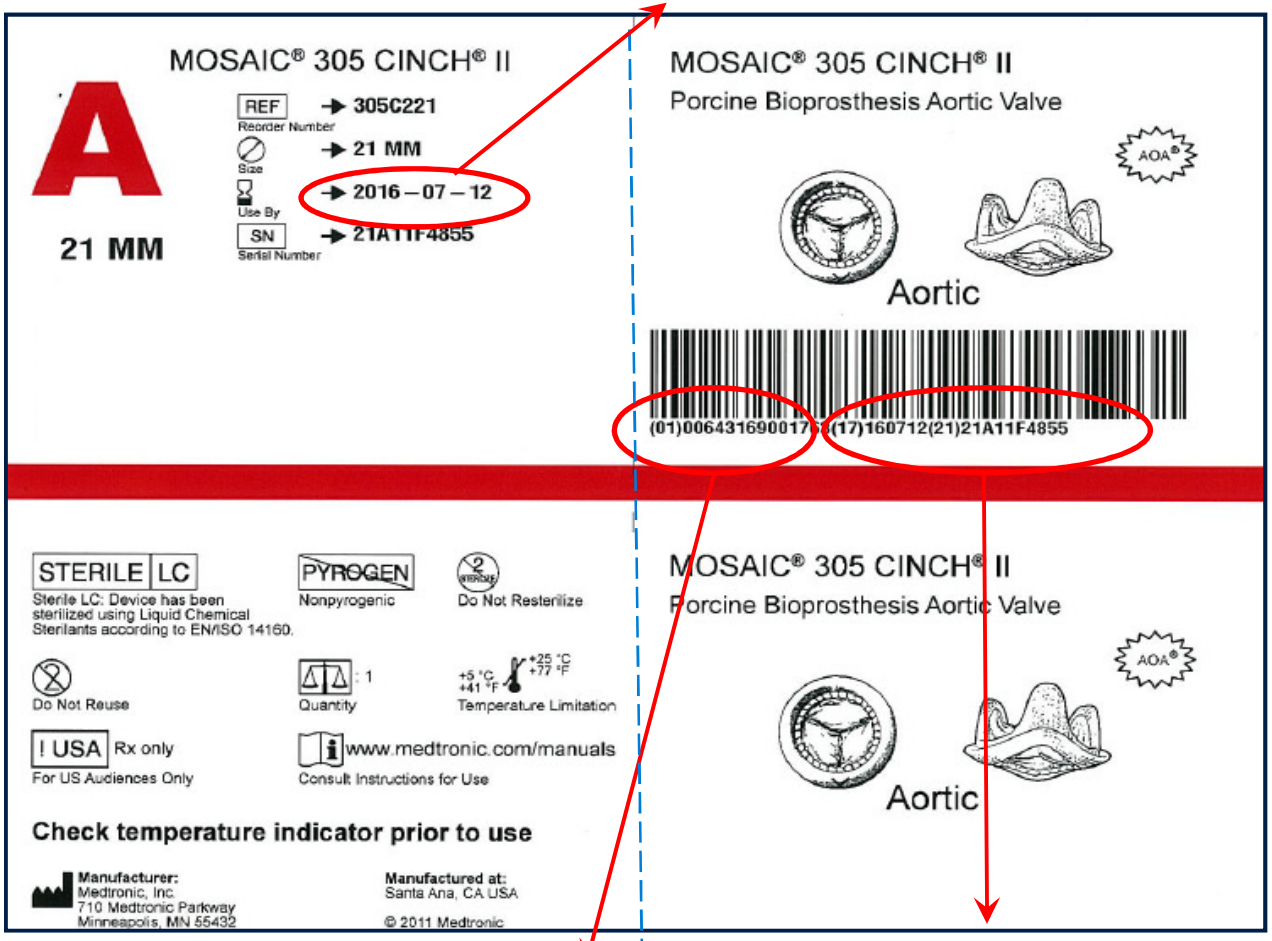
- **Steering Committee** – Program leadership and direction
- **Program Team** – Leads analysis and implementation within BUs; disseminates information
- **Business Unit Contacts** – Coordinates implementation activities within their BU

PLANNING: PROGRAM TEAM



ASSESSMENT & IMPACT: LABELS

Date Format = YYYY-MM-DD



Device Identifier

Production Identifiers

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PRINTER TECHNOLOGY

InkJet

- Image is created by spraying droplets of ink onto a substrate
- Requires ink reservoir or cartridges
- Printhead is either stationary over moving substrate or traversing with stationary substrate
- Typical print area = 0.5 inch (height) x unlimited (width)
- Same technology as the common desktop inkjet printer
- Compatible with band sealers and Medical Paper, Tyvek, Poly (plastic blend) substrates
- Barcode Capability: Linear Concatenated; 2D Data Matrix

Thermal

- Image is created by melting a coating onto the substrate material
- Requires ribbons rater than ink cartridges or reservoirs
- Typical print area = 2 inches or 5 inches (height) x unlimited (width)
- Compatible with form/fill/seal packaging machines, labelers, and poly (plastic blend) substrates
- Barcode Capability: Linear Stacked; Linear Concatenated; 2D Data Matrix

Other

- Additional printer technologies may exist however Medtronic can offer technical expertise on the two varieties described here and can extend discount pricing from Medtronic preferred suppliers.
- Please note that Evolution, Flexographic printers and Ink Coders cannot print barcodes with variable production data without significant modification every lot.

VERIFICATION TECHNOLOGY

Compliant Equipment

- LVS Integra 9510 table-top light box paired with a laptop and proprietary grading software
- Approved for the verification of Medtronic barcodes on saleable product
- LVS Integra 9510 Specifications

Barcode Verification

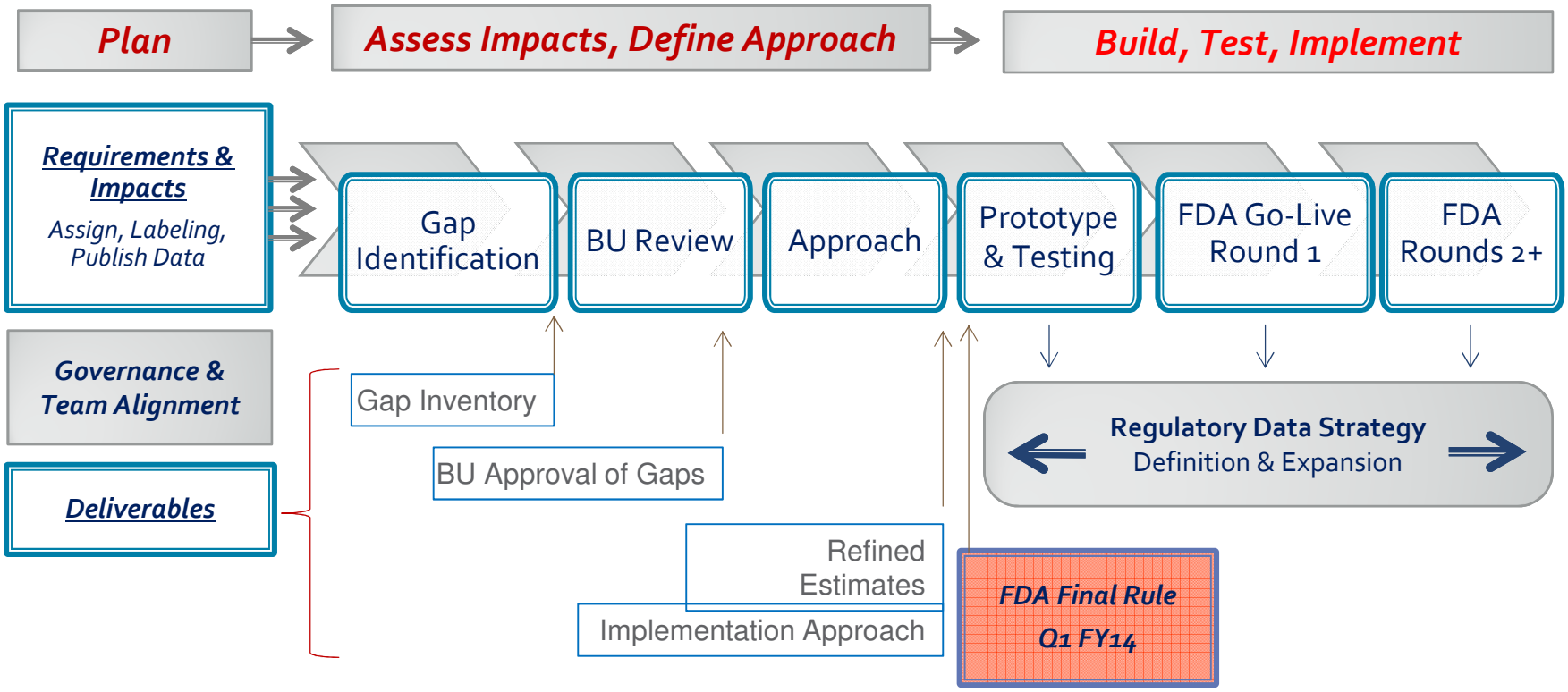
- Assessment of the print quality, structure, and layout of a barcode in accordance with ISO/IEC 15416 (linear barcodes) and/or ISO/IEC 15415 (2-D data matrixes)
- The purpose is to “grade” the quality of barcode using a globally understood grading system which translates into the “scannability” of the barcode through the supply chain

Barcode Grading

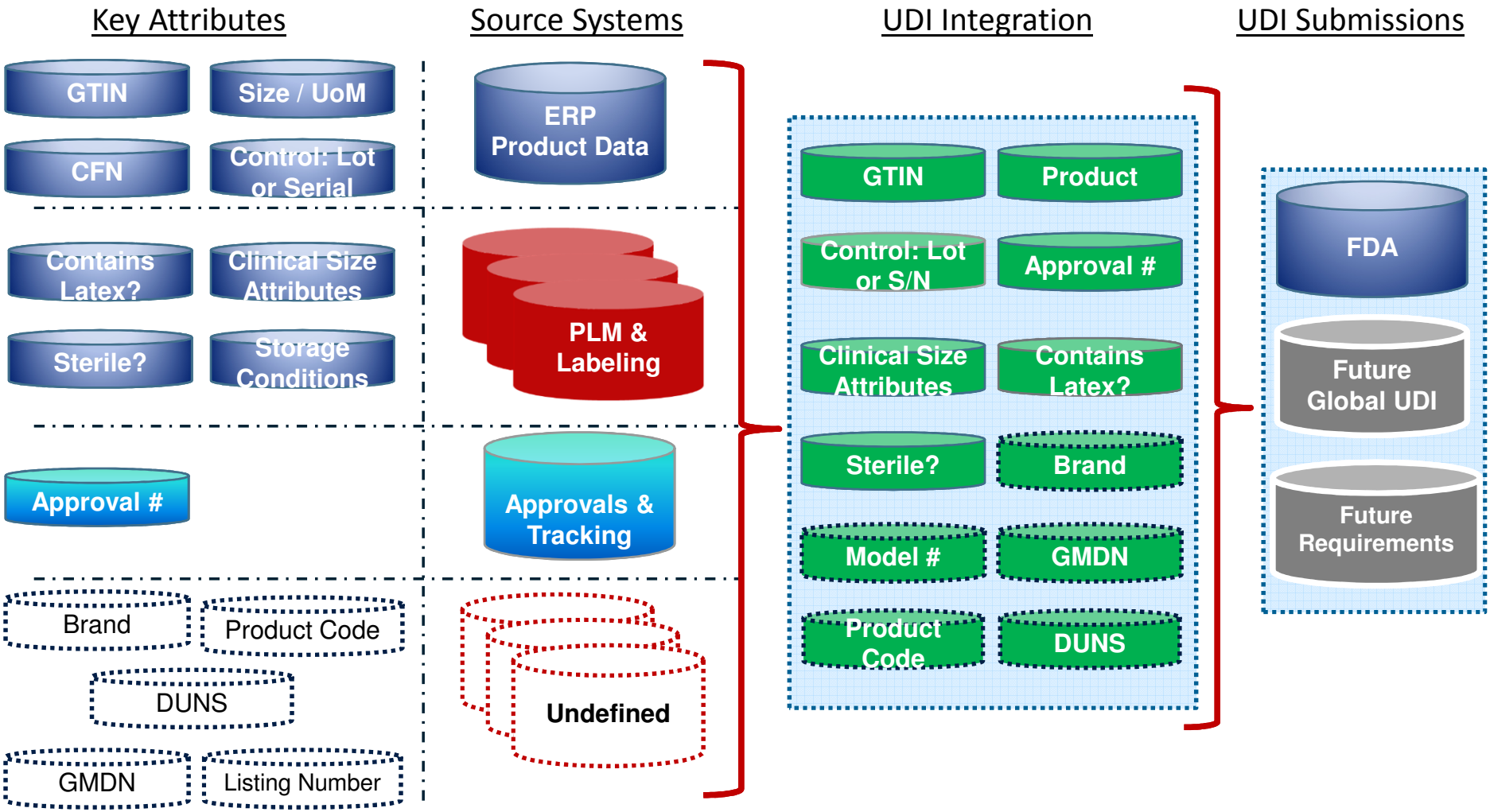
- Multiple parameters graded in a single scan; parameters vary between linear barcodes and 2-D data matrices
- Parameters graded on a scale 4 to 0 (A to F), as defined in table below
- Barcode grade is equal to the lowest parameter grade
- Propriety software performs grading
- Grading can be significantly impacted by printer capability, substrate, and ink/ribbon formulation, barcode size, and print direction.

Grade	Range	P/F	Comment
A	4.0 – 3.5	Pass	High quality data capture
B	<3.5 – 2.5	Pass	Efficient data capture
C	<2.5 – 1.5	Pass	Adequate data capture
D	<1.5 – 0.5	Fail	Generally not accepted by industry
F	<0.5 – 0.0	Fail	Not acceptable

ASSESSMENT & IMPACT: DATA



PUBLISHING TO GUDID



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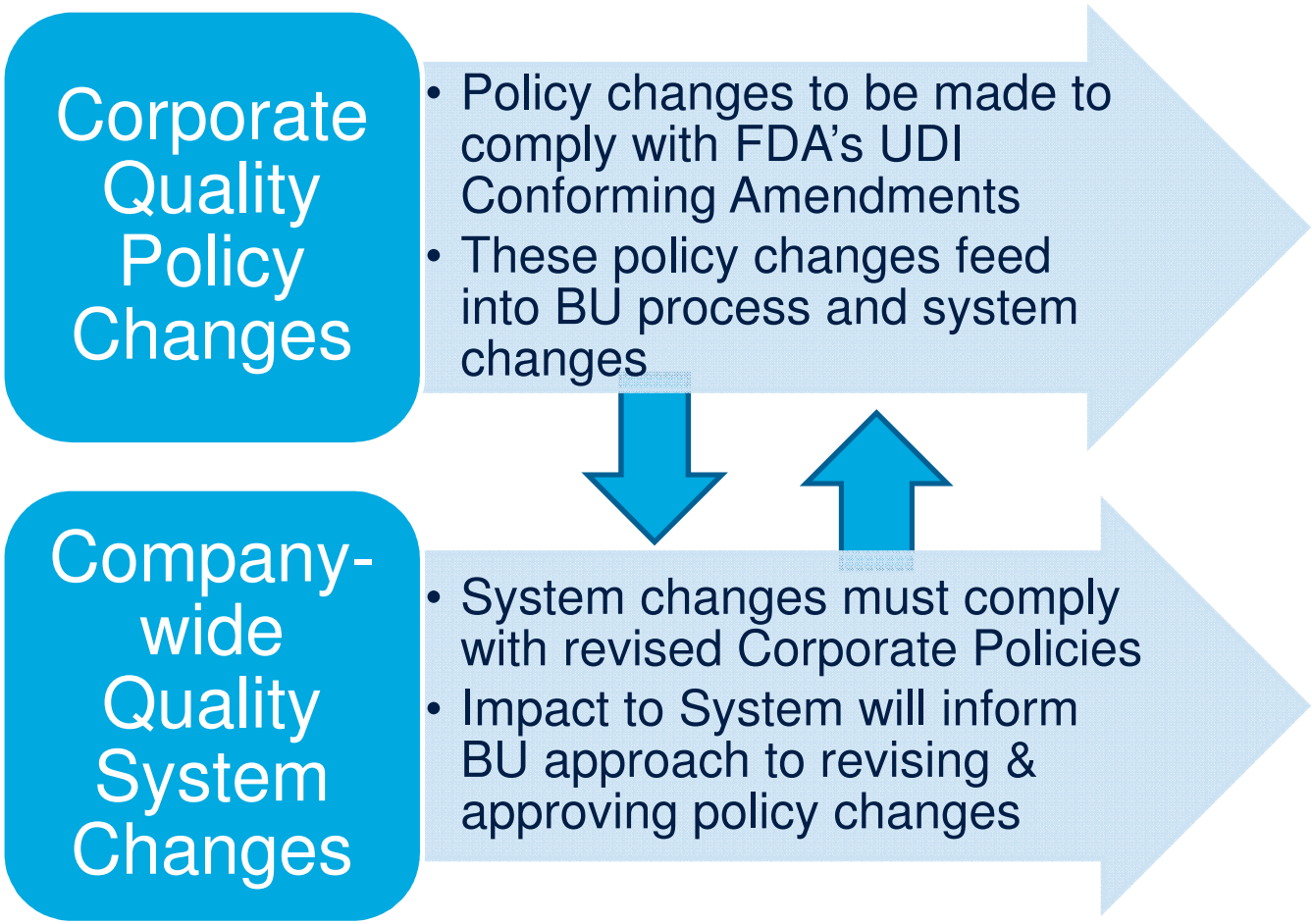
CHANGES & PARALLEL THREADS



LESSONS LEARNED & BEST PRACTICES

- Establish ownership early
- Established one source of truth early
- Keep preparation for Global UDI requirements in the forefront at all times
- Allow time for adjustment for the unexpected
- Build change control into your processes
- Document, document, document
- Build a strong team and a sustaining program

FINAL THOUGHTS

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U.S. FDA COMMITMENT TO SUCCESSFUL UDI IMPLEMENTATION

- FDA has provided a very collaborative environment between industry and the agency to work through difficult implementation issues.

- FDA acknowledges UDI implementation requires a learning process as we cannot anticipation every situation given, the diversity of device types and the magnitude and volume of device types.

- FDA has provided multiple communication channels for industry to ask questions, provide feedback, and work together.

Q&A

THANK YOU

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