The Case for Better Data
Health care has safety and quality problems because it relies on outmoded systems of work.

Poor designs set the workforce up to fail, regardless of how hard they try.

If we want safer, higher-quality care, we will need to have redesigned systems of care, including the use of information technology to support clinical and administrative processes.

Committee on Quality of Health Care in America
Institute of Medicine report: To Err is Human
Manual Entry Injects Human Error

Manual Data Entry
Handwritten or Spreadsheet entry sent via Fax / eMail

Supplier Community

RM Component Data Intake Form

Mfg Data Entry

MES

Customers

FG Component Data Intake Form

Dist Data Entry

Distribution
**Data Elements for Import**

**510K** - A premarketing submission made to FDA to demonstrate that the device to be marketed is as safe and effective, that is, substantially equivalent (SE), to a legally marketed device that is not subject to premarket approval (PMA). Exp. K785196, EXEMPT, PREAMMENDMENT, ENFORCEMENT

**FDA Product Code** - a 7 character alphanumeric code. The Code identifies the specific product by Industry Code, Class, Subclass, Process Indicator Code (PIC), and Product Exp. 79G--DJ

**Manufacturing Registration Number** - The FDA Manufacturer is the site-specific location where the product is manufactured, produced or grown. FDA needs to know the actual manufacturer of the product. For these products, the site-specific location must be submitted as the FDA Manufacturer. Exp. 3002807115

**Medical Device Listing** - Establishments that are required to register with the FDA are also required to list the devices that are made there and the activities that are performed on those devices. Exp. D094639
Regulatory Data Validation Automation

**Previous**

- Product Master Data is solicited from supplier via intake form
- Manufacturing/distribution systems NIA
- Product Purchased from Supplier
- Product submitted to PREDICT for validation, data quality issue discovered at the border

**Current**

- Product Master Data is solicited from supplier via intake form
- Manufacturing/distribution systems NIA
- Product submitted to PREDICT for validation, data quality issue discovered at the border
- Regulatory data combination with Medical Device Listing cannot be validated
- Regulatory data combination sent to FDA for manual validation against PREDICT data
- Data approved for use

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Data Pools Simplify Key Processes

Eliminate Varied Data Request Formats

Eliminate Debate on Required Data

Reduce Data Administration & Validation

Eliminate Supply Chain Disruption
GDSN Success Factors

• Simplified Manufacturer data creation process
• Precise standards for each attribute
• Global Industry harmonization (GDSN)
• Improved data validation process
• Method to verify data has been shared/synchronized
• Improved regulatory data alignment
Learn more…

Information on Cardinal Health & Standards
www.cardinalhealth.com/gs1

Information on GS1 & GDSN Certified Data Pools
www.gs1.org/gdsn