The Case for Better Data

To Err is Human

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*

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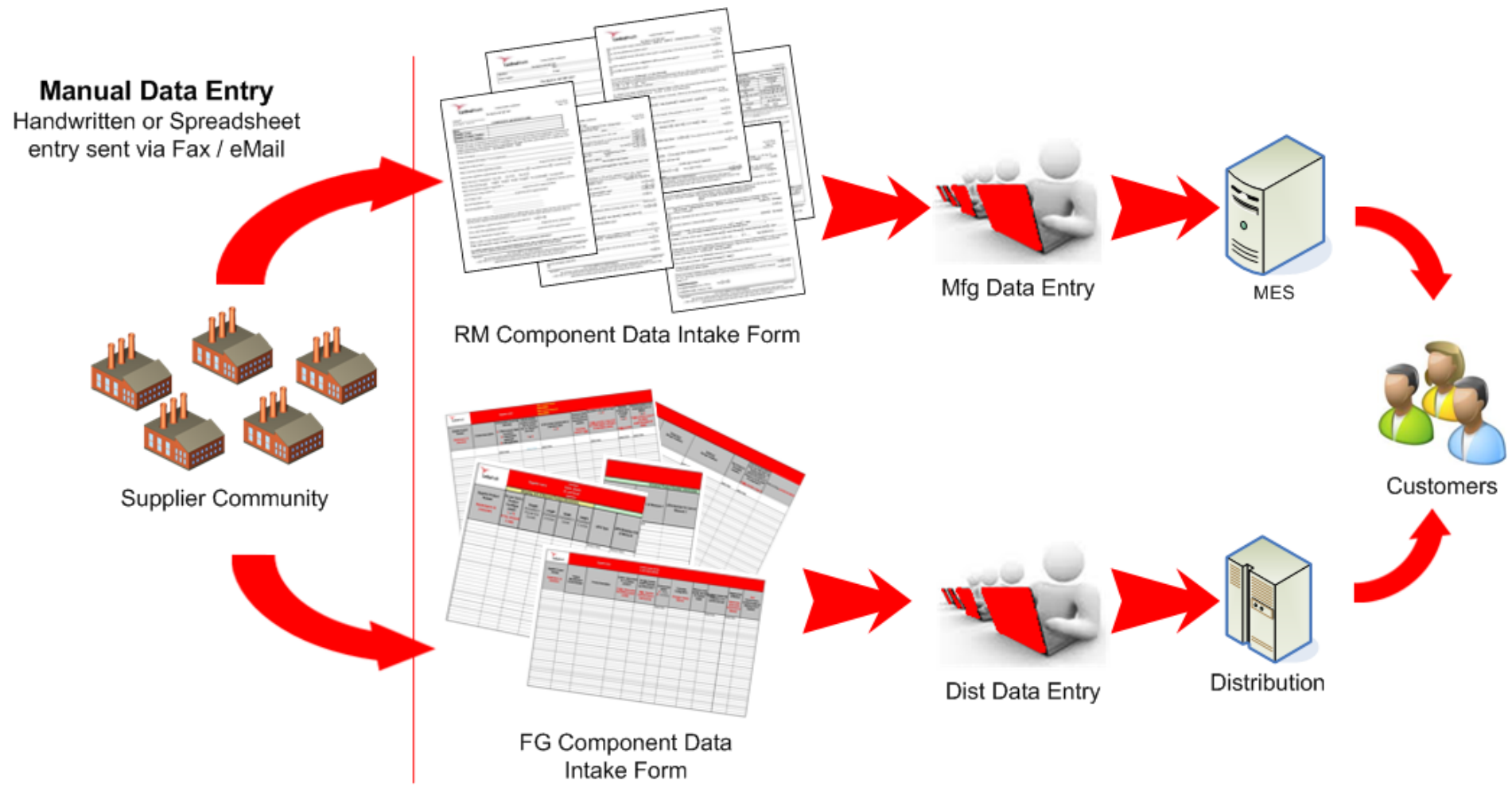
Manual Entry Injects Human Error



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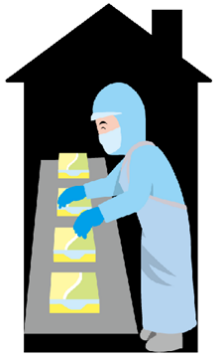
Data Elements for Import

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



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

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

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

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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

Data approved for use

Regulatory data combination with Medical Device Listing cannot be validated

Validate Establishment Registration #, Procode, 510K based on FDA.Gov Public Data

Regulatory data combination sent to FDA for manual validation against PREDICT data

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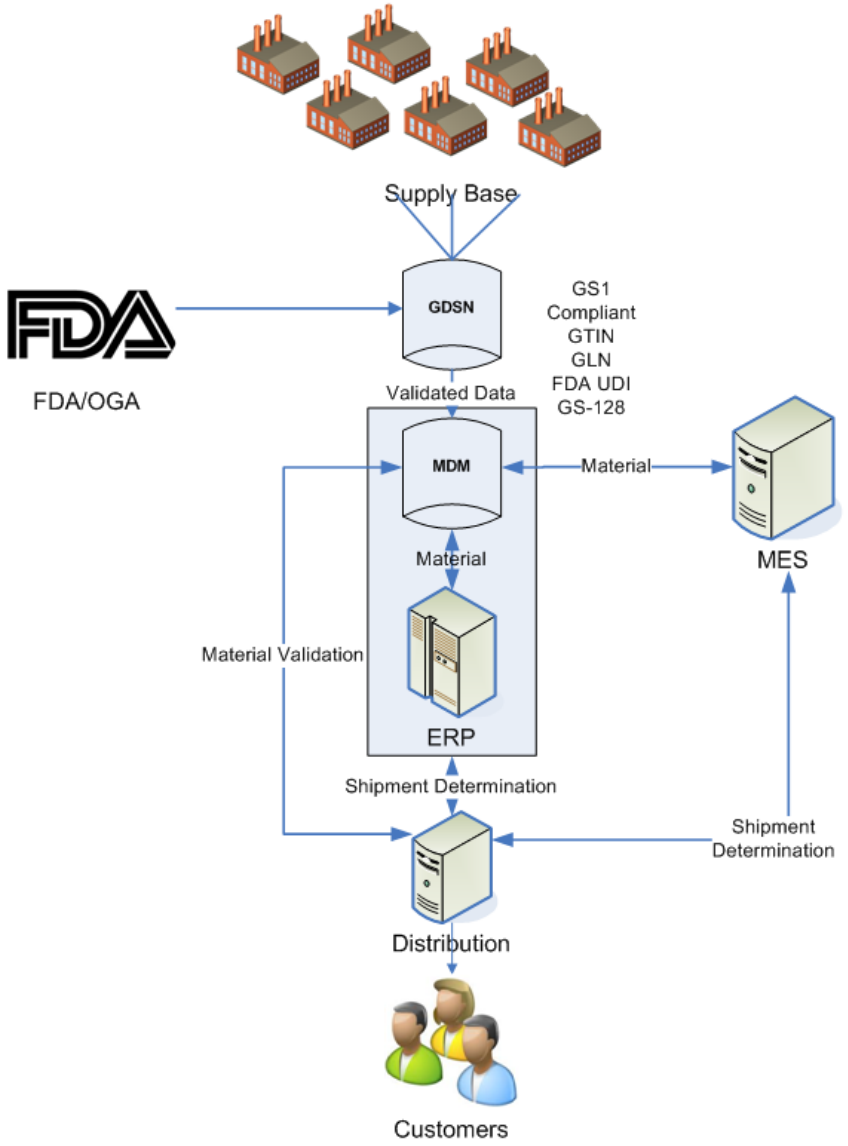
Data Validation To-Be Model



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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

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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

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Learn more…

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

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

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