GDSN / UDI Breakout Session

Lessons Learned

GS1 Healthcare Conference
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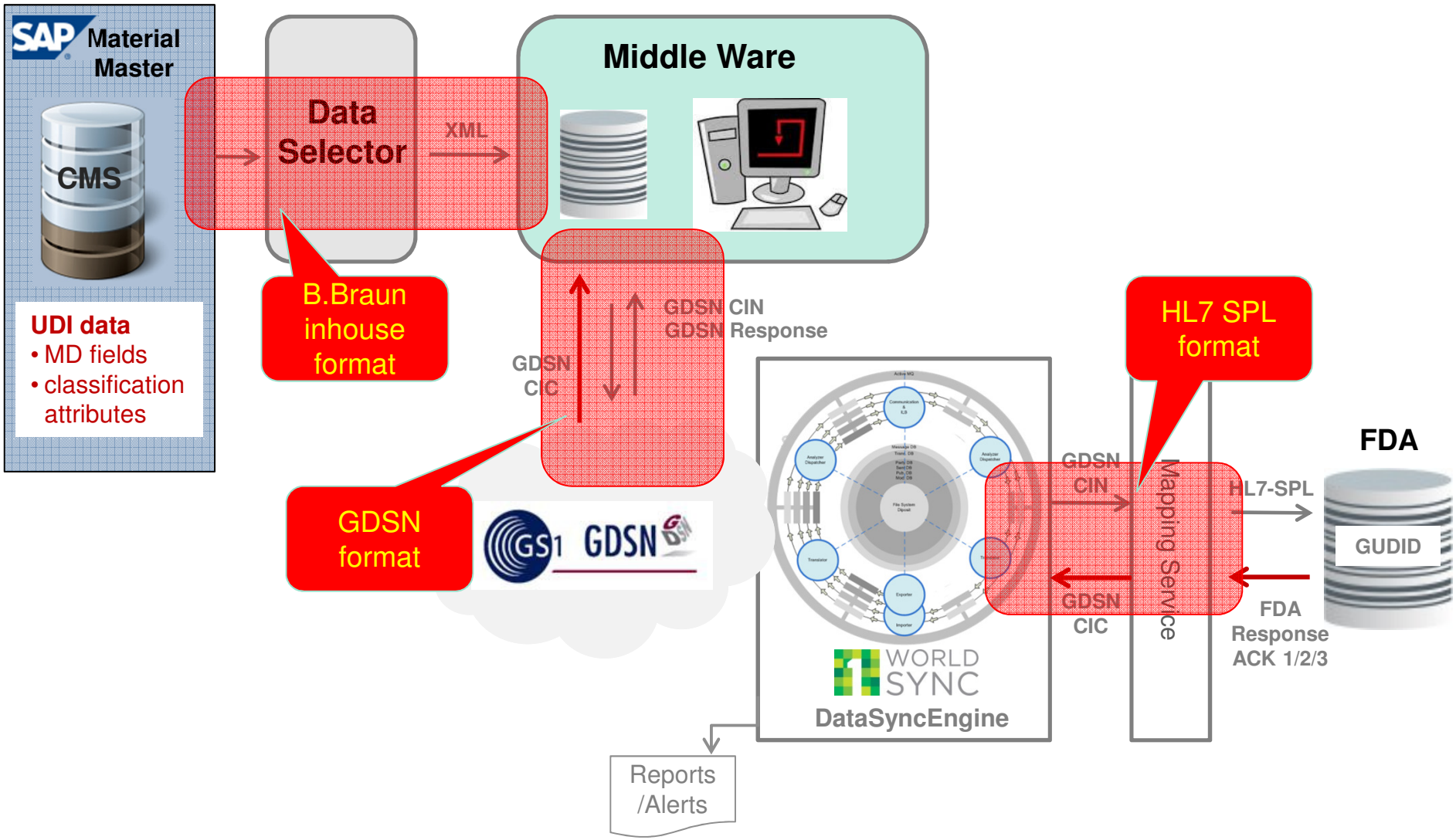
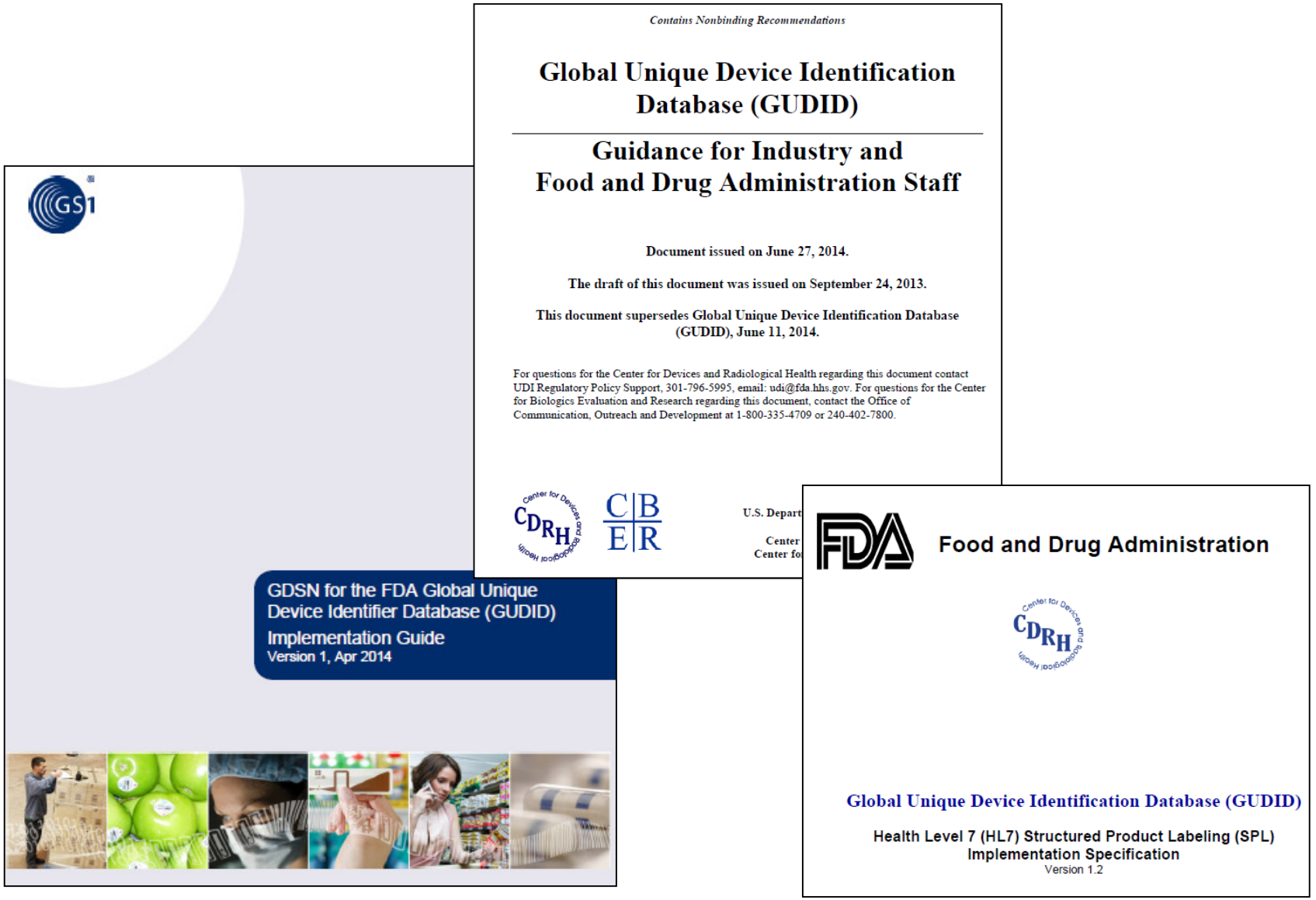
Process Overview + Data Mapping



The most important Documents



GS1

GDSN for the FDA Global Unique Device Identifier Database (GUDID)
Implementation Guide
Version 1, Apr 2014

Contains Nonbinding Recommendations

Global Unique Device Identification Database (GUDID)

Guidance for Industry and Food and Drug Administration Staff

Document issued on June 27, 2014.

The draft of this document was issued on September 24, 2013.

This document supersedes Global Unique Device Identification Database (GUDID), June 11, 2014.

For questions for the Center for Devices and Radiological Health regarding this document contact UDI Regulatory Policy Support, 301-796-5995, email: udi@fda.hhs.gov. For questions for the Center for Biologics Evaluation and Research regarding this document, contact the Office of Communication, Outreach and Development at 1-800-335-4709 or 240-402-7800.

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Food and Drug Administration

Global Unique Device Identification Database (GUDID)

Health Level 7 (HL7) Structured Product Labeling (SPL) Implementation Specification
Version 1.2

Lessons learned

Key for Data Quality

- standardized data maintenance processes (SOPs) + well educated data owners
- data validation as early as possible (ideally at the point of data generation)
- in later process steps you only can optimize error handling !

Legacy Data

- split in batches to handle a higher number of devices + perform data quality checks
- recommendation → monitoring tool (data completeness, label compliance)

Testing is time-consuming

- mapping errors will occur – going through a learning curve is not a bad thing
- learn to interpret FDA‘s response msg / define rules how to deal with error msg (SOPs)
- once the mapping setup is successfully tested – don‘t touch it !
- 4 test scenarios required to get an account on FDA‘s productive GUDID

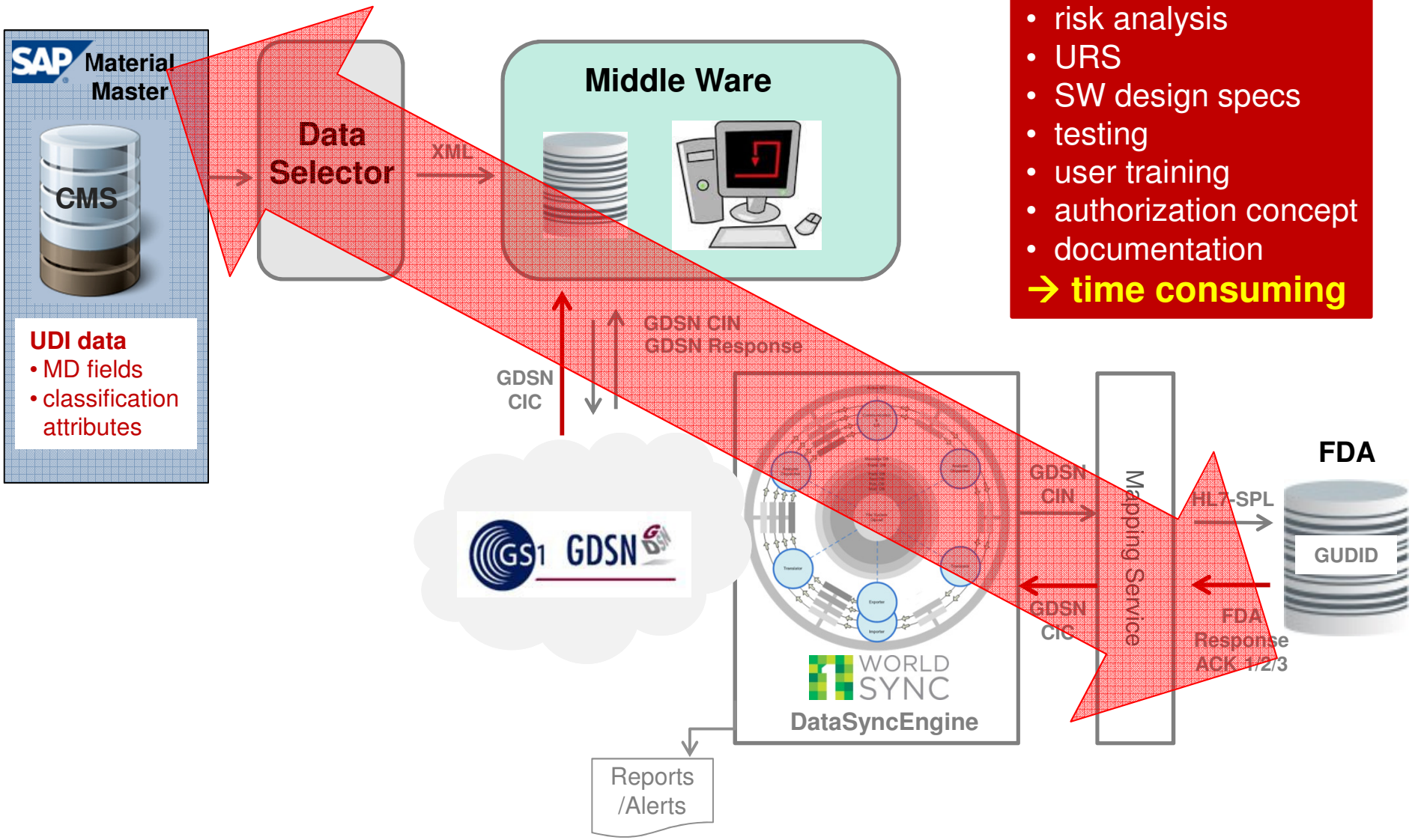
GUDID account structure

- the right setup incl. roles is important (GUDID account – coordinator – LDE – 3rd-Party)
- for some account changes the FDA Help Desk needs to be contacted (response time!)

GUDID rules

- DI trigger fields / Grace Period
- internal rules to safeguard your life-cycle data management processes

Process Validation



- validation plan
- risk analysis
- URS
- SW design specs
- testing
- user training
- authorization concept
- documentation

→ **time consuming**

Why we decided to use GDSN to provide UDI Data

Strategic decision
- GDSN to be the main channel for material master data exchange with 3rd-party
- regulatory compliance (UDI)
- commercial purposes (customers)
- can be used globally

Simplification
- just one middle-ware necessary for all data exchange use cases
- differentiation via Information-Provider GLNs / target market
- one technical interface between our data in in-house format to 3rd-party formats
- no need to deal with HL7 SPL on our side / no special knowledge required

Efficiency through Standardization
- once implemented it's relatively easy to expand to other use cases
- reduced project cost + implementation time

Support + User Communities
- GDSN support well organized by GS1 Global and MO's
- user groups to exchange experiences and work on GDSN improvements


Thank you for your time.
Questions ?
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