Unique Device Identification

Challenges for Manufacturers – Focus UDID

GS1 Healthcare Conference
Copenhagen, Oct 22, 2014

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SHARING EXPERTISE

FDA's UDI Requirements (Medical Devices)

1

- unambiguous device identification (distribution + use)
- accredited issuing agencies only (GS1, HIBCC, ICCBA)

2

- data assoc. with med device identification + labeling
- > 60 data elements per device

3

- machine-readable identification
- device ID + production IDs
- package levels / device itself

GS1

GTIN

Lot No.
Serial No.
Expiry Dt.
Manuf. Dt.

UDI
(numbering)

- **DI** Device Identifier
  →static data
- **PI** Production Ident.
  →dynamic data

UDID
(database)

Static Data Elements

- **DI** = primary access key
- …
- …
- …

AIDC
(coding)

machine – readable data carrier

- Bar Code
- RFID

risk-based implementation	class 3 : Sep 2014	class 2-IMP : Sep 2015	class 2 : Sep 2016	class 1 : Sep 2018

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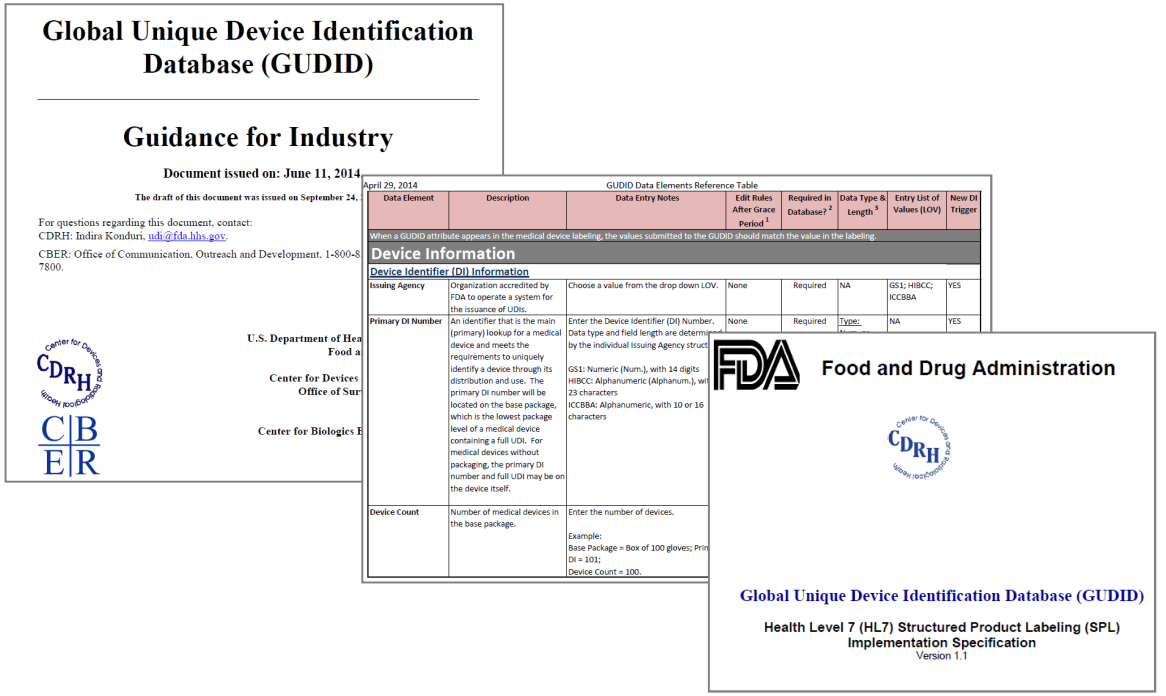
Challenge UDID

The major aspects :

- Data Sources and Owners
- Internal Data Administration
- Data Exchange



Global Unique Device Identification Database (GUDID)

Guidance for Industry

Document issued on: June 11, 2014

The draft of this document was issued on September 24,

For questions regarding this document, contact:
CDRH: Indira Konduri, udi@fda.hhs.gov.

CBER: Office of Communication, Outreach and Development, 1-800-8
7800.

U.S. Department of Hea
Food a

Center for Devices
Office of Sur

Center for Biologics E

April 29, 2014 GUDID Data Elements Reference Table

Data Element	Description	Data Entry Notes	Edit Rules After Grace Period [1]	Required in Database? [2]	Data Type & Length [3]	Entry List of Values (LOV)	New DI Trigger
When a GUDID attribute appears in the medical device labeling, the values submitted to the GUDID should match the value in the labeling.							
Device Information							
Device Identifier (DI) Information							
Issuing Agency	Organization accredited by FDA to operate a system for the issuance of UDIs.	Choose a value from the drop down LOV.	None	Required	NA	GS1; HIBCC; ICCBBA	YES
Primary DI Number	An identifier that is the main (primary) lookup for a medical device and meets the requirements to uniquely identify a device through its distribution and use. The primary DI number will be located on the base package, which is the lowest package level of a medical device containing a full UDI. For medical devices without packaging, the primary DI number and full UDI may be on the device itself.	Enter the Device Identifier (DI) Number. Data type and field length are determined by the individual Issuing Agency struct GS1: Numeric (Num.), with 14 digits HIBCC: Alphanumeric (Alphanum.), wit 23 characters ICCBBA: Alphanumeric, with 10 or 16 characters	None	Required	Type:	NA	YES
Device Count	Number of medical devices in the base package.	Enter the number of devices. Example: Base Package = Box of 100 gloves; Prin DI = 101; Device Count = 100.					

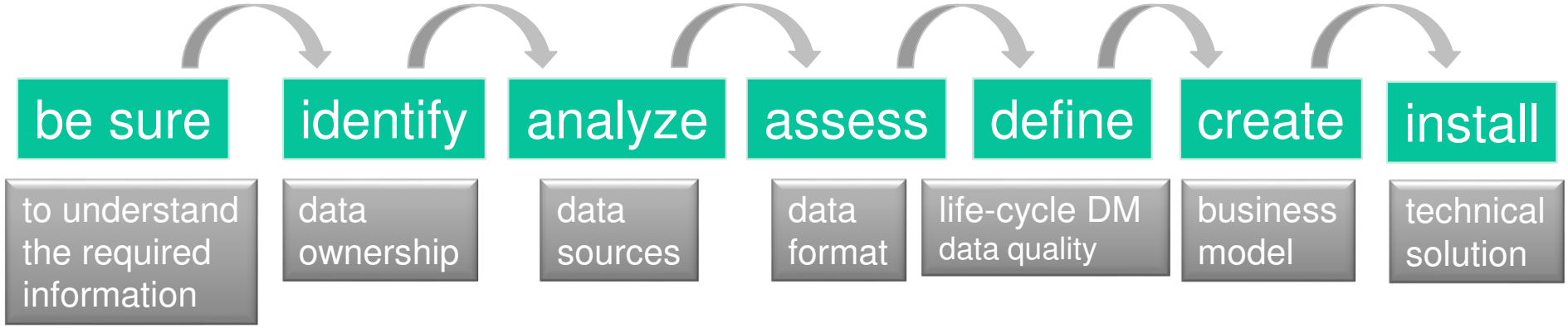
Food and Drug Administration

Global Unique Device Identification Database (GUDID)

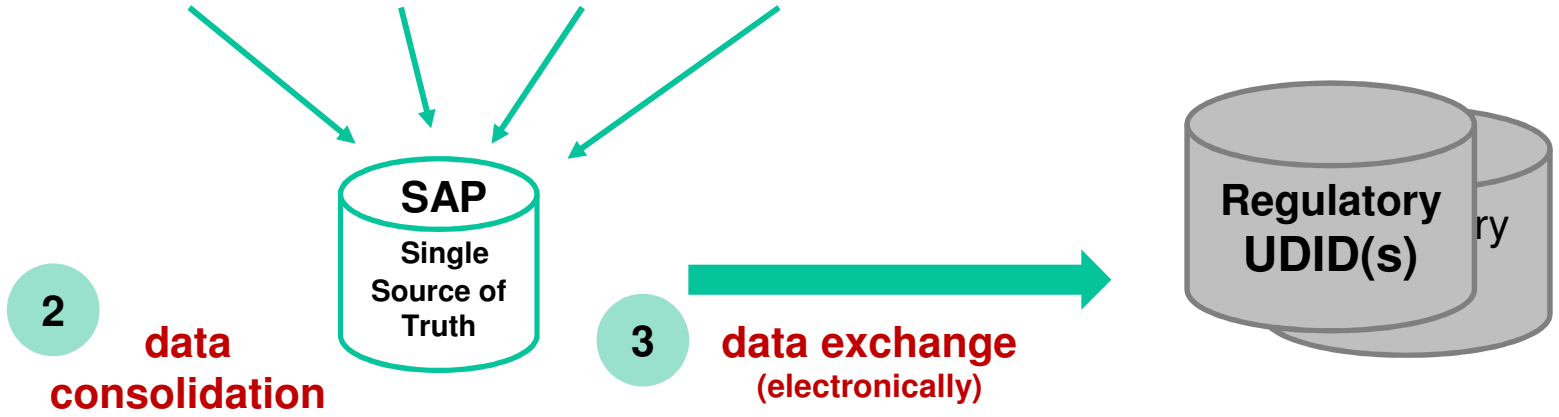
Health Level 7 (HL7) Structured Product Labeling (SPL) Implementation Specification
Version 1.1

UDI Database(s)

1 analysis and planning



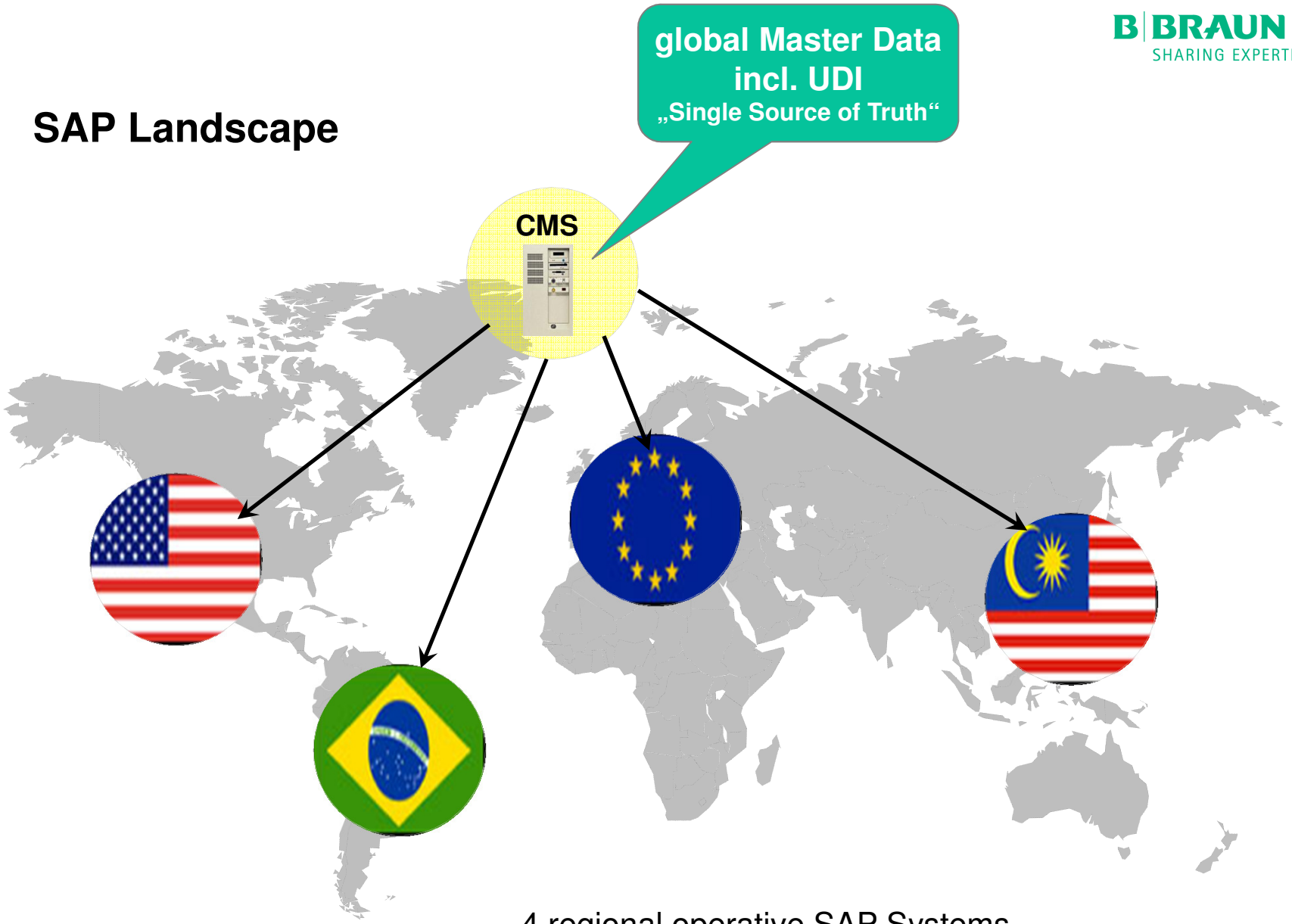
sources : ERP System, LotusNotes-DBs, Excel-files, Access-files, drawings, paper work, ...



2 data consolidation

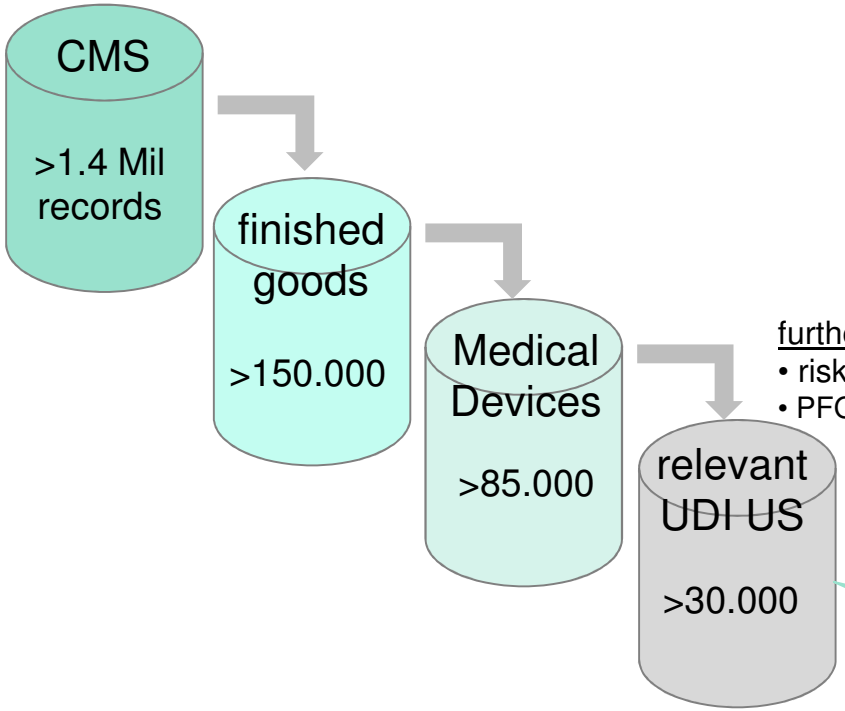
3 data exchange (electronically)

SAP Landscape

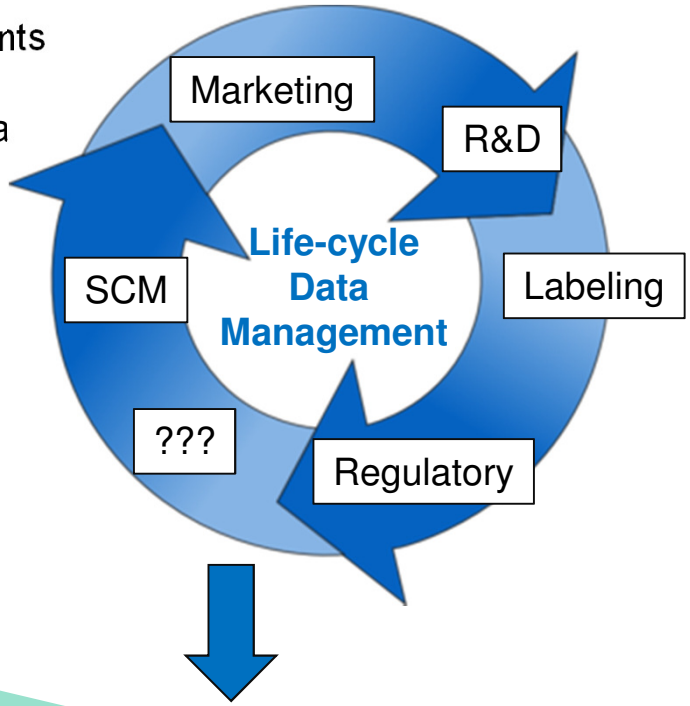


4 regional operative SAP Systems
1 global SAP Master Data System

Material Master Data Management



- several departments
- around the world
- global + local data
- autom. workflows
  - new products
  - data changes



<u>further aspects</u>
- risk classes (3, 2IMP, 2, 1)
- PFG and OEM !

<u>Introcan Safety</u>

• material no	• xxx	• xxx	• xxx
• brandname	• xxx	• xxx	• xxx
• pack. hierarchy	• xxx	• xxx	• xxx
• weight	• xxx	• xxx	• xxx
• length	• xxx	• xxx	• xxx
• sterility	• xxx	• xxx	• xxx
• single-use	• xxx	• xxx	• xxx
• latex	• xxx	• xxx	• xxx
• GTIN	• xxx	• xxx	• xxx
• MR Safety	• xxx	• xxx	• xxx

>250 data attributes per record

Need to figure out :
1. Master data records relevant for UDI
2. Data attributes relevant for UDI

Material Master Data – UDI Relevance

relevant UDI US

>30.000

Introcan Safety

• material no	• xxx	• xxx	• xxx
• brandname	• xxx	• xxx	• xxx
• pack. hierarchy	• xxx	• xxx	• xxx
• weight	• xxx	• xxx	• xxx
• length	• xxx	• xxx	• xxx
• sterility	• xxx	• xxx	• xxx
• single-use	• xxx	• xxx	• xxx
• latex	• xxx	• xxx	• xxx
• GTIN	• xxx	• xxx	• xxx
• MR Safety	• xxx	• xxx	• xxx

>250 data attributes per record

Why to figure out attributes relevant for UDI ?
→ FDA GUDID needs to be updated

How to recognize changes at attributes relevant for UDI ?
→ SAP change pointer concept

Actions?
→ change pointers trigger data exchange process

SAP data concept

SAP classification (3)
- global UDI data (core)
- local UDI data
- monitoring

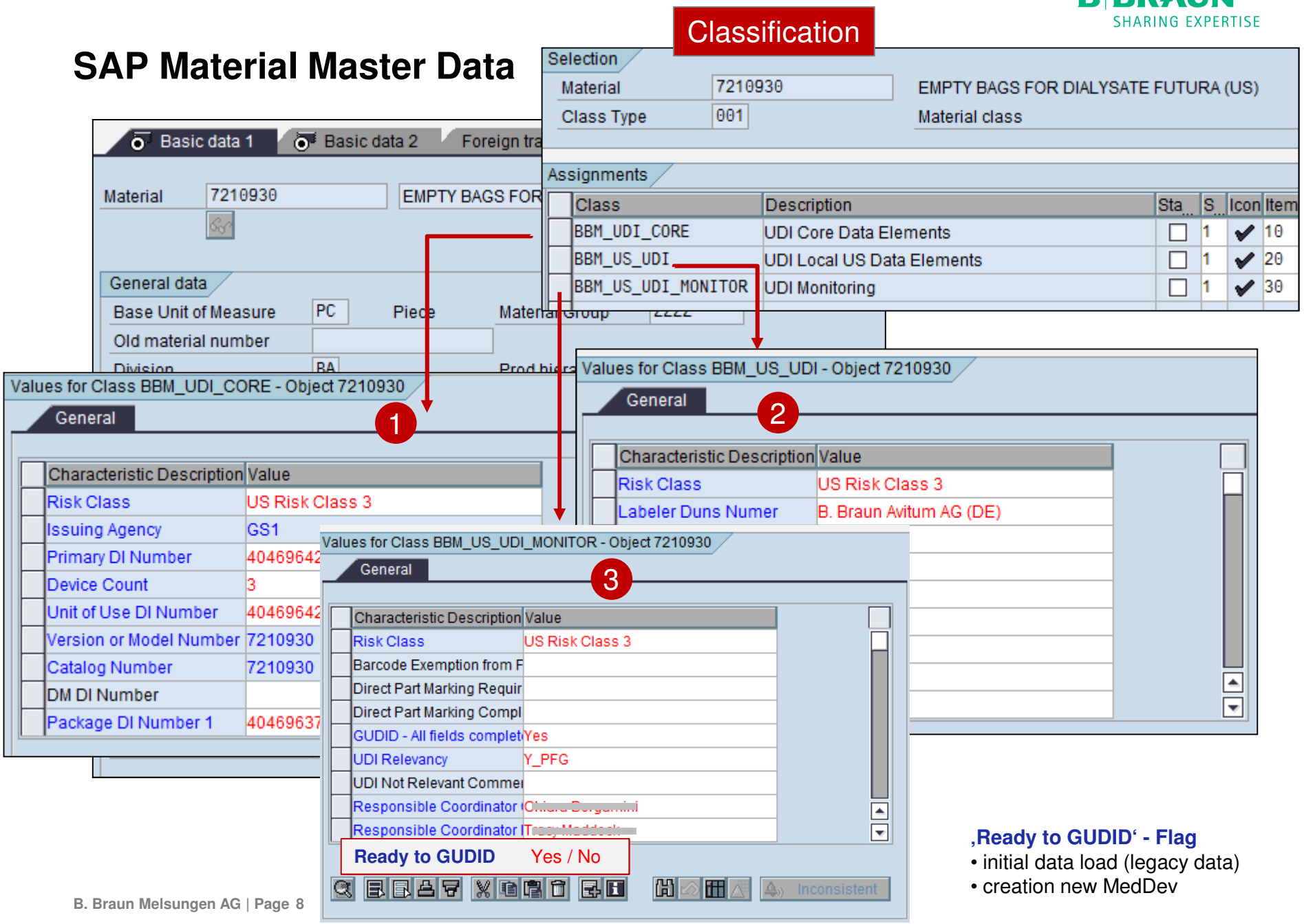
monitoring attributes
- responsibilities
- labeling status
- data completeness

\+
"Ready to GUDID"

flag triggers Data Selector

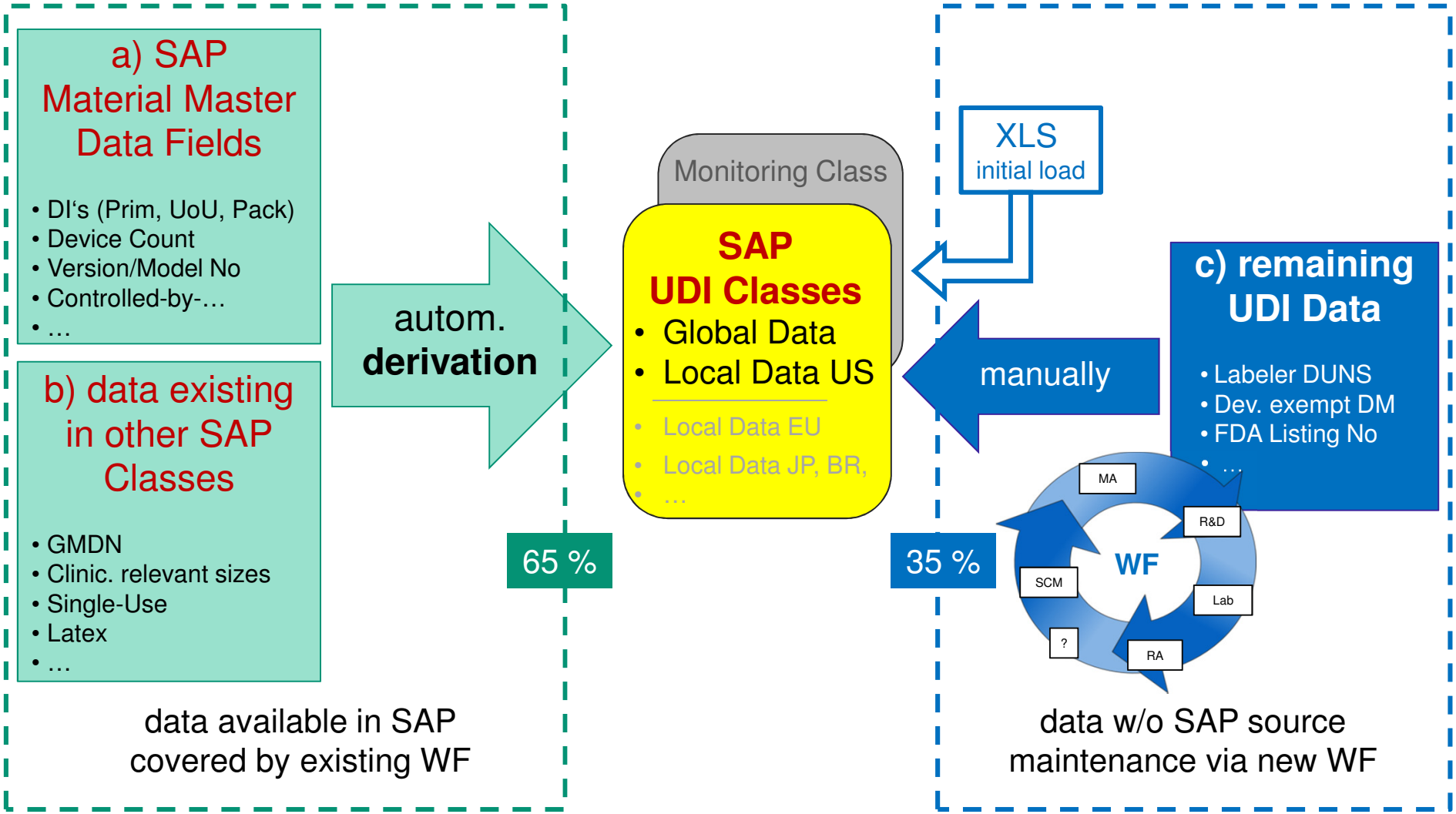
important for initial data upload into FDA GUDID

SAP Material Master Data



‚Ready to GUDID' - Flag
- initial data load (legacy data)
- creation new MedDev

UDI Data Consolidation in SAP



SAP Classification

Example :
product category ‚cannula'

autom.
derivation
into UDI classes
acc. rules (BRF)

UDI relevant
information
in SAP classification

different data
depending on
the product category
available

PENCAN 25GX6" (0.53X156MM) (333877)

PENCAN 25GX6" (0.53X156MM) — Marketing Release: INT

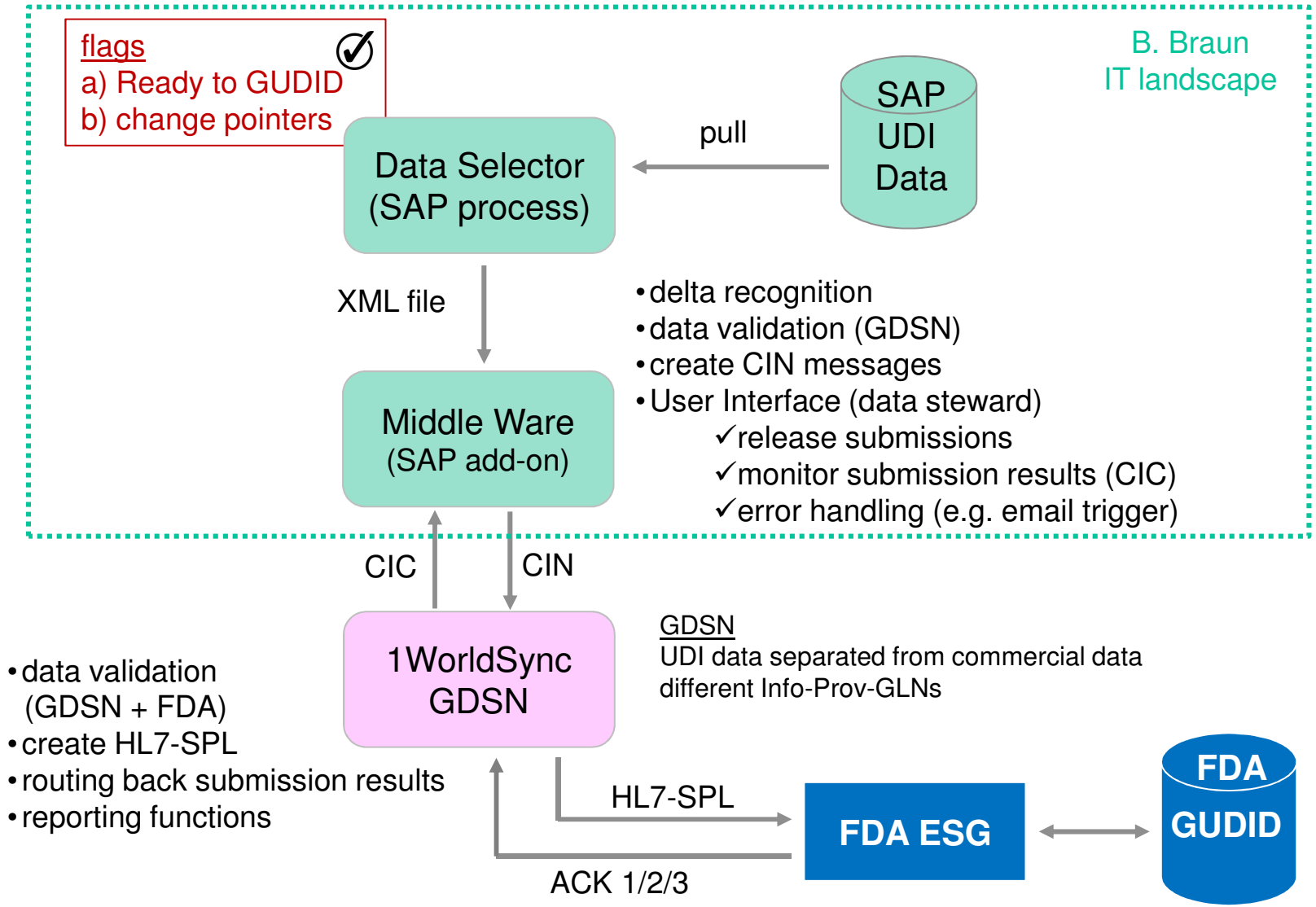
Details | Masterdata | Material Texts | Documents | Products | B. DoCS

Regional anesthesia cannulas

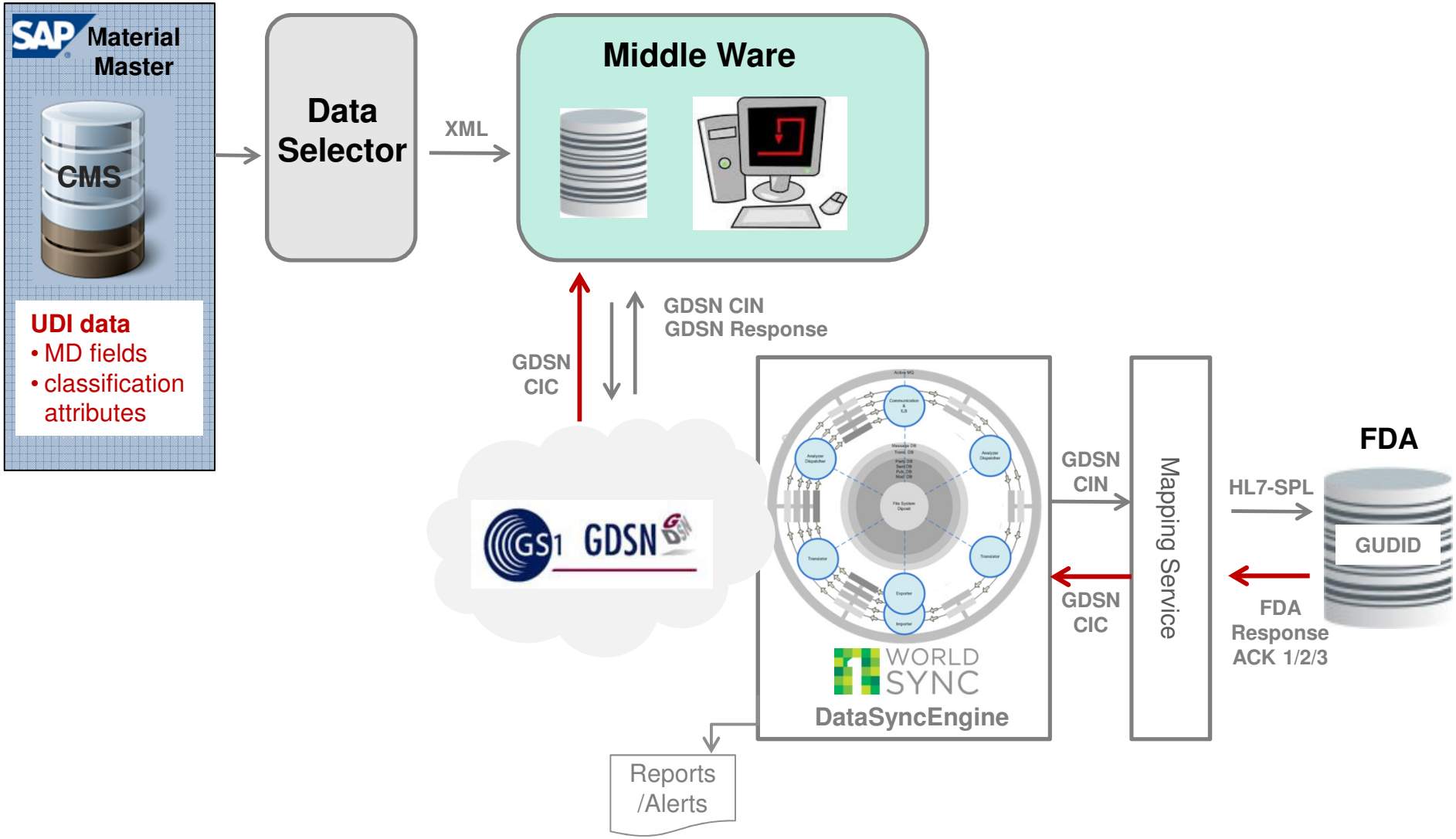
Attribute Name	Attribute Value
Application	Spinal
B. Braun brand name	Pencan®
Color	orange
Gauge (cannula)	25
Graduation	-
Guide cannula	No
Hub design	square
Length of cannula (inch)	6 1/4"
Length of cannula (metric)	156.0 mm
Material of mandrin	stainless steel
Outer-ø cannula	0.53 mm
Packaging contains DEHP	No
Packaging contains Latex	No
Packaging contains PVC	No
Product (unpack.) cont. DEHP	No
Product (unpack.) cont. Latex	No
Product (unpack.) contains PVC	No
Product contains BPA	Yes
Product contains DEHP	No
Product contains Latex	No
Product contains Nickel	Yes
Product contains PVC	No
Product name (HC)	Pencan®
Product type	Needle
Sterility	sterile
Type of Sterilization	EO
Type of bevel	pencil point
Type of packaging	Blister

extract

UDI Data Selection, Monitoring and Exchange



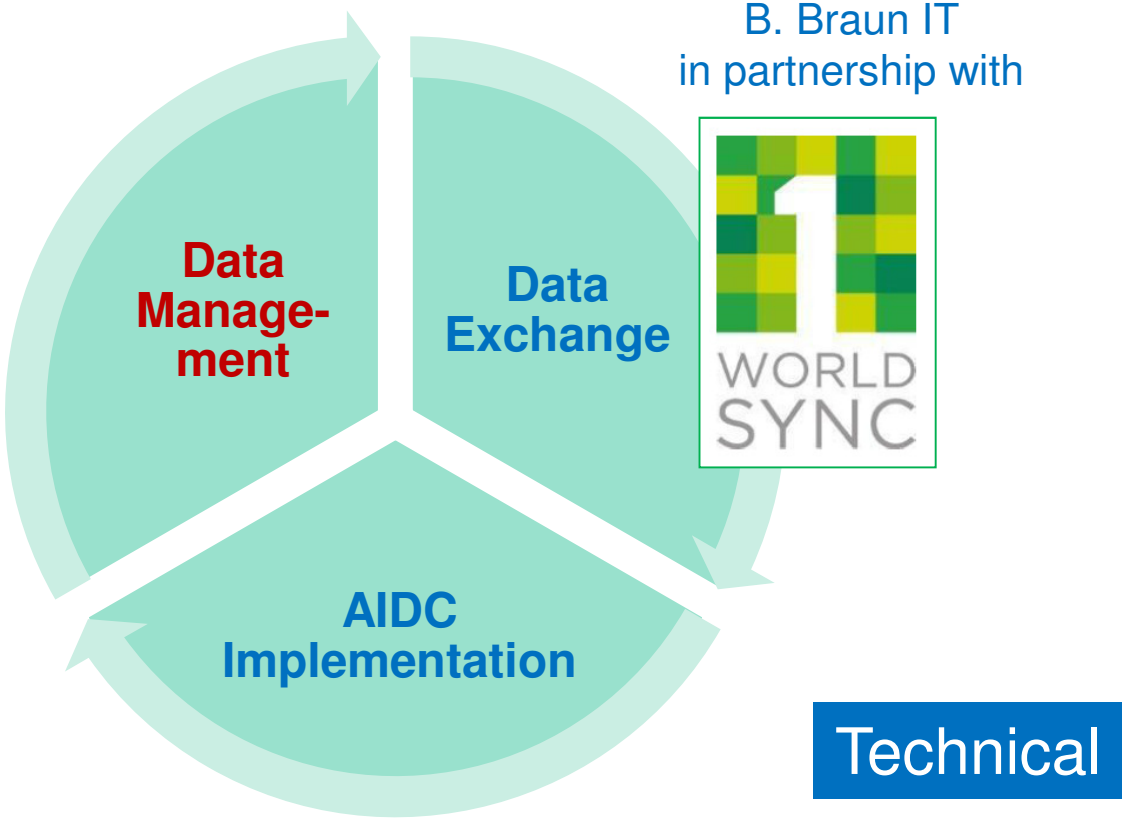
Process Overview



UDI Implementation Challenges

Organisational

B. Braun internal
- workflows
- process validation
- SOP‘s
- people
- education
- etc



B. Braun IT
in partnership with

WORLD SYNC

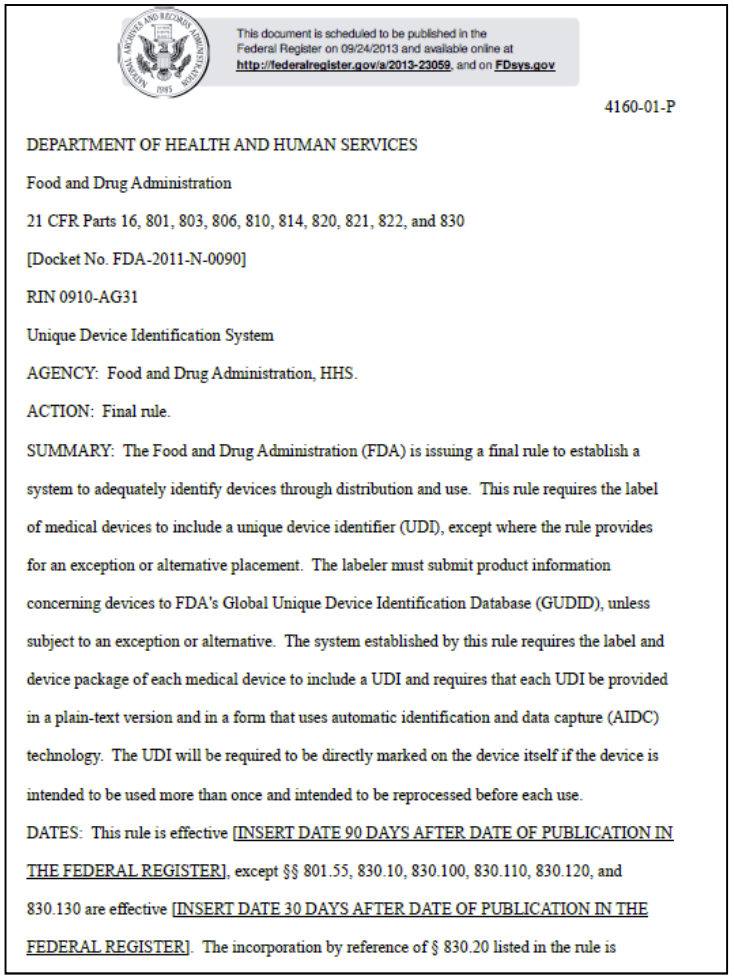
Technical

B. Braun Engineering / Labeling
in partnership with printer system providers

Before you start UDI implementation

Compliance Group
to interpret the regulation …

… and to create an internal
implementation guide !



This document is scheduled to be published in the Federal Register on 09/24/2013 and available online at http://federalregister.gov/a/2013-23059, and on FDsys.gov

4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 16, 801, 803, 806, 810, 814, 820, 821, 822, and 830

[Docket No. FDA-2011-N-0090]

RIN 0910-AG31

Unique Device Identification System

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule to establish a system to adequately identify devices through distribution and use. This rule requires the label of medical devices to include a unique device identifier (UDI), except where the rule provides for an exception or alternative placement. The labeler must submit product information concerning devices to FDA's Global Unique Device Identification Database (GUDID), unless subject to an exception or alternative. The system established by this rule requires the label and device package of each medical device to include a UDI and requires that each UDI be provided in a plain-text version and in a form that uses automatic identification and data capture (AIDC) technology. The UDI will be required to be directly marked on the device itself if the device is intended to be used more than once and intended to be reprocessed before each use.

DATES: This rule is effective [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER], except §§ 801.55, 830.10, 830.100, 830.110, 830.120, and 830.130 are effective [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. The incorporation by reference of § 830.20 listed in the rule is


Thank you for your time.
Questions ?
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