Unique Device Identification
Challenges for Manufacturers – Focus UDID

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FDA’s UDI Requirements (Medical Devices)

1. Unambiguous device identification (distribution + use)
   - Accredited issuing agencies only (GS1, HIBCC, ICCBA)

2. Data association with medical device identification + labeling
   - > 60 data elements per device

3. Machine-readable identification
   - Device ID + production IDs
   - Package levels / device itself

UDI (numbering)
- **DI** Device Identifier → static data
- **PI** Production Ident. → dynamic data

UDID (database)
- **DI** = primary access key
- ... 
- Static Data Elements

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
Challenge UDID

The major aspects:
- Data Sources and Owners
- Internal Data Administration
- Data Exchange
UDI Database(s)

1. analysis and planning
   - be sure
     - to understand the required information
   - identify
     - data ownership
   - analyze
     - data sources
   - assess
     - data format
   - define
     - life-cycle DM data quality
   - create
     - business model
   - install
     - technical solution

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

2. data consolidation
   - SAP
     - Single Source of Truth

3. data exchange
   - Regulatory UDID(s)
     - (electronically)
SAP Landscape

4 regional operative SAP Systems
1 global SAP Master Data System

global Master Data incl. UDI
„Single Source of Truth“
Material Master Data Management

CMS

>1.4 Mil records

finished goods

>150,000

Medical Devices

>85,000

relevant UDI US

>30,000

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

further aspects
• risk classes (3, 2IMP, 2, 1)
• PFG and OEM!

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

>250 data attributes per record

Marketing

R&D

Life-cycle Data Management

SCM

Labeling

Regulatory

Marketing

R&D

Labeling

Regulatory

???

new products

data changes

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

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

Classification

'Ready to GUDID' - Flag
- initial data load (legacy data)
- creation new MedDev
UDI Data Consolidation in SAP

a) SAP Material Master Data Fields
- DI's (Prim, UoU, Pack)
- Device Count
- Version/Model No
- Controlled-by-…
- …

b) data existing in other SAP Classes
- GMDN
- Clinic. relevant sizes
- Single-Use
- Latex
- …

data available in SAP covered by existing WF

SAP UDI Classes
- Global Data
- Local Data US
  - Local Data EU
  - Local Data JP, BR, …

Monitoring Class

c) remaining UDI Data
- Labeler DUNS
- Dev. exempt DM
- FDA Listing No

autom. derivation

65 %

XLS initial load

35 %

WF

data w/o SAP source maintenance via new WF

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SAP Classification

<table>
<thead>
<tr>
<th>Attribute Name</th>
<th>Attribute Value</th>
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<tbody>
<tr>
<td>Application</td>
<td>Spinal</td>
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<tr>
<td>B. Braun brand name</td>
<td>Pencan®</td>
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<td>Color</td>
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<td>Gauge (cannula)</td>
<td>25</td>
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<td>Graduation</td>
<td>-</td>
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<td>Guide cannula</td>
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<tr>
<td>Hub design</td>
<td>square</td>
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<td>Length of cannula (inch)</td>
<td>6 1/4&quot;</td>
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<tr>
<td>Length of cannula (metric)</td>
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<td>Material of mandrin</td>
<td>stainless steel</td>
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<td>Outer-a cannula</td>
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<tr>
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<tr>
<td>Packaging contains PVC</td>
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</tr>
<tr>
<td>Product (unpack.) cont. Latex</td>
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<tr>
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<tr>
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<tr>
<td>Type of Sterilization</td>
<td>EO</td>
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<tr>
<td>Type of bevel</td>
<td>pencil point</td>
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<tr>
<td>Type of packaging</td>
<td>Blister</td>
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</tbody>
</table>
UDI Data Selection, Monitoring and Exchange

Flags:
- a) Ready to GUDID
- b) Change pointers

Data Selector (SAP process):
- XML file

Middle Ware (SAP add-on):
- Delta recognition
- Data validation (GDSN)
- Create CIN messages
- User Interface (data steward)
  - Release submissions
  - Monitor submission results (CIC)
  - Error handling (e.g. email trigger)

1WorldSync GDSN:
- UDI data separated from commercial data
- Different Info-Prov-GLNs

GDSN UDI data separated from commercial data different Info-Prov-GLNs

FDA ESG

B. Braun IT landscape

GUDID

XML Pull

ACK 1/2/3
Process Overview

- **Material Master**
  - CMS

- **Data Selector**
  - XML

- **Middle Ware**
  - GDSN CIN
  - GDSN Response

- **UDI data**
  - MD fields
  - classification attributes

- **DataSyncEngine**
  - FDA Response ACK 1/2/3
  - GDSN CIC
  - GDSN CIN

- **GDSN**
  - GUDID

- **Mapping Service**
  - HL7-SPL
  - FDA Response ACK 1/2/3

- **Reports / Alerts**

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UDI Implementation Challenges

Organisational

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

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

B. Braun IT
in partnership with
Before you start UDI implementation

Compliance Group to interpret the regulation …

… and to create an internal implementation guide!
Thank you for your time.
Questions?