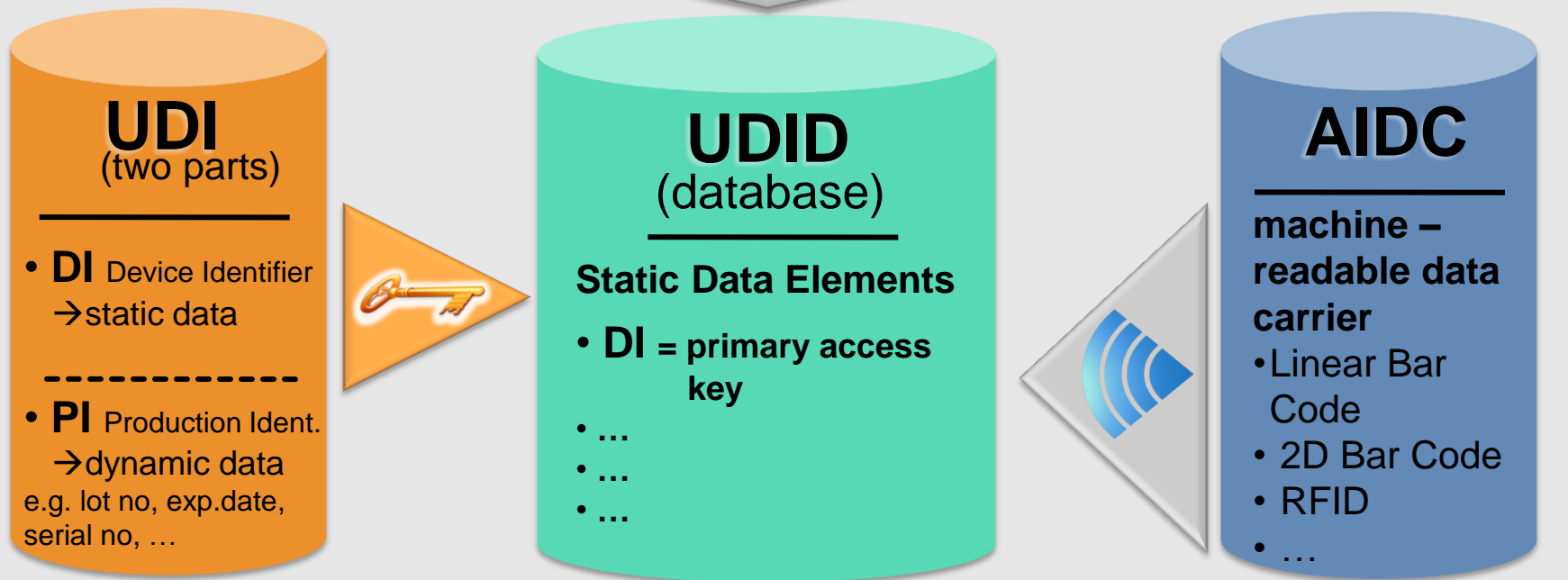# **U**nique **D**evice **I**dentification
Implementation from a manufacturers view

Volker Zeinar

GS1 Healthcare Conference
Sydney, March 2012

B | BRAUN
SHARING EXPERTISE

UDI System at a Glance

UDI - System

UDI
(two parts)

- **DI** Device Identifier
  → static data

- - - - - - - - - - - -

- **PI** Production Ident.
  → dynamic data
  e.g. lot no, exp.date,
  serial no, …

UDID
(database)

Static Data Elements

- **DI = primary access key**
- ...
- ...
- ...

AIDC

machine – readable data carrier

- Linear Bar Code
- 2D Bar Code
- RFID
- …

PI = however the production is controlled (doesn't imply serialisation of every MD)

information associated with medical device identification + labeling

technology neutral (ISO) data content = DI + PI

B | BRAUN
SHARING EXPERTISE

Main areas of work are

- ❑ Allocation of UDI codes
- ❑ Label Preparation
- ❑ AIDC Realization in Production
- ❑ UDI Database
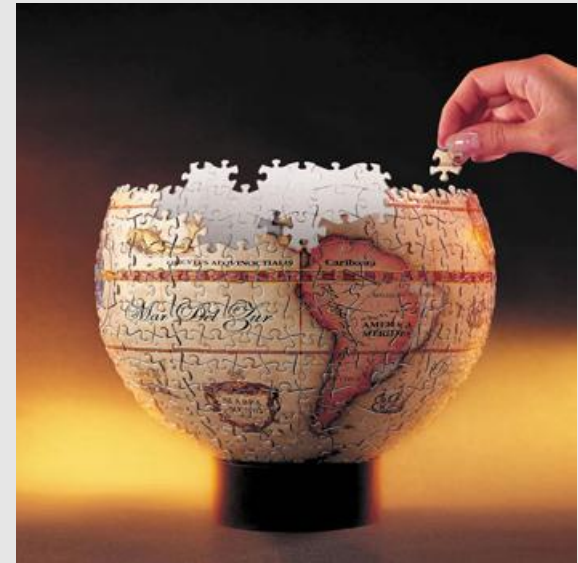
Allocation of UDI codes

- become a member of a Standards Development Organization
  - GS1 (or other ISO standard)

- ensure that UDI codes can be stored in the companies ERP system(s)

- define the products
  which need a UDI code
  - e.g. only finished goods

- define product pack. levels
  which need a UDI code

- define internal processes
  for UDI code allocation
  - responsibilities
  - who triggers the allocation of a new UDI code and when ?
  - which changes require a new UDI code

**business rules + ERP system + internal processes**

Label Preparation

- check all product labels of all packaging levels concerned

    - space available for UDI in AIDC and HRI format

- perform label artwork adjustments if necessary

- define per product label which AIDC carrier can be implemented

    - e.g. linear BC or 2D

(01)04022495212825(17)130100(10)8A2901088

- avoid multiple BC on the same label

    - means : UDI and something else

    - UDI carrier shall be readily identifiable

4 022495 212825

(17)130100(10)8A2901088

- initiate internal label changing procedure

    - several step approval process :QM. RA, Marketing, Production, LLD, …

- documentation of any label changes in the respective manner

    - artwork an new information on the label

    - update drawings , …

- …

artwork + documentation

Label Preparation
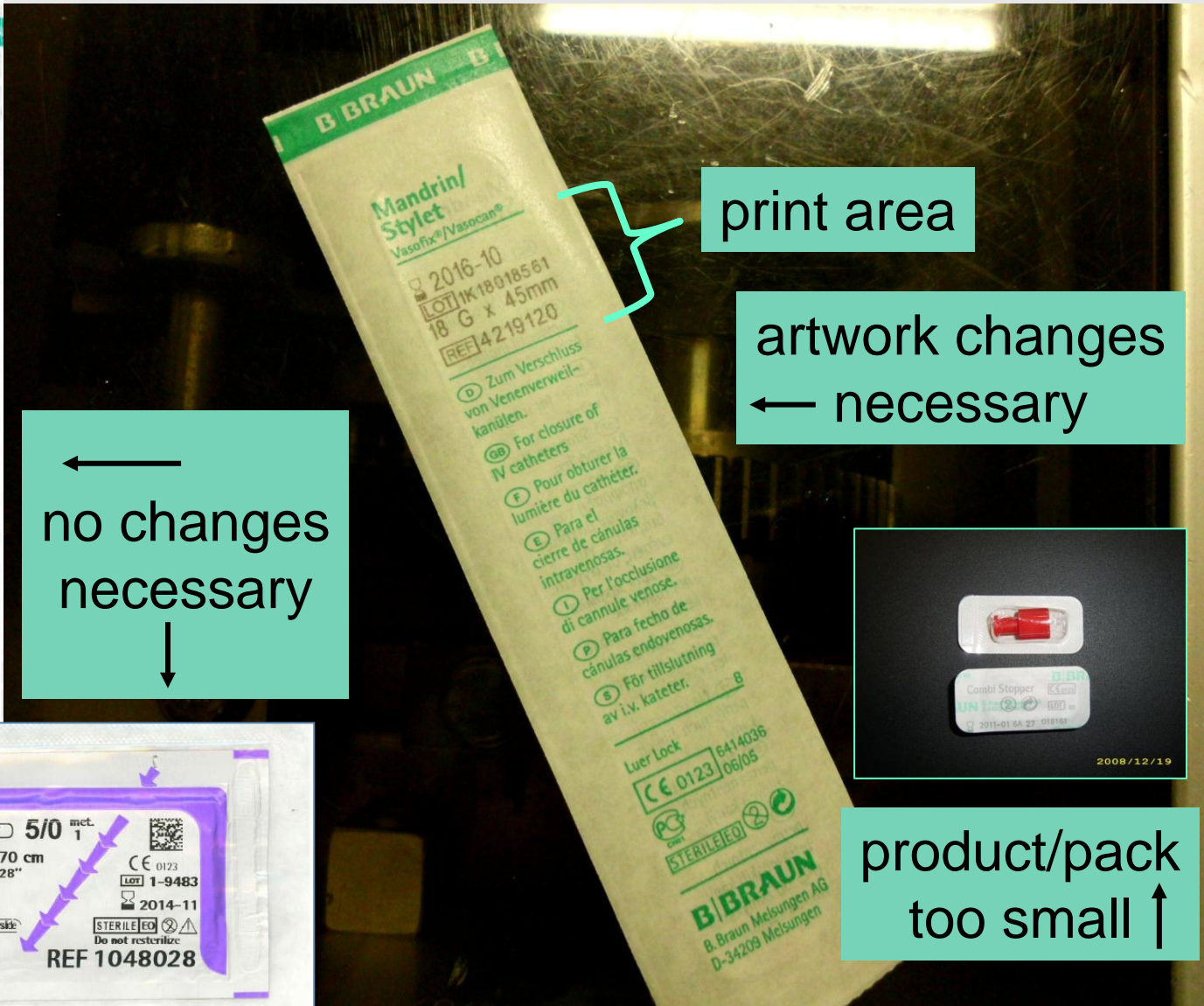
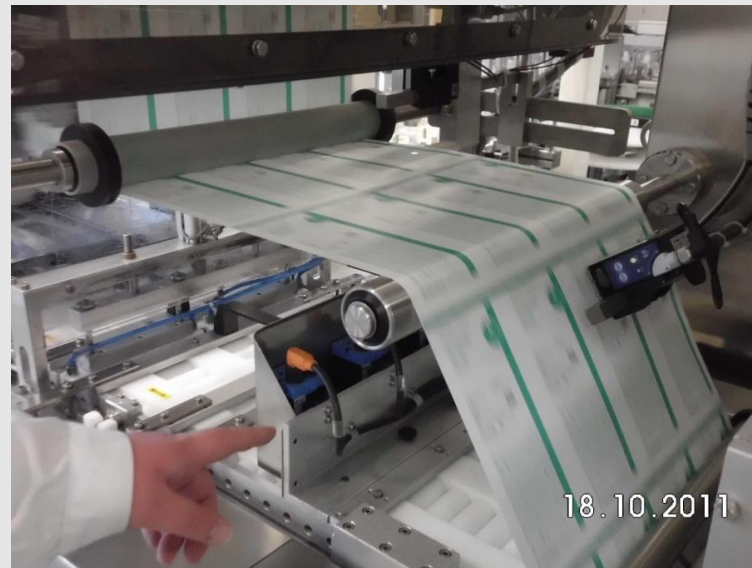print area

artwork changes ← necessary

no changes necessary

product/pack too small ↑

AIDC Production : Technical Preparation

B BRAUN
SHARING EXPERTISE

1	print technology and line speed	suitable for AIDC ?
2	packaging material and ink suitable for AIDC	translucent, absorptive, validated ink, …
3	how to check AIDC quality and how to handle any discrepancies	full autom. lines, bypass conveyors ?
4	data transmission to printer systems	autom. ERP interface, manual data entry ?
5	feasibility studies per print technology and AIDC carrier	to check all aspects, particularly quality
6	replacement of print technology !	will probably be the normal case for primary pack
7	change process (qualification, validation, documentation)	
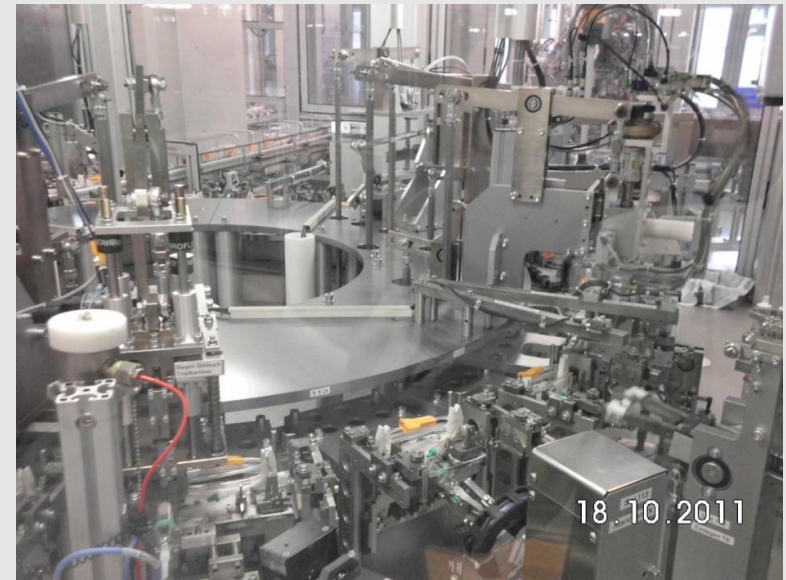
highly automated
production proc.

highly controlled
chance proc.

movable print head
(inkjet)
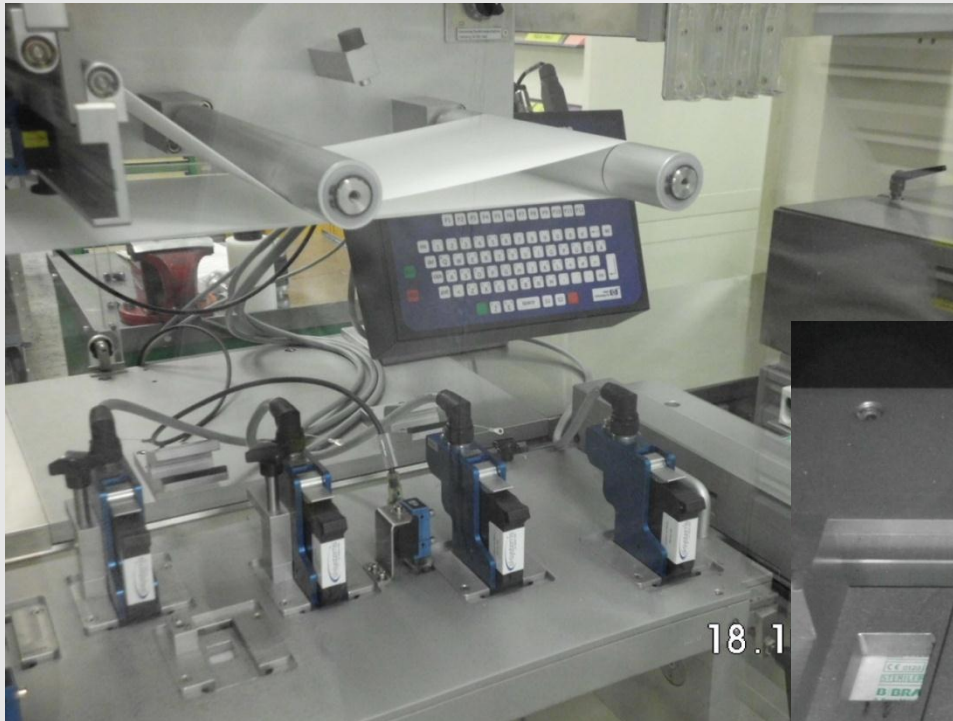
4 fixed print heads in parallel
print area extremely limited

AIDC Production : Standard Process Tech. Changes

B | BRAUN
SHARING EXPERTISE
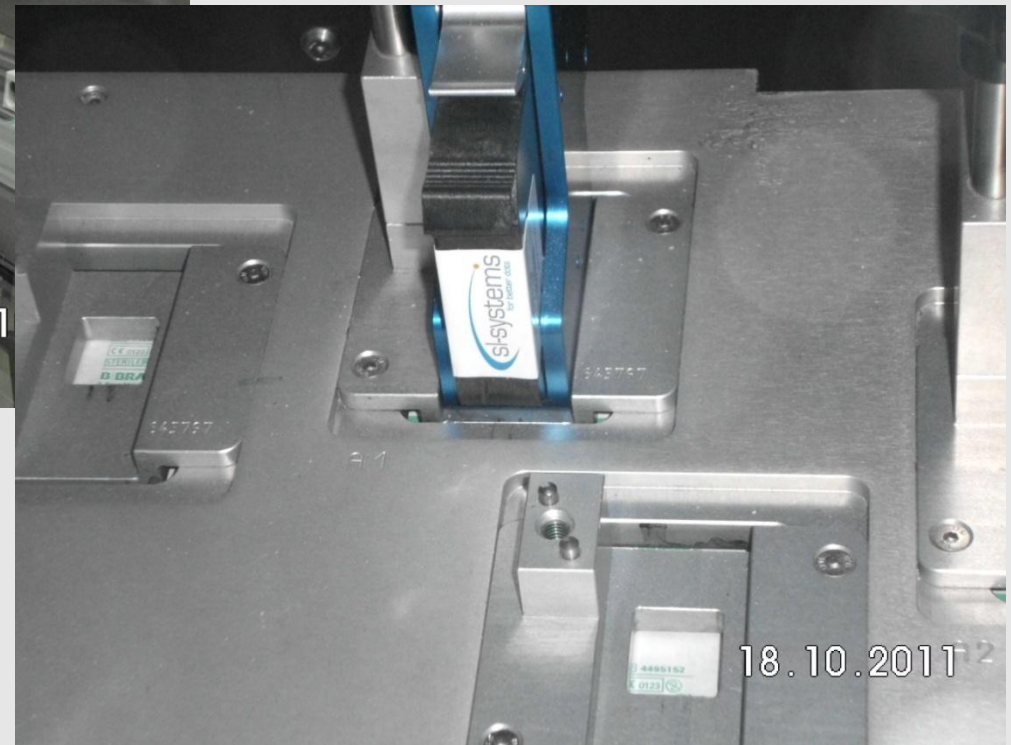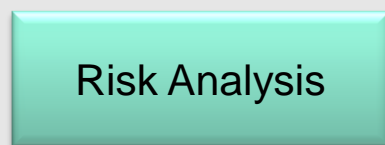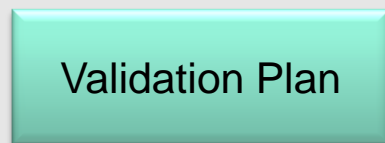
```
┌─────────────────┐
│  Risk Analysis  │        required for every packaging line !
└─────────────────┘
        │
        ▼
┌─────────────────┐
│ Validation Plan │───┬─── • **Design Qualification (DQ)**
└─────────────────┘   ├─── • **Implementation Qualification (IQ)**
        │             ├─── • **Operation Qualification (OQ)**
        │             └─── • **Performance Qualification (PQ)**
        ▼
┌─────────────────┐
│Validation Report│
└─────────────────┘
        │            all documents to be signed by :
        │        project manager, production manager, Site Quality Control Manager,
        ▼        Validation Representative, Quality Planning, Machine Fitter, Quality
┌─────────────────┐        Control Inspector, etc.
│    Release      │
└─────────────────┘
```

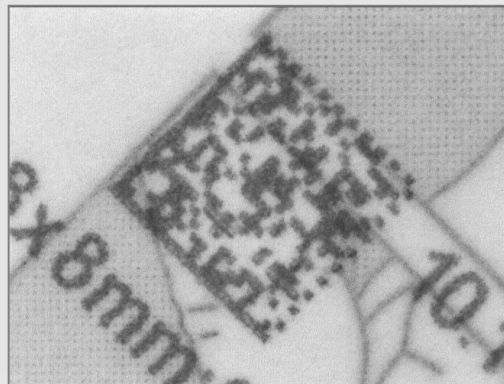**variable data within the AIDC carrier = in-line printing !**

technical framework

- limited space means → small carriers + high data density
  - e.g. DM size : 6x6 - 10x10 mm

- production/packaging line speed
- packaging material
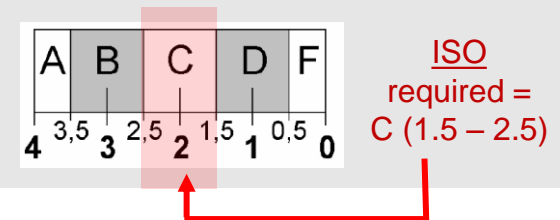- printing technology
- ink

DM through the camera of the verifier

quality issues

- quality verification (ISO)
- translucent paper
- impact on contrast
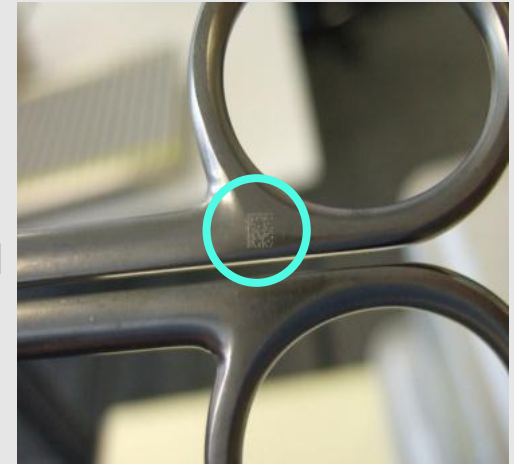

ISO required = C (1.5 – 2.5)

AIDC Production : DPM Specialties
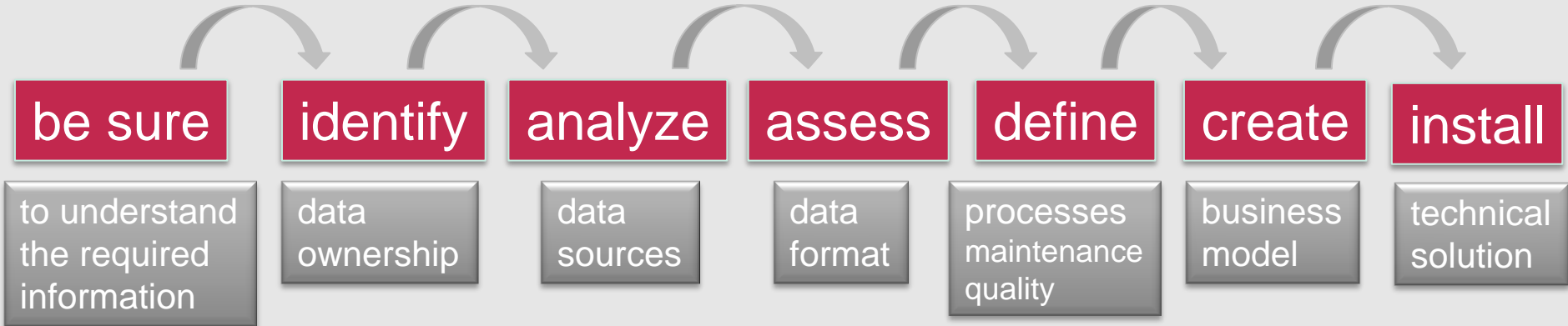
DPM = Direct Part Marking

- only 2D DataMatrix possible (RFID future option)
    - for a safe reading a min. plane surface of 3x3mm needed

- size at surgical instruments extremely limited
    - not all SI's can be encoded (size, material, etc.)

- implants !?!?
    - size
    - corrosion
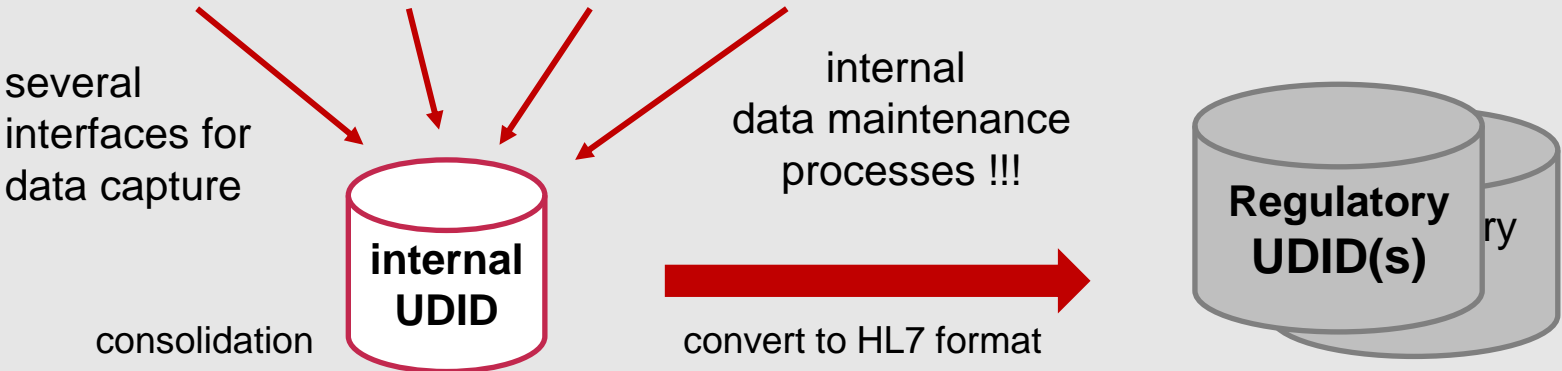   - biocompatibility
    - warranty issues
    - etc.

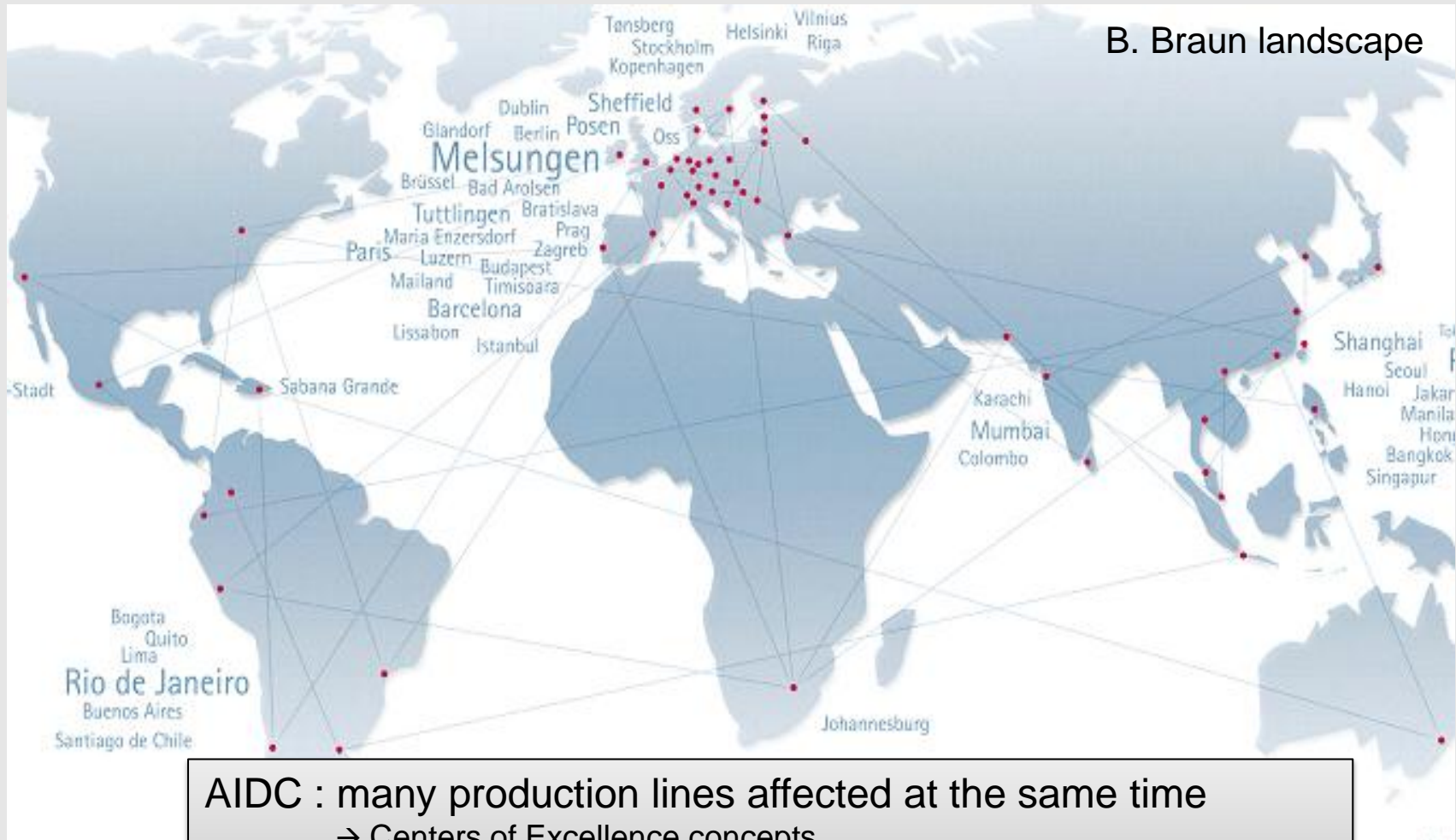- high-quality DPM technology required (laser, dot peen, etc.)

906R STAINLESS

Providing Information to a UDID

B | BRAUN
SHARING EXPERTISE

be sure → to understand the required information

identify → data ownership

analyze → data sources

assess → data format

define → processes maintenance quality

create → business model

install → technical solution

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

several interfaces for data capture

internal data maintenance processes !!!

internal UDID

Regulatory UDID(s)

consolidation

convert to HL7 format

data sources/format/quality/ownership + IT systems

Fact : UDI Implementation will be complex

B. Braun landscape

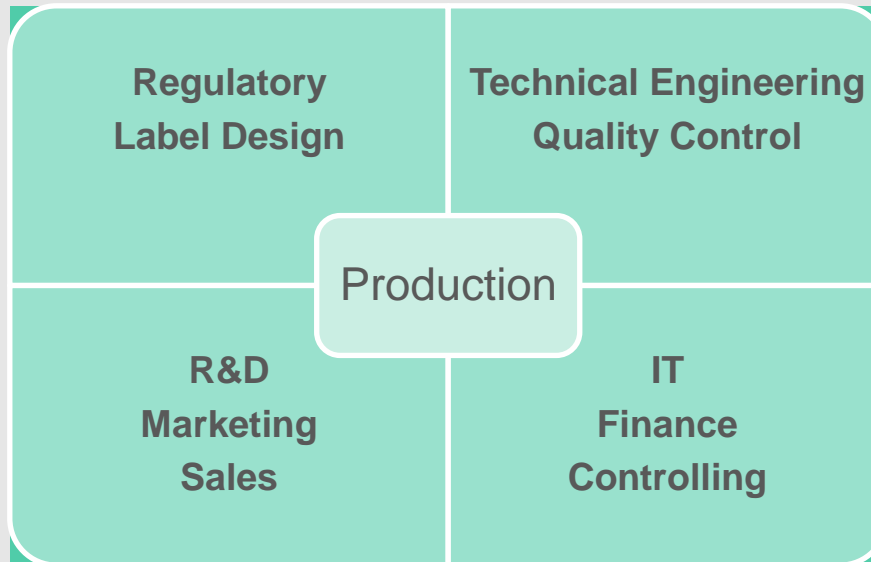AIDC : many production lines affected at the same time
  → Centers of Excellence concepts
UDID : processes for data collection, up-to-dateness + upload
  → many people need to be sensitized !

Fact : UDI Implementation will be complex

- guidance globally / implementation locally
- cross-functional project teams
- strong project organization
- TOP management support essential !

Regulatory Label Design	Technical Engineering Quality Control
Production	
R&D Marketing Sales	IT Finance Controlling

stepwise implementation is a must (starting with highest risk-class first)

Thank you very much for your attention !

Volker Zeinar
B. Braun Melsungen AG (Freelancer)
Germany
volker.zeinar@bbraun.com