



Unique Device Identification

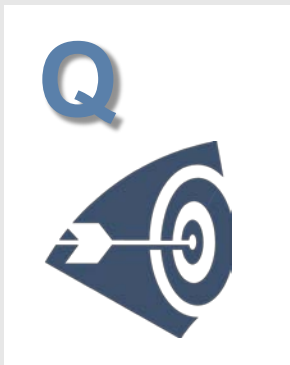
A Manufacturers View

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B | BRAUN
SHARING EXPERTISE

UDI Guidance is an important milestone for a better, unambiguous MedDev identification to improve patient safety !



Quality

- product itself + identification
- impact on syst. outcome



Global business

- cross-border trade
- multilingual labeling



Country-specific deviations

- counterproductive
- supply chain efficiency?



Costs issue

- implementation efforts
- secure investments

Only a globally accepted UDI Guidance will have positive impact !

Importance of the Implementation Sequence

UDI becomes law

Both in parallel : AIDC + UDID entries

+ 1 year

Step 1

- **Highest** Risk Class
- review results 1
- system adjustments (?)

+ 3 years

Step 2

- **Medium** Risk Class(es)
- review results 2
- system adjustments (?)

+ 5 years

Step 3

- **Lowest** Risk Class
- review results 3
- system adjustments (?)

REVIEW !

achieved results (experiences) need to be analyzed before the next step starts

complexity will increase step-by-step

- diversity of MD product portfolio, no. of products, UDID entries, etc. -

Why do we need ,*so much*' time ?

**UDI regulations will mainly focus on
AIDC marking of the consumption unit level !
(primary pack or product itself)**

Key Challenge : Primary Pack

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
 - speed reduction by an additional print not acceptable
- packaging material (Tyvek, coated/uncoated paper, label, ...)
- printing technology (inkjet, thermo transfer, etc.)
 - often replacements necessary !



quality issues

- DM quality verification : ISO/IEC 15415 (final grade 1,5)
- absorptive / translucent paper in use
- only validated ink permitted
 - impact on contrast between ink and paper ?



DM through the camera of the verifier

our experience :
verifier fails / low-cost image scanner reads

Key Challenge : Multilingual labeling

sample ,secondary pack‘



16

languages

26



One product presentation for many markets (supply chain efficiency)

sample ,primary pack‘



UDI is an **additional** labeling requirement !

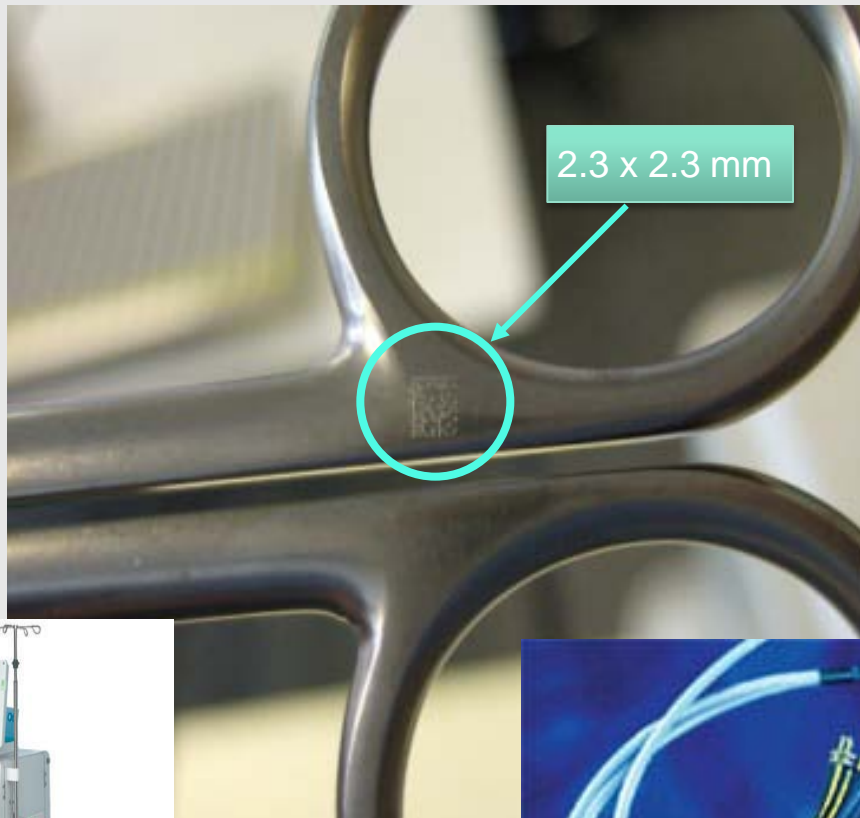
AIDC Carrier

- globally harmonized data content
- technology neutral

Key Challenge : Direct Part Marking

no problem at bigger devices / machines

- metal plates
- labels / stickers
- tags
- ...



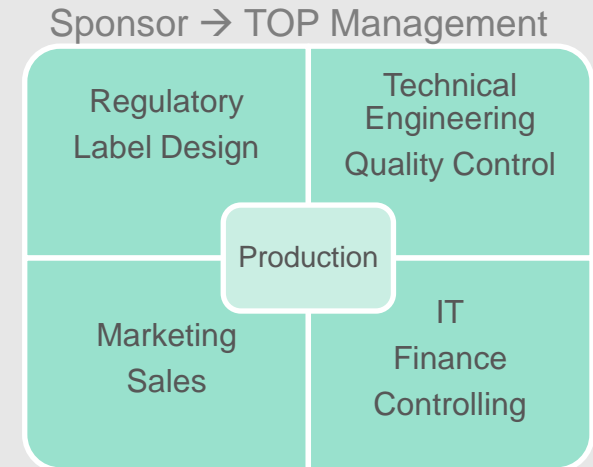
but significant technical efforts at many other reusable products

- product characteristics
- carrier size
- DPM technology
- durability
- ...



Fact : AIDC implementation is time consuming

- technical feasibility studies
 - pack. material, print technology, ink, impact on production speed, ...
- investment planning + release
- new hardware / software (for in-line printing)
- label artwork / packaging paper
 - redesign to have space for AIDC carriers
- technical engineering efforts
 - HW installation, lines 7 days/24h in use, ...
- perform test trials
- measurements to fulfill AIDC carrier quality requirements
 - 100% control by camera systems vs. sample checks
 - e.g. in full-autom. pack. lines, how to handle faults, sort-out/bypass
 - define internal globally harmonized test methods
- process qualification and validation
- documentation
 - drawings, process descriptions, notified bodies, ...
- ...



cross-functional project teams + top-management support

Key Challenge : UDI Database

Set of global core elements :

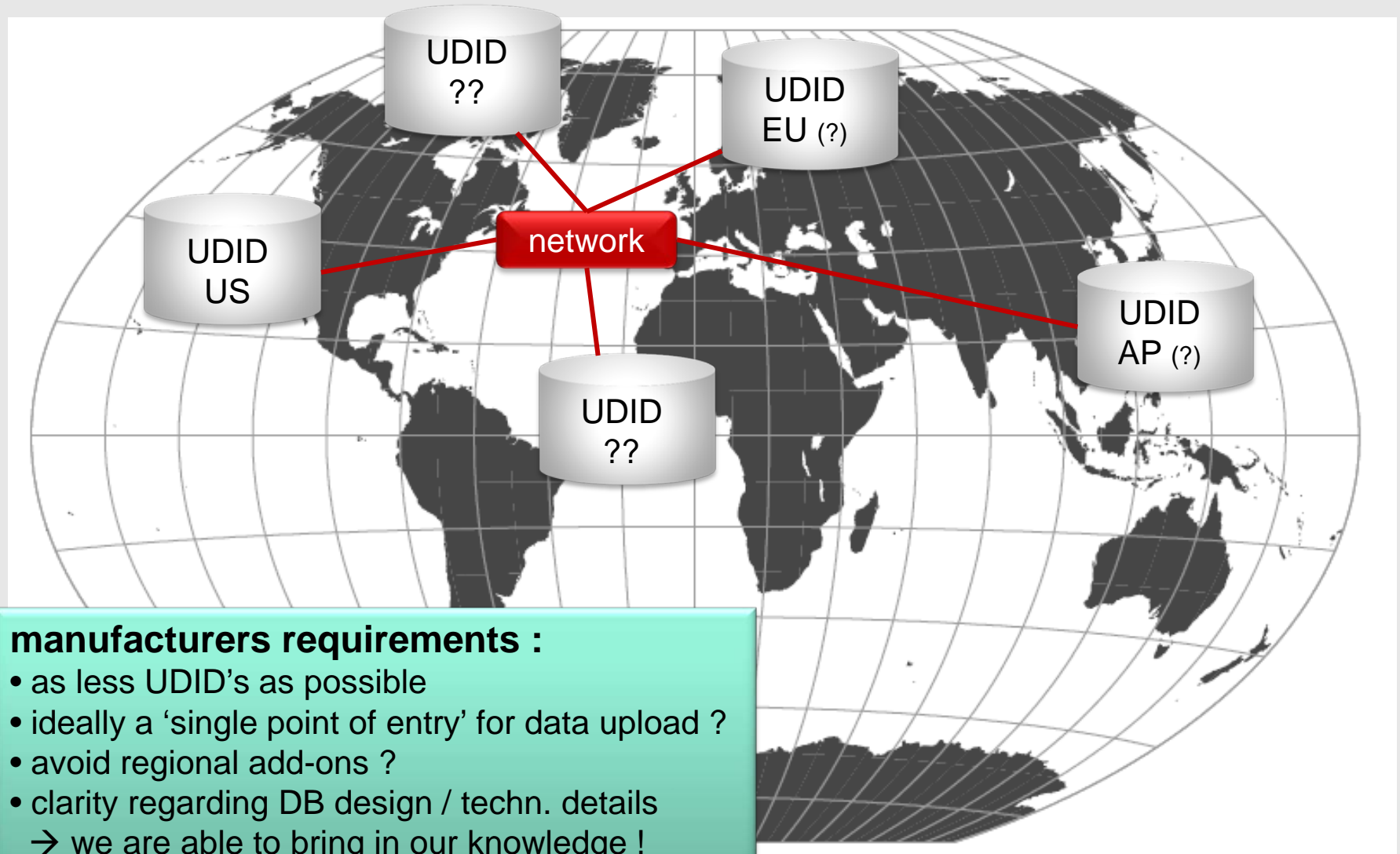
- Packaging Hierarchy (unlimited no.), per pack. level
 - Device Identifier / Unit of Measure / Quantity
- Manufacturer Name
- Manufacturer Contact Information (address, email, phone)
- Nomenclature (e.g. GMDN code)
- Nomenclature Term (e.g. GMDN term)
- Trade Name
- Device Model Number (REF No./catalog no.)
- Controlled by (e.g. expiry date, manif. date, lot no., serial no., ...)
- Size/Volume/Length/Gauge... (clinically relevant characteristics)
- Product Description (additional clinically relevant info.)
- Special Storage/Handling Conditions
- Labeled as 'single use'
- Sterility / Package sterile
- Need to be sterilized before use
- Restricted number of reuses
- Containing Latex
- Authorized Representatives (list of countries and addresses)
- License / marketing Authorization (e.g. registration no.)
- URL for additional information
- Critical warnings or contraindications

manufact. need to ensure

- data availability in e-format
- data quality / accuracy
- up-to-dateness
- proper processes
(data maintenance + upload to 3rd-party)



Key Challenge : UDI Database



manufacturers requirements :

- as less UDID's as possible
- ideally a 'single point of entry' for data upload ?
- avoid regional add-ons ?
- clarity regarding DB design / techn. details
→ we are able to bring in our knowledge !

Fact : UDI Implementation will be complex



AIDC : many production lines affected at the same time

→ Centers of Excellence concepts

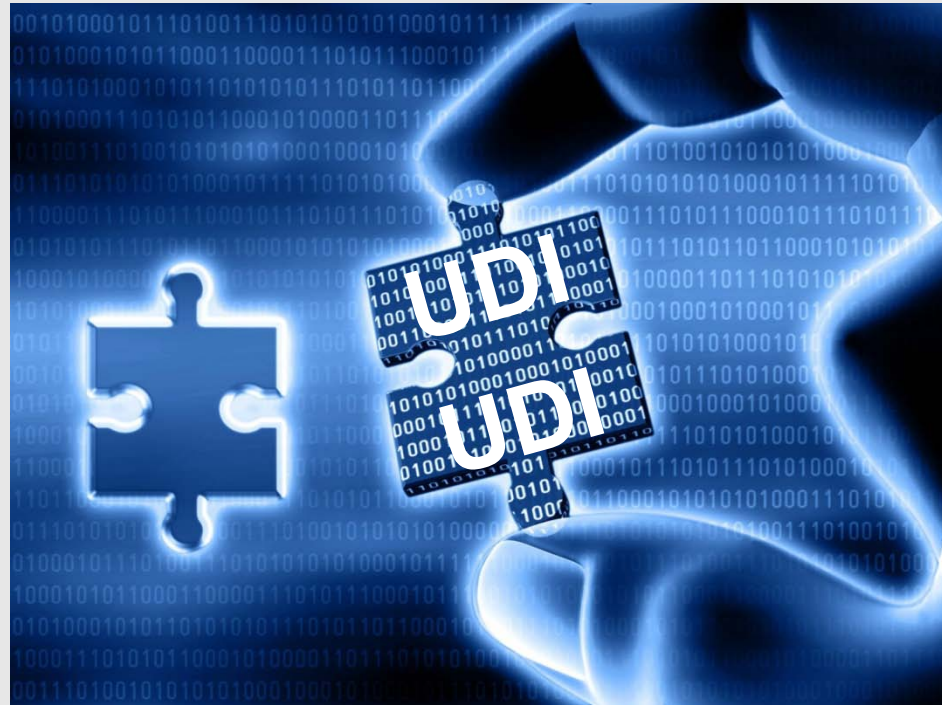
UDID : processes for data collection, up-to-dateness + upload

→ many people need to be sensitized !



UDI is the foundation, leading to improved processes for...

- Reimbursement
- Traceability
- Post Market Surveillance
- Electronic Health Record
- Product Recall
- Cross Border Trading
- Anti-counterfeiting
- Research
- Data Quality
- Authentication



UDI creates transparency, improves processes, increases efficiency and makes isolated systems interoperable

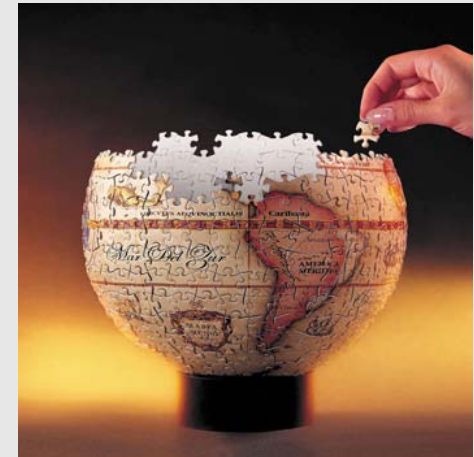
UDI will bring great benefits for:



- ✓ PATIENT SAFETY
- ✓ IMPROVED VIGILANCE & MARKET SURVEILLANCE
- ✓ GLOBAL TRADE

BUT it is essential that

- ✓ A pragmatic (risk-based) approach is adopted
- ✓ Healthcare providers are fully resourced to respond
- ✓ Regional authorities co-operate to ensure a truly **GLOBAL** and **HARMONISED UDI** approach



→ otherwise much time and resources would be wasted !

Thank you very much for your attention !

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