Implementing the UDI system in a SME environment

LINET spol. s r.o.
GS1 registered since 2010
UDI user since 2016

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Hospital equipment
Nursing home equipment
Gynecological practises
Goal

Answer the questions:

- What is expected scope of UDI system implementation?
- What should be considered?
- Who should be involved?
- When to start?

“Too many companies have waited for the last minute to take action toward UDI compliance” Beth Gibson, GS1 US, July 2016
UDI worldwide harmonization
UDI history in Linet

/ 2010
- Special label with GTIN based on customer request only
- Start of cooperation with GS1

/ 2014
- First contact with UDI FDA regulation
- No further action

/ 2015
- Request of public hospital in Sweden: „Unique Device Identifier (UDI) for each medical device“

/ 2016
- UDI required for devices sold in USA (class II)
- Decision to implement UDI for all products as preparation for EU MDR 2017/745
Technical label evolution 06/2015

DI (Device Identifier) / GTIN (Global Trade Item Number)

GTIN

DATE

Serial Number

PI (Production Identifier)

1D bar code
GS1-128

2D bar code
GS1 Datamatrix

03/2019
What is behind? PROJECT!

Goal: Establish ongoing UDI PROCESS in compliance with UDI rules and as part of existing QMS
Why project?

- UDI implementation is very complex task
- More than two departments involved

Based on:
- Regulatory review and understanding of UDI requirements
- Preliminary GAP analysis
- Risk management/SWOT analysis
- Consulations with external party
Strategic decisions

Issuing agency selection – strategic partner

/ GS1, HIBCC, ICCBBA or ???

- Is a agency accredited by national authority/EC?
- Is the agency capable to be strategic partner?
- Do you already use existing codes from one of the existing agencies? If yes, what is your experience with the agency?
- Are your products sold internationally?
- How many DI’s will you need?
- What is an expectation of your customers?
Strategic decisions

Type of implementation
1. Do-it-yourself Implementation
2. Limited Partner Implementation
3. Full-On Outsource Implementation

Do you have sufficient resources?
Strategic decisions

- Types of submission to UDID’s

1. Manually
   - UDID Web interface

2. Automatically
   - Internal Software
   - Hosted Software (Software as a Service)
   - Outsourced Service

/ How many DI’s you have?
/ Are your products sold internationally?
/ How many UDID you have to fill?
UDI process as part of QMS

- UDI process is NOT stand-alone process
- Management commitment
- Risk based approach
- Operating procedure incl. responsibilities and authorities
- Supplier controls – Issuing agency evaluation
- Software/Process validation
- Bar codes acceptance activities
- …
Who should be involved - Project team

- **Regulatory Affairs**
  - Regulatory requirements
  - Data submissions

- **IT**
  - ERP system connection
  - SW validation
  - Printers, scanners

- **RnD**
  - Drawings
  - Labels stability, IFU

- **Production**
  - Equipments, Labels printing,
    Work instructions

- **Quality Assurance**
  - QMS, Process risk evaluation
  - Internal audit, Process change evaluation

- **Purchasing**
  - Suppliers controls, purchase of equipment,
    Contract manufacturers

- **Product Management/Marketing**
  - Label size, UDI label placement on device

- **Quality Control**
  - Production acceptance activities
  - Legibility of the label

- **HR**
  - People, training
  - Responsibility/authority

- **Who should be involved - Project team**
Main tasks

One-time:
- Planning and administration and the costs to integrate the UDI into existing information systems
- Installing, testing, and validate barcode printing software
- Training employees
- Redesigning labels of devices to incorporate the barcode and date format
- Purchasing and installing equipment needed to print and verify the UDI on labels
- Recordkeeping and reporting requirements
- Direct marking of certain devices

Ongoing:
- Labor, operating, and maintenance associated with equipment for printing operations
- Labor related to software maintenance and training needed to maintain the UDI information system
Challenges

Internal
- Data management
- Communication
- Costs

External
- More than one UDI Database (National UDID)
- National deviations – e.g. Basic UDI-DI for EU
Summary

- UDI system is NOT only bar code on the label and data submission – it is ongoing process
- UDI compliance is complex task

- Take the action, do not underestimate UDI implementation
Thank you for your attention

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