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UDI-Implementation

at ulrich medical

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Overview

1. Introduction ulrich medical – Company Profile
2. UDI project at ulrich medical in reversed order
3. Connected via M2m (machine 2 machine)
4. UDI-Project implementation
5. UDI-Challenge
6. The Key Factors

1. Company Profile - *ulrich medical*

Company Name Ulrich Ltd., Ulm

traditional independent family-owned company since 1912

Trademark ulrich medical

Branch Medical technology (development, production & Sales)

Locations Headquarter in Ulm, Germany
Sales Subsidiary in Chesterfield, Missouri, USA

1. Company Profile - *ulrich medical*

Divisions	Spinal systems, Contrast media injectors, Tourniquets/Surgical Instr.
Sales structure via	Direct Sales in Germany and exclusive distribution partners worldwide
Employees	ca. 330 emp.
Trainee %	ca. 7%
Revenue (2016)	76 Mio. Euro

5. UDI- Implementation in reversed order

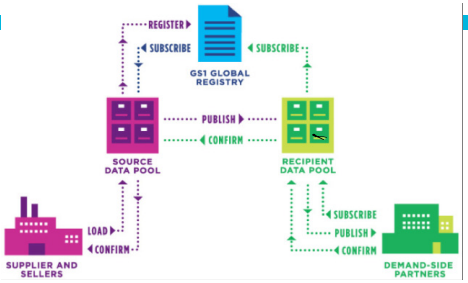
3. Connected via M2M

The less steps your process manually adapt, the more efficiency you may achieve!

Achieve full-automation (efficiency) by using M2M-Solution to submit data to the FDA

- Data-merging
- Submission of amended Master data
- Recognition & submission of new data entries
- automatic data extraction into xml.
- receive and adapt CIN automatically

3. Connected via M2M → GDSN-Pool



- Publish once & send to all (customers & third parties)
- High automation through M2M-Solution
- Future-proof due to its expandability
- Always up-to-date on market reviews

GDSN

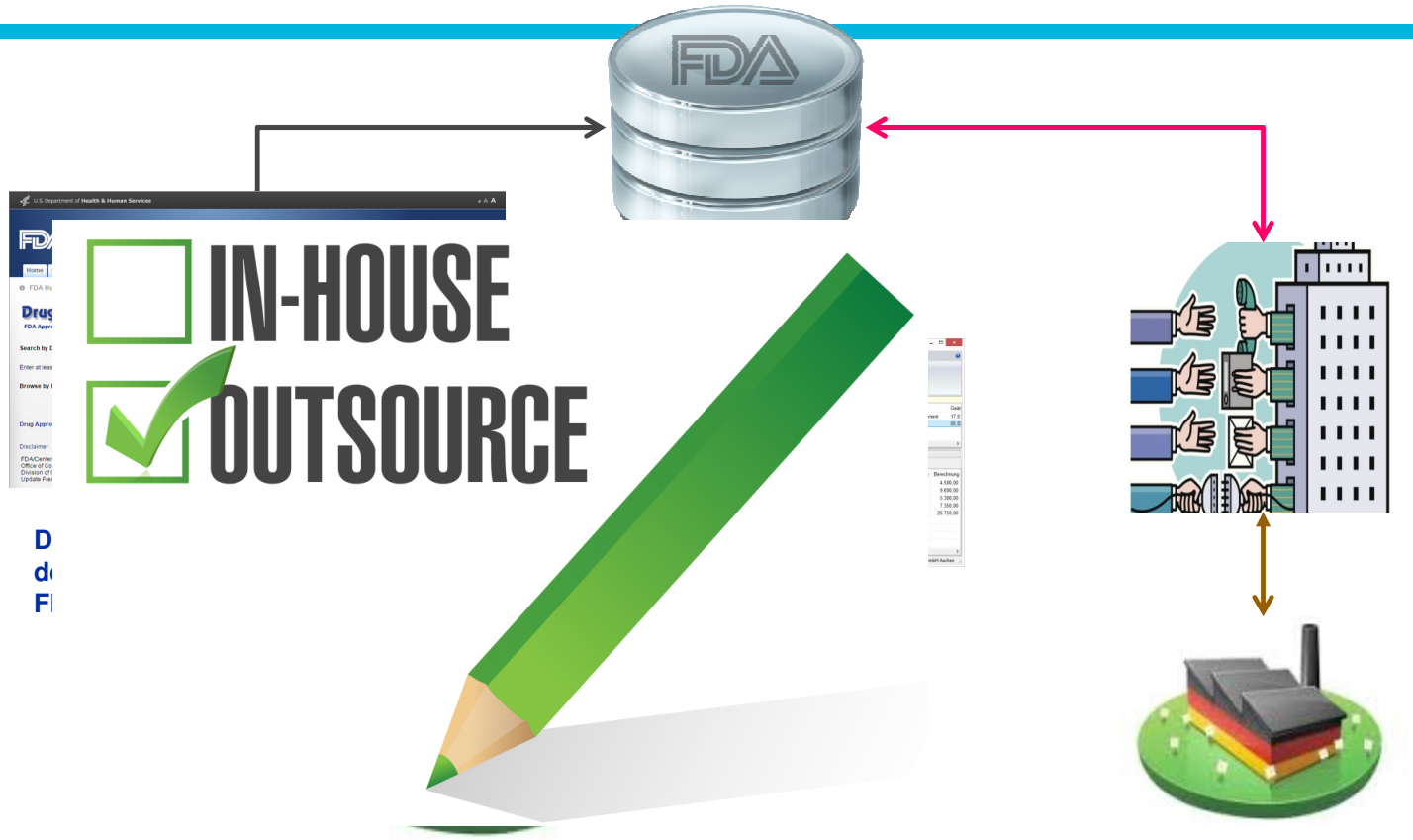
The + + +

WORLD SYNC

d Value

- High GUDID-Competence
- Most flexible supplier (.xls; xml; etc.)
- Suits our limited budget as midsize-company
- Trustworthy process
- as Simple as fast implementation

3. Connected via M2M – Desicion to outsource



4. UDI-Project Implementation

Organizationally

1. Setup internal Project involving add. Dept. (QM, Regulatory, Development)
2. Workshop with 1WS → Identifikation and definition of requirements
3. Request for access to the GUDID testing platform
4. Review of all concerned master data
5. Processing basic Master Data for initial test-submission
8. Request a production GUDID Account

Technically

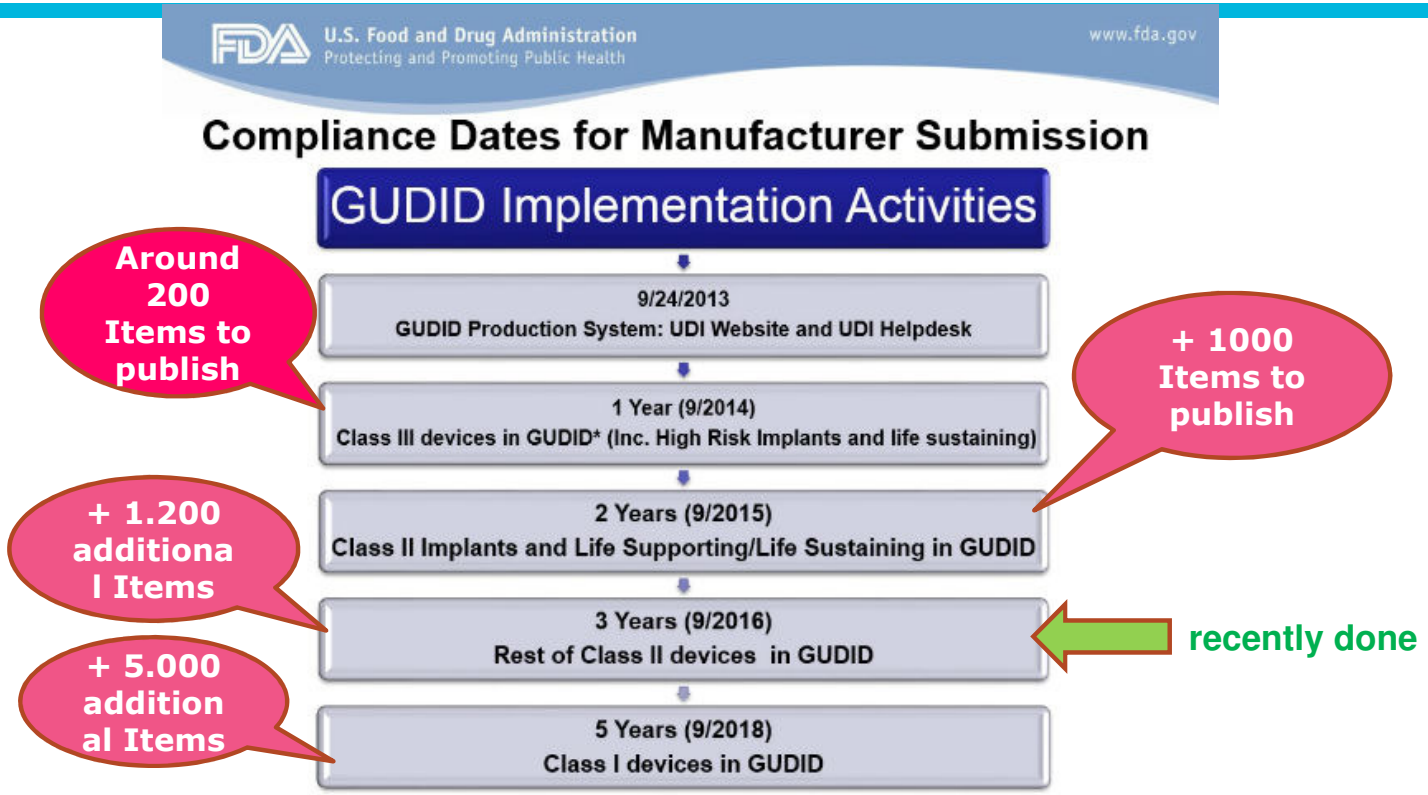
4. Integration of required attributes to our ERP-System
5. Trial Data Export to Excel-Template as a backup and for Testing purposes
6. Attending technical Workshop with 1WS → Requirements M2M-solution
7. Accomplishment of required tests as per FDA-Specification → review by 1WS
8. Coding of M2M-Interface
9. Testing of M2M-Interface
10. Publishing Data to GUDID-Platform

UDI - Start

2007 UDI was signed into law as a part of an FDA amendment act

- The intend was to improve patient care through an unique identifier on medical devices
- challenging rule on FDA act mandates a submission of various information to GUDID
- Submission is phased according to the Device Class and shall be made electronically

2. UDI Challenge



Source: FDA Website

6. The Key Factor - *UDI*

To access GUDID

6. The Key Factors - *UDI*

6. The Key Factor - *UDI*

To access UDI

6. The Key Factor – *GS 1-Code*

THANK YOU
for your
ATTENTION!