UDI Platform by p36 GmbH

How to achieve continuous global UDI Compliance

MARCH 2021
WHAT IS UNIQUE DEVICE IDENTIFICATION (UDI)?

UDI helps identifying products (via Label) and publishing product master-data in public databases.

Worldwide unique identification of Medical Devices

- Improve Patient Safety
- Improve Recall Processes
- Improve Market Surveillance
THE GLOBAL UDI CHALLENGE

- US applicable
- China applicable
- South Korea applicable
- EU applicable soon
UDI PLATFORM SOLUTION APPROACH

1. SAP CLOUD-BASED
   - SAP as trusted and reliable Platform Provider
   - Various integration technologies available
   - Efficient Change Management for externally driven requirements

2. EXPAND TO OTHER COUNTRIES
   - Common Device Data Model & Multi-Agency-capability
   - Extend to other countries
     - Content Packages containing the specific data model & data validation rules
     - Includes Submission Interface

3. CONFIGURE, DON’T CODE
   - Design & configure UDI processes (low code)
   - Flexible workflows and User Interfaces
   - Cross-Market Reporting and Audit Trail

4. MANAGED SERVICE
   - Market Monitoring
   - Change Implementation
   - New requirements
   - GxP Compliance Support
   - Active Customer Support
STAY COMPLIANT WITH OUR UDI PLATFORM

- UDI governance solution based on the SAP Business Technology Platform
- Integrates operational ERP processes into heterogenous IT landscapes (SAP and non-SAP)
- Integrates with regulatory governance & submission processes of Unique Device Identification (UDI) related product data on one platform
ONE CONCEPT, DIFFERENT MARKETS

THE SITUATION
- The UDI system is already applicable in the United States & South Korea, Europe will follow in September 2021
- More countries (e.g., China, Saudi Arabia, Australia) are about to follow

THE CHALLENGE
- Cover changing requirements of different regulatory authorities, timelines of existing and new authorities with their own UDI regulations
- Your single UDI project extends to an ongoing UDI program

THE SOLUTION
- UDI Platform including the Common Device Data Model as a central governance solution for all UDI related master data
UDI PLATFORM - ADAPTABLE TO YOUR NEEDS

YOU ALREADY HAVE MAINTAINED MOST OF YOUR UDI-DATA IN YOUR ERP?
- Validation of your data
- Simplified Release-Workflow
- Submission Management

YOU HAVE YOUR DEVICE DATA READY BUT NO AGENCY SPECIFIC DATA?
- Data enrichment
- Validation of your data
- Customized Release-Workflow
- Submission Management

YOU WANT TO MANAGE MOST OF YOUR UDI-DATA ON THE PLATFORM?
- Create new maintenance flows
- Data enrichment
- Validation of your data
- Customized Release-Workflow
- Submission Management
WHY US FOR YOUR UDI CHALLENGE?

- Native integration into operational processes
- End-2-End UDI data governance & submission solution
- Data reuse concept (Common Device Data Model)
- Global UDI compliance concept
- Managed Service approach
- Validation support for GxP Compliance

**Early adopter:**
- EU | EC (EUDAMED)
- China | NMPA (CGUDID)
- South Korea | MFDS
- Saudi Arabia | SFDA (Saudi-D)
CONTACT US!

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