projektraum36

How to achieve continuous worldwide UDI Compliance

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What is Unique Device Identification (UDI)?

Worldwide Unique Identification of Medical Devices

- Improve Patient Safety
- Improve Recall Processes
- Improve Market Surveillance
The global UDI Challenge
Our UDI Platform mission

„Deliver the best **UDI governance solution** on the market – based on deep UDI expertise, cloud focus and long-term commitment to our customers.“
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 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
   - Continuous Compliance Support
One Platform for worldwide UDI compliance

- Content Packages
  - Separated data models per authority

Common Device Data
- Single Source of truth

*coming soon
UDI Platform governance & submission process

1. Landscape integration
2. Common Device Data governance
3. Regulatory specific data governance & validation
4. Data submission
5. Cross-market Reporting
Let's talk!

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