Achieve UDI Compliance with the UDI Platform

Cloud-based · SAP-integrated · future-proof

Operational and regulatory processes – bridge the gap

Our UDI Platform is an SAP Cloud Platform-based UDI governance solution which integrates operational ERP processes with regulatory governance and submission processes of Unique Device Identification (UDI) related product data on one platform – seamlessly integrated into heterogenous IT landscapes (SAP and non-SAP).

Global UDI challenge

The Unique Device Identification (UDI) system is already applicable in the Unites States as well as in South Korea and will become applicable as part of EU Medical Device Regulation (MDR) in May 2021 as well. Many more countries around the globe (e.g. China, Saudi Arabia, India) are to follow and your UDI-project will extend to an ongoing UDI-program.

In case you're active in more than one market, your UDI setup must be able to cover the requirements of various regulatory authorities in order to submit Product Master Data to UDI databases worldwide – and we provide the strategic answer to your UDI challenge with the UDI Platform.

Handle the complexity of multiple markets with one platform

We build Content Packages for each regulatory authority and provide them as solution extensions on top of the UDI Platform core – fast, flexible and easy to use. Based on our experience with already available Content Packages for FDA and EUDAMED, we are currently developing further Content Packages for various markets*, including China and South Korea.

Content Packages are the centerpiece of the UDI Platform. They enable you as a medical device manufacturer/labeler to meet the requirements of different regulatory authorities, containing the specific data model, data validation rules and the complete handling of exchanging data with the authorities to achieve global UDI compliance.

As it was designed to support various regulatory authorities from scratch, the following basic concepts are implemented in our UDI Platform:

- Common Device Model, allowing to re-use data for various regulatory specific data governance processes
- Standard Services to re-use existing Product Master Data from SAP and non-SAP source systems and returning information to your source systems
- Flexible User Interfaces
- Customizable workflows for distributed data governance

Each Content Package consists of:

- Specific data model with controlled vocabulary
- Specific validation and changeability rules (e.g. Grace Period Handling)
- Data exchange with authorities' databases via the respective submission adapter
- Fulfilment of regulatory requirements (Audit Trail, handling of electronic records, 21 CFR Part 11)
- Advanced reporting on the product and submission lifecycle

*New Content Packages are to follow as soon as other regulatory authorities announce further details about their UDI regulations. They can be added easily to the UDI Platform at any time for worldwide UDI compliance.

We enable you to continuously maintain global compliance

UDI is not a one-time task, it is going to be an ongoing process. More regulatory authorities are to follow, and the existing UDI databases will come up with changes of requirements – therefore, you should benefit from the capabilities a cloud-based Software-as-a-Service solution provides.

We monitor the market requirements and take action if new requirements arise. Specific changes of existing authorities are implemented timely and will be provided into your cloud solution account for continuous compliance.

New Regulatory Authorities and their UDI Databases are covered by new Content Packages delivered on top of the UDI Platform core and can be ordered if you operate in the affected market.

Adaptable to all your needs

Due to its intelligent design, our cloud-based solution fits to every company size and existing process configurations. No matter if you already have most of your device data already on hand or start from the very beginning with your UDI processes – the UDI Platform is configurable to start where you are.

Traditional

Most UDI data already in ERP

Hybrid

Agency-specifics missing

Full cloud

Not much UDI data in ERP yet

Find out more: www.udiplatform.com

Validation

We help our customers with Continuous Compliance support to achieve GxP compliance in the Cloud. Our Professional Services team offers extensive validation support as well as an automated qualification infrastructure. This ensures a smooth validation process and an accelerated time-to-value with our Cloud solutions.

About p36

We deliver highly innovative Software-as-a-Service solutions for the Life Sciences industry by combining outstanding SAP technology know-how with special expertise in regulatory topics in the Life Sciences.

Our SAP Cloud Platform-based SaaS solutions are built on intelligent design to optimize UDI related processes and to ensure GxP compliance in the cloud – implemented with large technological expertise and high quality focus.

Contact us!

Send us a short message to info@p36labs.com to get more information and see a live demo.

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