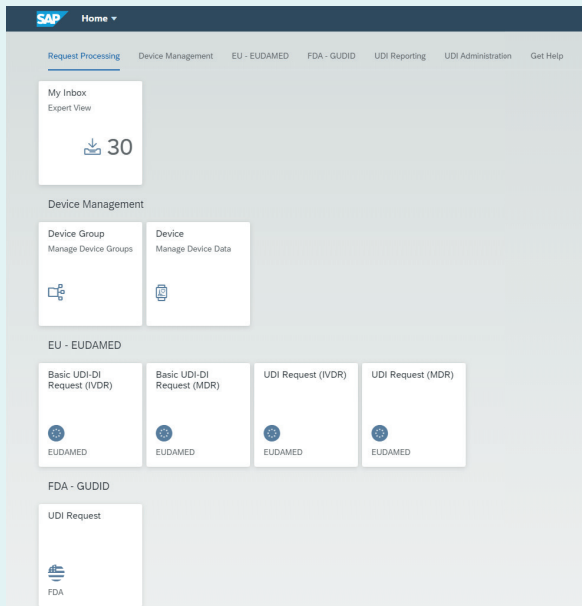


Get a first impression



Find out more: www.udiplatform.com

Validation

Cloud based solutions need an adapted approach for Computer System Validation (CSV).

Our validation partner Chemengineering Business Design provides a CSV approach adapted to the UDI solution and the specific requirements of the medical device industry in order to audit-proof operate the UDI Platform in accordance to the regulatory requirements in Europe and overseas.

chemengineering

About p36

p36 delivers 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 solutions are built on intelligent design, anticipate market trends and are implemented with large technological expertise.

Contact us!

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

CONTACT

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Achieve UDI Compliance with the UDI Platform

Cloud based · SAP-integrated · future-proof



Stay compliant with our UDI Platform – natively SAP integrated.

Our UDI Platform is an SAP Cloud Platform based managed service which integrates operational ERP processes with governance and submission processes of Unique Device Identification (UDI) related product data on one platform – seamlessly integrated into your existing hybrid SAP Landscape.

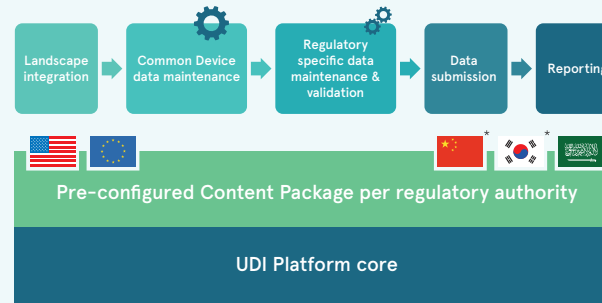
Global UDI challenge

Due to the fact that many countries around the globe will follow the US Food and Drug Administration (FDA) with their own implementation of UDI regulations, manufacturers of medical devices must now take action to continue transmitting their product master data to UDI databases worldwide.

The EU MDR will apply in 2020 and although its database (EUDAMED) launch was postponed to 2022, many other countries (e.g. China, Saudi Arabia and South Korea) will also adopt their own UDI regulations from 2020. Therefore, building a strategic setup for UDI is inevitable.

The strategic solution to UDI

The UDI Platform is the strategic answer to your global UDI Challenge. Its unique Content Package concept allows you as a medical device manufacturer/labeler to meet the requirements of regulatory authorities around the world – fast, flexible and easy to use.



*coming soon

UDI Platform solution at a glance

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

- Re-use existing product master data from SAP and non-SAP source systems
- Flexible user interfaces
- Customizable data governance workflows
- Submission and unified status handling
- Return any information back to your source (SAP-) systems

Available Content Packages

Starting with FDA and EUDAMED, we build Content Packages for each regulatory authority and provide them as solution extensions on top of the UDI Platform core.

Our Content Packages are the answer to the specific requirements of regulatory authorities, containing the specific data model and validation rules as well as the complete handling of exchanging data with the authorities. Content Packages can be added easily to the UDI Platform at any time to achieve worldwide UDI compliance.

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 are at the very beginning with your UDI processes or already have most of your device data on hand – the UDI Platform is configurable to start where you are.

Traditional



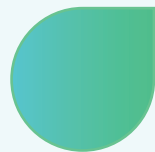
Most UDI data already in ERP

Hybrid



Agency-specifics missing

Full cloud



Not much UDI data in ERP yet

We care – our managed service approach

UDI is not a one-time task, it is going to be an ongoing process in your company.

The existing UDI databases will come up with changing requirements – that is why we take advantage of the capabilities a cloud based software application provides.

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