



SUCCESS STORY

by p36 – driving cloud innovation.

APRIL 2021

The RAUMEDIC Group has been manufacturing customer-specific products from thermoplastic polymers and silicones for more than 70 years.

In doing so, the company is active worldwide with its own research as a development partner and manufacturer for the medical technology and pharmaceutical industries.

RAUMEDIC is currently preparing for the upcoming European Medical Device Regulation (EU MDR).

GETTING READY FOR UDI WITH THE UDI PLATFORM



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THE TARGETS

- ◆ Maintain UDI compliance within the USA and achieve UDI compliance within Europe under the EU MDR
- ◆ Create the basis for follow-up projects aimed at global UDI compliance
- ◆ Re-use existing SAP master data and create a single source of truth for UDI data

THE CHALLENGE

- ◆ Comply with different UDI requirements of various regulatory authorities and the related timelines
 - ◆ Submit device and device group data to EC EUDAMED
 - ◆ Submit device data to FDA GUDID
- ◆ Cover the upcoming challenges in a strategic and future-proof manner

THE REQUIREMENTS



Master data analysis as a basis to define a future maintenance process of UDI-relevant master data



Integration of the UDI Platform into RAUMEDIC's SAP ERP systems & transfer of product master data



Preparing product data for submission to upcoming authorities

WHY p36?



UDI Platform is the solution for regulatory requirements in SAP's Industry Cloud for Life Sciences



Strong long-term expertise of p36 GmbH in the areas of UDI and SAP Cloud services



Managed service approach to support the customer during the implementation and the complete ongoing UDI lifecycle

THE RESULTS



- ◆ RAUMEDIC is ready for EUDAMED & productive with FDA GUID
- ◆ New business processes and master data management workflows
- ◆ One single source of truth for UDI master data tackling global UDI requirements
- ◆ Ready to expand to future UDI requirements
- ◆ Integration of UDI Platform with SAP ERP for continuous data exchange

BENEFITS



One internal UDI data pool for single source of truth

Saving up to 70% of data maintenance activities based on unique Common Device Data concept



Strategic future-proof planning for upcoming authorities

Agile set up of target process landscape while still respecting the regulatory boundaries





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