OSAPIENS CASE STUDY

Clear Route to Healthy Product Content

Medical technology manufacturer PAJUNK® automates its product information management with BYRD services and solutions.

PAJUNK®

Industry:

Medical Devices

Number of employees: 650

Annual revenue: 115 Mio. Euro

Products:

osapiens HUB for Medical Devices (BYRD Health)

Highlight Results:

Timely publication with FDA /GUDID

Implementing data governance improvements

Pajunk Group is among the world's leading international medical technology manufacturers for regional anaesthesia, neurology, pain therapy, minimally invasive surgery and biopsy. The owner-managed company has its headquarters in Geisingen, Germany, and sales offices in Geisingen, Atlanta (USA) and Newcastle (UK).

In regional anaesthesia, pain management and neurology, Pajunk is the market-leading full-range supplier for all single stage and continuous procedures with its product systems of cannulas, catheters and nerve stimulators.

Initial situation and challenge

In the past, Pajunk could only transfer and publish its product information to buying groups and governmental regulatory authorities with a high degree of customisation and modification. A mass data upload was not possible.

The aim of the project was to be able to automate the publication of master data as much as possible, in accordance with the quality and validation rules of the various national and international healthcare authorities.

Pajunk chose BAYARD because of their deep industry expertise. BAYARD had recently contributed significantly to establishing a widely respected standard for product master data in the healthcare sector. This is based on HCDP (Healthcare Content Data Portal), a master data procurement portal in the healthcare industry used by leading purchasing groups, and COVIN (Content Validation Network), a regulatory framework that has also been aligned to the GDSN standard of the GS1 community

> "The consultants saved us a lot of time and effort by communicating **professionally and expertly** with officials at the FDA."

CHRISTIAN QUAß
DIRECTOR REGULATORY AFFAIRS | PAJUNK GMBH MEDIZINTECHNOLOGIE

> "Working alongside master data experts, we have partners who **understand our specific requirements in the healthcare sector** very well."

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The project

As a first step, the consultants worked with all departments responsible for product information management at Pajunk to develop a shared understanding of the data governance process within the organisation. Together, a clear vision and strategy for automated master data management was drafted and the necessary processes and a viable IT infrastructure were prepared. This preliminary work was an important prerequisite for a successful project within the agreed timeframe and on budget.

With a clear goal in mind, the two partners entered into the joint project. In order to implement a central solution for master data management, Pajunk introduced the product content eXchange platform BYRD. It bundles product master data from the company's ERP system with marketing and logistics content for each product in a central location. Within the solution, captured product content can be enriched, validated and transferred to various output channels by the project managers according to the quality rules of the healthcare authority. Without the need for manual, error-prone publishing of individual products.

Project Challenges

01 **Merge data from different sources** into a 'single source of truth'

02 **Convert ERP attributes into healthcare attributes**, based on country-specific healthcare standards

03 **Implement all regulatory requirements**

04 **Improvements** to the internal data governance process

Automated workflows in BYRD – theplatform use error messages to alert Pajunk staff directly to potential errors in the data set or missing attributes for a specific output channel. Those in charge can then correct data before it is transferred and published to the healthcare authorities.

Connection to the HCDP and the US FDA is in place

With BYRD and GS1 GDSN data pool b-synced Pajunk now also publishes automatically to the Healthcare Content Data Portal (HCDP) of the hospitals' purchasing group. HCDP is important to the German market and already has market coverage of around 75 percent.

Thanks to the expertise in the healthcare sector, the connection to the Global Unique Device Identification Database (GUDID) of the US Food and Drug Administration (FDA) was also successfully changed within a tight schedule from a manual individual HL7 data upload to a mass upload via an individual connector. "The consultants saved us a lot of time and effort by communicating professionally and expertly with officials at the FDA," Christian Quaß, Director Regulatory Affairs at Pajunk, is pleased to say.

UDI Connector up and running

An important prerequisite for placing medical devices on the market, not only in the European and US markets but also in many other countries such as China, Saudi Arabia and South Korea, is the uniform labelling of all products with a Unique Device Identification (UDI). The UDI is a legal requirement for the globally unique and machine-readable labelling of medical devices.

During the implementation of a UDI connector at the Pajunk Group, error feedback from the various health authorities was handled within the workflow and analysed and corrected by the Pajunk users.

"With **the BYRD solution** on board, **things are running smoothly.**"

CHRISTIAN QUAß
DIRECTOR REGULATORY AFFAIRS | PAJUNK GMBH MEDIZINTECHNOLOGIE

Milestones of project implementation

01 **Agile implementation** of the product content eXchange platform BYRD

02 **Compliance with GS1** Healthcare standards

03 **Development of a UDI connector** to support the seamless submission of data to the FDA

04 **Establishment of a workflow** for the creation, validation, transformation and publication of product information – prior to sharing with healthcare authorities

Results

Now, Pajunk employees responsible for product information management maintain their own product data centrally in BYRD and only share fully validated data with recipients such as the US GUDID and the German HCDP. GS1 organisations' Global Data Synchronisation Network (GDSN) forms the transport path for this.

A clear workflow regulates the creation, validation, transformation and publication of items at Pajunk before they are shared with the connected healthcare authorities. As a result, Pajunk can quickly be up and running with its customers using quality-checked product information according to UDI standards.

BYRD – theplatform exceptionally user-friendly

"The BYRD user interface is clearly structured and particularly easy to navigate," explains a delighted Alen-Kaan Şen, Regulatory Affairs, Pajunk GmbH Medizintechnologie.

In addition, a powerful data quality dashboard makes the status of data quality across all items in BYRD visible at all times.

> "Before publishing we can check separately for each healthcare authority **whether the data meet the quality and validation rules of the respective recipient.**"

Project outcome and experience

01 **Timely publication to FDA/GUDID**, taking into account validation and business rules of each authority

02 **Implementation of data governance** improvements reflected in BYRD

03 **Responsive team with PIM expertise** and know-how of Pajunk's global business

Outlook

The Pajunk Group now plans to deploy BYRD to standardise master data management for its three independently operating international sales subsidiaries. In the process, further complex regulatory requirements will have to be implemented in the various target markets. With the help of the specialists, further technical solutions will be provided, tested and launched.

Pajunk also wants to optimally prepare for the implementation of the EUDAMED database through the necessary organisational structure, processes and interfaces.

The Medical Device Regulation MDR requires manufacturers of medical devices to store product data related to their products for European use in EUDAMED. Medical devices offered in the USA must first be registered electronically in the FDA's GUDID product database. In the future, high quality, up-to-date product information from Pajunk Group should be able to be registered electronically in the EUDAMED database.

From January 2022, the Pajunk Group would also like to deliver its product content in quality-assured electronic form via the GDSN to the British NHS and, as soon as Machine-2-Machine is available, to the MHRA / DORS database. The BYRD Solution will also provide technical support to this project phase and implement the validation rules and all regulatory requirements into Pajunk Group's existing IT infrastructure and workflows.

Based on the positive experience and close cooperation, Pajunk Group plans to continue to rely on the expertise of the master data experts for the healthcare sector and to take all necessary steps for the digitalisation of master data management together.

You have questions?

Feel free to contact us
for more information.

Find out more

osapiens®

osapiens supports global companies from various industries in establishing sustainability within their organizations and positioning themselves for the future. To achieve this, osapiens develops holistic software-as-a-service solutions that create transparency and sustainable growth along the entire value chain, fulfill legal ESG requirements, and automate manual processes. osapiens aims to not only strengthen companies economically but also promote human rights and ecologically sustainable and responsible corporate governance as the global standard.

The company utilises its cloud-based technology platform, the 'osapiens HUB', and innovative technologies such as artificial intelligence to support companies in seamlessly implementing and automating compliance with international and national ESG laws and guidelines, including CSRD, EUDR, and CSDDD. The osapiens HUB facilitates responsible sustainability reporting. It is constantly evolving and expanding to incorporate new solutions for changing ESG regulations, as well as solutions for improved transparency and efficiency.

osapiens was founded in Germany in 2018 and currently serves over 1,700 customers worldwide. The company is headquartered in Mannheim and has offices in Berlin, Cologne, Munich, Madrid, Paris, Amsterdam, London, and Maine (USA). osapiens employs over 450 people from 60 countries. In 2022, osapiens was honoured with the German Founder Award in the 'Rising Star' category.

the ESG platform
to **make an impact**

1700 + **Customers**
60 + **Countries**
450 + **Employees**
60 + **Nationalities**

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