CASE STUDY

Arthrex: A Global Strategy for Product Data Syndication with Innovit & 1WorldSync™

Medical device manufacturer Arthrex implements Innovit PIM and 1WorldSync Data Pool to submit product data to FDA GUDID and other global recipients.

Arthrex is a global medical device manufacturer that specializes in orthopedic products. Like many healthcare suppliers, Arthrex faces the challenge of needing to provide updated and accurate product data to many different global recipients such as hospitals, GPOs, GUDID, NHS, RESAH, EUDAMED and others. This case study shares the Innovit and 1WorldSync experience in providing the solution that Arthrex implemented to help achieve a "global strategy for product data syndication" - starting with submitting data to the FDA's GUDID.

GUDID: Unique Device Identification (UDI) is born

In 2013, the United States Food and Drug Administration (FDA) released a final rule establishing a unique device identification system designed to adequately identify devices through distribution and use. The final rule required medical device labelers to include a unique device identifier (UDI) on device labels and packages, and directly marked on a device that is intended for more than one use.

As part of the regulation, medical device labelers are required to submit information to the FDA-administered Global Unique Device Identification Database (GUDID). The GUDID includes a standard set of product data about each device with a UDI.

The FDA UDI regulation will be implemented over a period of seven years. Compliance dates are based on device classifications - Class III (September 24, 2015), Class II (September 24, 2016) and Class I (September 24, 2020).

Many medical device manufacturers, including Arthrex, have already had to prepare for FDA's UDI and meet compliance dates for Class III and Class II devices. Many more medical device manufacturers are in the midst of preparing for the upcoming Class I compliance date in 2020. These organizations may be asking themselves questions like:

- What is the scope of products impacted (exempt or not)?
- What are my obligations under the FDA UDI regulation?
- How do I transform UDI compliance into a competitive advantage?
- How can I source my data from multiple locations, formats and systems, controlled by different functions?
- How can I ensure the data I provide to the FDA is complete and accurate?

GUDID Regulation: Key Challenges for Arthrex

Arthrex had product data stored in multiple backend systems (SAP and Oracle), with little standardization or business processes around data governance. They needed a way to organize all of their GUDID-related attribute data and send it to the FDA to meet the initial FDA Class III deadline on September 24, 2015. Arthrex's main challenges in meeting this deadline were:

- Understanding the complexities of the FDA legislation as it applied to Arthrex products.
- Trying to locate where existing data was stored.
- Identifying data that was not currently stored and needed to be created.
- Locating the functional department that "owned" each attribute of data.
- Aggregating all the data into a single point of truth for submission to the FDA GUDID.
- Implementing data governance processes to ensure the data was accurate and remains updated.

GUDID Compliance: Arthrex Launches "Make The Date" Project

Arthrex was in a similar position to many healthcare suppliers. It needed to learn about the FDA's UDI regulations and create a strategy to meet the initial Class III on September 24, 2015 deadline. With limited resources to apply to the new UDI regulation, the work effort required seemed like a daunting task.

The first task was to understand what data already existed and where it was stored. During this process, the Arthrex team quickly realized that their data was scattered in many different systems and places – some of the attribute data only existed on the physical product labels themselves. Submitting data to the GUDID from these disparate locations would have been extremely inefficient. Consequently, this became an important business driver to create a single "source of truth" to store all their product data in a centralized location - in order to submit high quality data efficiently to GUDID.

To realize the goal of having a "source of truth" for product data, Arthrex launched an internal project called "Make The Date". The scope of this project included:

- Implementing a Product Information Management (PIM) solution.
- Implementing GS1 standards (including barcodes).
- Implementing a GDSN data pool.

> "We are very pleased and excited about our relationship with Innovit and 1WorldSync. The integrated solution we deployed thru them has allowed Arthrex to organize our product data to meet the critical GUDID deadline, but even more importantly, we are now positioned strategically for long-term success to provide product data to our other recipients worldwide."
>
> Wes Bloemker, Manager, GIS Compliance at Arthrex

The Solution: A Single "Source Of Truth" For Arthrex

Arthrex selected Innovit's PIM solution (iICE MDM) to be its new "source of truth" for product data. And 1WorldSync Item Manager to be its GDSN data pool. The implementation for the project was led by 1WorldSync's professional services team in partnership with Innovit.

As part of the implementation, data was sourced from a variety of Arthrex's backend systems including SAP, Oracle, and Excel documents. This data was aggregated and imported into the Innovit PIM solution to create a centralized "source of truth" for the product data. This allowed Arthrex to maintain its data in a single location, and use the Innovit PIM's preconfigured validation rules to proactively identify missing or incorrect data that needed to be corrected, before submitting the data to GUDID. This approach ensured that the data Arthrex ultimately submitted was high-quality and error-free. Finalized product data is published from the Innovit PIM to Arthrex's GS1 data pool, 1WorldSync Item Manager, for submission to GUDID.

Arthrex also used the workflow functionality in the Innovit PIM to establish data governance processes. This included "New Item" and "Item Update" workflows to ensure data was property maintained and updated by the appropriate data owners. Other internal change control procedures and quality control systems were also implemented to ensure the highest accuracy of the data. Arthrex even formed a UDI Master Data Committee to regulate these workflow processes. The committee aimed to train and familiarize the data owners with their responsibilities in maintaining their data. Ultimately, these data governance initiatives helped to harmonize the various Arthrex functional groups (i.e. design engineering, sterilization, regulatory affairs, finance, packaging, engineering, product management, marketing) that participated in the creation and maintenance of Arthrex product data.

Utilizing the solution from Innovit and 1WorldSync, Arthrex was able to efficiently aggregate, store, maintain, and validate its product data in a single "source of truth". This made it extremely simple to seamlessly syndicate product data that was high-quality to GUDID by the Class III deadline on September 24, 2015.

The "Make The Date" project was a tremendous accomplishment for Arthrex – ultimately it allowed them to be compliant with the FDA regulations - which meant they could continue to sell their products within the United States and continue achieving their mission statement of "helping surgeons treat their patients better".

Beyond GUDID: A Global Strategy for Product Data Syndication

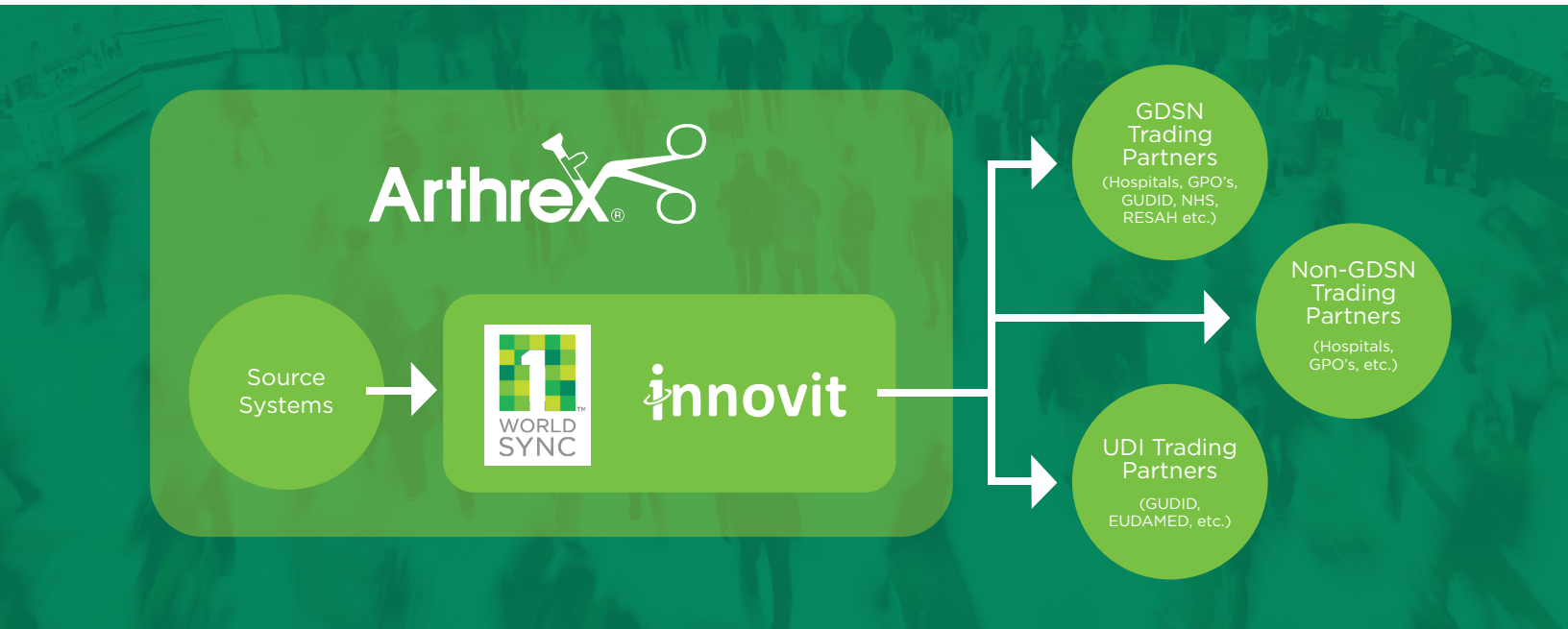
Meeting the GUDID Class III compliance deadline was an important short-term milestone for Arthrex, but right away the company understood that GUDID was merely one of many recipients that required product data. Therefore, a critical long-term goal of Arthrex was to have a global strategy for product data syndication.

The Innovit PIM and 1WorldSync Item Manager solution allowed them to do this. As described, Arthrex imported source data from multiple systems (SAP, Oracle, and Excel documents) into the Innovit PIM. Data is maintained one-time, and then automatically associated to various recipient "views" using preconfigured recipient-specific attributes, code value lists and validation rules.

Once all the data has been validated within the Innovit PIM, Innovit's "one-to-many" GDSN and UDI multi-connectors simultaneously syndicate the data to multiple GDSN recipients such as hospitals, GPOs, NHS (UK), RESAH (France), etc. and directly to UDI (HL7) recipients such as GUDID and EUDAMED. The UDI multi-connector is also 21 CFR Part 11 compliant and GAMP validated.

Finally, Arthrex also has the capability to send "non-GDSN" using the Innovit PIM automated export functionality to syndicate product data to customers (hospitals, GPOs, etc.) not yet using GS1 standards.

Ultimately, by maintaining a broader vision beyond GUDID, Arthrex was able to leverage the end-to-end Innovit and 1WorldSync solution (as depicted in the diagram below) to achieve its goal of having a global strategy for product data syndication.



About Arthrex

Arthrex is a global medical device company and leader in new product development and medical education in orthopedics. With a corporate mission of helping surgeons treat their patients better, Arthrex has pioneered the field of arthroscopy and developed more than 11,000 innovative products and surgical procedures to advance minimally invasive orthopedics worldwide.

Arthrex continues to experience unprecedented growth and demand for its products throughout the world; however, the company remains a privately held company with a family business culture committed to delivering uncompromising quality to the healthcare professionals who use its products, and ultimately, the millions of patients whose lives it impacts. For more information, visit https://www.arthrex.com/.

About 1WorldSync

1WorldSync has a long standing partnership with Innovit. 1WorldSync™ is the leading provider of product content solutions, enabling more than 25,000 global companies in over 60 countries to share authentic, trusted content with customers and consumers, empowering intelligent choices for purchases, wellness, and lifestyle decisions. Through its technology platform and expert services, 1WorldSync provides solutions that meet the diverse needs of the industry. 1WorldSync is the only product content network provider and GDSN Data Pool to achieve ISO Certification 27001. For more information, please visit www.1worldsync.com.

About Innovit

Innovit's globally certified PIM solutions manage, optimize and accelerate the syndication of a company's product master data for omni-channel and e-commerce growth. Our user-friendly interface, coupled with 100% configurable data models and workflow capabilities on the cloud, ensure that Master Data and Product Information propel businesses forward cost-effectively, efficiently and easily. Innovit's pre-configured data syndication modules provide out-of-the-box data validation and publication capabilities for GDSN and leading e-commerce portals like Amazon and Alibaba. Operating since 2000, Innovit is based in San Francisco CA with offices in London, Sydney and Melbourne. Innovit supports MDM and PIM implementations worldwide with customers such as Johnson & Johnson, Kellogg's, 3M, Colgate-Palmolive and B. Braun across diverse industries including healthcare, CPG and automotive aftermarket. For more information, please visit www.innovit.com.

Contact Us

Learn how your company can work with Innovit and 1WorldSync for your Product Information Management (PIM) needs.

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