innovit

More than UDI Compliance

Balancing Regulation with Innovation

A leading global medical device provider needed to balance an ever-increasing number of government regulations and compliance requirements with innovative and scalable processes.

ADVANCING SCIENTIFIC DISCOVERY AND IMPROVING PATIENT HEALTHCARE

10,000 products. 150,000 customers. For six decades, the company has provided high-quality products that improve healthcare and advance scientific discovery.

THE UDI CHALLENGE

The global adoption of Unique Device Identification (UDI) policies presents a major challenge for enterprise medical device manufacturers trying to understand and comply with a growing list of regulations. In addition, manufacturers must still submit UDI data to a myriad of country-specific regulatory agencies, each with a variation to this standard.

Trying to build, configure and maintain individual solutions for each country that will support the local attribute definitions, code value lists, and validation rules can be costly and non-scalable.

There are also additional government regulations surrounding product identification, track & trace, pre- market registration, and post-market surveillance. It becomes increasingly difficult to keep up with the skills and knowledge required to comply with each jurisdiction's unique requirements for high quality data throughout a product's lifecycle. Manufacturers are also expected to offer more affordable pricing to healthcare providers, lowering supply chain costs overall. This gives healthcare providers the ability to deliver better patient care and safety.

> *The adoption of UDI policies around the world presents a major challenge for global medical device manufacturers trying to understand and comply with this flurry of country specific regulations."*

THE CHALLENGE

10,000 products can yield high volumes of product information and accompanying data. With 36 offices and over 8,000 employees across several continents, the initial challenge was clear - what data exists and where is it stored? The company discovered that data was scattered throughout many different systems and manually maintained in a variety of formats. Additionally, no specific data governance process was in place.

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Tel: +1 512 730 3800
Fax: +1 888 478 4438

www.innovit.com
303 Twin Dolphin Drive
6th Floor
Redwood City
San Francisco
CA 94065 USA

INNOVIT PIM SOLUTION

The Company implemented Innovit's PIM solution to address their product master data management challenges and establish best practice processes. The solution ultimately:

- Enabled the aggregation of all data into a single source of truth for publication to 1WorldSync and submission to the FDA GUDID
- Ensured syndication of trusted product information on a global scale while supporting patient safety
- Improved resource efficiency to lower healthcare costs
- Improved trading partner collaboration and supply chain efficiency

ABOUT INNOVIT

Operating since 2000, Innovit is an end-to-end Master Data Management (MDM), Product Information Management (PIM), Global Data Synchronization (GDSN) and NPI Workflow solutions provider that is based in San Francisco CA with offices in London, Sydney and Melbourne. Innovit helps customers enhance revenue streams, reduce supply chain costs, improve online product marketing effectiveness, and ensure regulatory compliance.

CONTACT US

Find out how Innovit can assist with Bringing Quality To Master Data!
Contact us

1 512 730 3800 sales@innovit.com

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