Innovit UDI Multi-Connector

ACHIEVING TIMELY REGULATORY COMPLIANCE GLOBALLY

Unique Device Identification (UDI) is a system first instituted by the FDA to mark and identify medical devices within the healthcare supply chain. It was implemented to help improve patient safety by solving traceability challenges such as product recalls and counterfeit devices. This regulation grouped devices into three risk classifications (Class III, Class II, Class I) and required medical device manufacturers to submit UDI information about their products to the GUDID (Global Unique Device Identification Database) – a central repository of device information intended for public access by healthcare providers and clinicians.

Suppliers of Class III and Class II devices in America have already had to meet submission deadlines. Class I manufacturers are now preparing for this requirement as the September 2020 compliance date quickly approaches.

Other countries and regions are now fast-tracking the adoption of UDI regulations in their respective jurisdictions including the European Union with the Medical Device Regulation (MDR). 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 regulations. In addition, manufacturers are presented with the challenge of submitting UDI data to a myriad of country-specific regulatory agencies, each with their variation to this standard.

Innovit's UDI Multi-Connector solves these challenges by allowing device manufacturers to implement a "global system and unified process" that is fully integrated with internal systems to submit product data to multiple UDI regulatory agencies simultaneously.

COMMON CHALLENGES

- Fragmentation of UDI attributes across multiple systems
- Variability of data requirements across different target markets and regulatory agencies
- Inability to keep up with ongoing changes to UDI standards and attributes
- Individual and siloed connectors for different regulatory agency databases
- High cost of validating custom-built systems

INNOVIT UDI MULTI-CONNECTOR

Innovit's UDI Multi-Connector is a GAMP5 validated and 21 CFR Part 11 compliant solution that allows device manufacturers to submit UDI data to different regulatory databases including GUDID and EUDAMED. Suppliers and brand manufacturers automatically get a pre-packaged list of attributes, code lists and validations for submission to the regulatory agencies of their target markets. Innovit's UDI Multi-Connector also automates the submission of UDI data in the specific data format and messaging protocol required by the regulatory agency (e.g. HL7/SPL for the FDA). A complete message exchange history is also stored in Innovit's solution to provide data stewards in Regulatory Affairs departments with full visibility and traceability of their data submission history.

innovit

"Innovit UDI Multi-Connector enables organizations achieve timely compliance with local UDI regulations."

CAPABILITY HIGHLIGHTS

Data Import	Import templates for data consolidation
Data Maintenance	Pre-configured UDI attributes
	Pre-configured UDI attribute code lists
	Pre-configured UDI attribute validation rules
	Global and regulatory agency specific data maintenance
	Risk classification management
Data Governance	UDI attribute validations for each target market
	Workflow processes for data enrichment and approval
	Granular role-based security
	Audit trail for data and message exchange history
	eSignature for full approval traceability
Data Submission	GUDID
	EUDAMED (UDI Module*) * Please review the Innovit MDR Multi-Connector datasheet for submission of all six MDR modules

Tel: +1 512 730 3800

Fax: +1 888 478 4438

www.innovit.com

303 Twin Dolphin Drive

6th Floor, Redwood City

CA 94065, USA

HOSTING

Different hosting options are available through Innovit for PIM customers.

- **Hybrid Cloud:** Shared server but dedicated environment
- **Public Cloud:** Multi-tenanted with shared server and shared environment
- **Private Cloud:** Dedicated server and dedicated environment

BENEFITS

- Achieve compliance with local UDI requirements
- Automate data validation and submission
- Enhance data quality and governance
- Reduce operational and IT cost

ABOUT INNOVIT

Innovit's globally certified product data management solutions protect revenue streams, reduce supply chain costs, improve online product marketing effectiveness and ensure regulatory compliance. Delivering the fastest time to value for a complete end-to-end solution with preconfigured modules that have out of-the-box data validation, the broadest global coverage for data synchronization, and publication capabilities to support maximum syndication advantage for omni-channel ecommerce. Operating since 2000, Innovit is based in San Francisco CA with offices in London, Sydney and Melbourne and customers such as Johnson & Johnson, Kellogg's, 3M, Colgate Palmolive and B. Braun across diverse industries including healthcare, CPG and automotive aftermarket.