

## UDI Cloud for Medical Devices

Regulatory Overview and Best Practices



### The UDI Challenge

In 2007, the Food and Drug Administration Amendments Act (FDAAA) was signed and within it was contained a requirement for FDA to establish a unique device identification provision with the intent to improve patient safety by improving the flow of information on medical devices. On September 24, 2013, the U.S. Food and Drug Administration (FDA) issued the final rule that established the need for the Unique Device Identification (UDI) System. This legislation requires all registered medical devices distributed in the U.S. to carry a globally Unique Device Identifier (UDI), a unique numeric or alphanumeric code with an identifier specific to each device or model as well as an identifier with current production information.

The impetus of the FDA UDI mandate is to address a data issue in the medical device industry whereby manufacturers, distributors and hospitals and clinics, unlike the pharmaceutical industry, which has had the National Drug Code (NDC) in the US for decades, do not abide by any standard device identification methodology and each generally applies their own product identifier (item ID, SKU) to the same device. This has resulted in a multitude of codes that are currently used across the supply chain complicating transactions, quality management, tracking of adverse events, recall, maintenance, and extracting data about a device from manufacturing, distribution and health records.

To address these concerns, an inclusion in the FDA Amendments Act called for establishment of a UDI system for medical devices. The key requirement being for manufacturers and brand owners to establish globally unique device identifiers for all finished medical devices distributed in the United States.



*Current and Future State of Medical Device Identification*

The objective is to develop a system to identify medical devices, which is *Consistent, Unambiguous, Standardized* and *Unique* at all levels of packaging and *Harmonized* internationally.

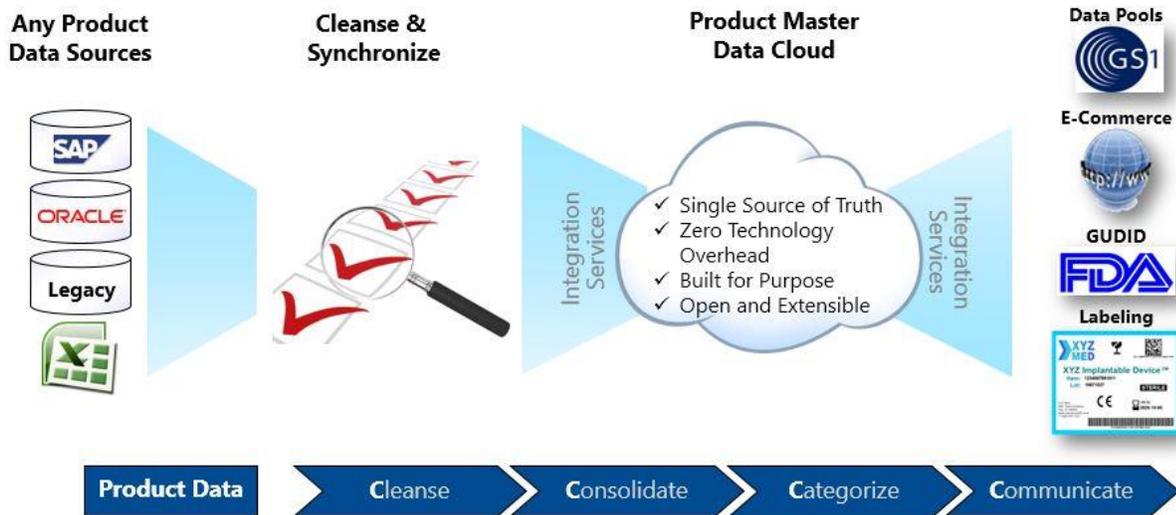
## KPIT's UDI Cloud Solution

We have seen many medical device companies take short-term, tactical approaches to addressing UDI requirements and in doing so, they are accepting that they will be revisiting their solution approach in the future to implement an enterprise-level solution in the future. Some forward-looking companies, however, are viewing the UDI mandate as an opportunity to get their product master data organized and under appropriate system-controlled governance, thereby laying a foundation that will yield business benefits beyond regulatory compliance.

Key capabilities of the solution should include:

- Flexible, fast and powerful enterprise data quality management (EDQM) to cleanse, de-duplicate and standardize product data coming from multiple sources.
- An open architecture that can exchange data and manage cross-platform processes (such as approvals) with various disparate data sources and destinations, including the FDA GUDID.
- Standards and Regulatory Compliance, including 21 CFR Part 11 Compliance, GS1 product identifiers (GTIN), HIBCC (SLS) product identifiers and GS1 product data pools (GDSN).
- Configurable phase-gates for product data approval workflows.
- Extensible data model to capture all DI and PI attributes required today and in the future
- Highly configurable, adaptable and rules based governance processes.

It is with these design tenants that we have developed the KPIT UDI Cloud solution.



*KPIT UDI Cloud: Preconfigured Attribution & Pre-Built Integration to Cleanse, Consolidate, Categorize and Communicate UDI Data*

KPIT has developed a compliant and cost-effective approach for UDI compliance by establishing a product data management foundation for achieving meaningful business benefits, including:

- Improving operational efficiencies with trusted product information
  - Accelerating new product introductions and change requests
  - Sharing accurate product information with the extended value chain
  - Establishing a single source of truth for product label data

For further information, please visit us at <http://www.kpit.com/industries/life-sciences/home>