WEBINAR SUMMARY

November 10, 2022

Medtech Insight

Pharma Intelligence

UDI Requirements: The Fear of the Unknown

Anusha Gangadhara, Business System Analyst, IQVIA
Michael King, Senior Director, Product & Strategy, IQVIA
Jason Berning, Associate Business Development Director, Regulatory Technology Solutions, IQVIA (Moderator)

KEY TAKEAWAYS

- The UDI system aims to prevent issues that may impact patient safety.
- Meeting UDI requirements is an increasingly complex step in product life cycle management.
- The country-specific evolution of UDI requirements calls for a robust regulatory intelligence system.
- IQVIA's single-source-of-truth connected intelligence system optimizes visualization of product performance.

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OVERVIEW

In recent years, global regulatory requirements have evolved in many areas of the MedTech product life cycle management. From a patient safety perspective, a new target of focus is Unique Device Identification (UDI). While at a strategic level, global regulators are aligned in recognizing the importance of enhancing the traceability of medical devices. At an operational level, divergence has emerged across countries.

Specifically, while global regulations often stipulate UDI as a requirement, data submission standards around UDI requirements vary from country to country, which entails differences in data structure definitions. Other political and economic factors create additional commercial considerations that further condition the types of UDI solutions that may be required.

CONTEXT

Anusha Gangadhara and Michael King discussed the complex and often conflicting regulatory environment that MedTech companies face when it comes to designing UDI systems and workflows, and how a comprehensive, single-source-of-truth UDI solution can support them in sorting out country-specific operational challenges.

KEY TAKEAWAYS

The UDI system aims to prevent issues that may impact patient safety.

UDI provides unambiguous identification of a specific medical device on the market. The UDI system was designed with the aim of standardizing and harmonizing regulators' ability to track the provenance and supply of medical devices throughout their life cycle, and to share information about multiple attributes of medical devices whose practical implications may impact patient safety: stitching, internal organization, manufacturing process identification, verification and validation certifications, market approvals, supply chain, distribution, and performance.

Two other objectives of the UDI system are to distinguish between different products with identical item numbers, which is sometimes a byproduct of merger and acquisition activities, and to ease adverse event reporting.

At the provider level, UDI can be incorporated into inventory management systems since it helps answer relevant questions such as:

- Which product is sitting on what hospital shelf?
- What product had safety events reported last week in X country at Y hospital?
- Where did I manufacture this product amongst my manufacturing sites?
- In what markets are the other lots from the same batch currently available across the globe?

> In having this global identifier and in tagging it alongside other things, the data consent we have in medical devices becomes much bigger and much more manageable in terms of being able to do things such as post-market reports and clinical evaluation reports.
>
> *Michael King, IQVIA*

King said that UDI also enables organizations to move data consistently through different electronic systems (e.g., ERP, PLM, and RIM systems) and to map product-specific data to root cause analyses tied to patient outcomes when there are product failures or complaints.

Meeting UDI requirements is an increasingly complex step in product life cycle management.

The complexity around meeting UDI requirements stems from the fact that medical device risk levels and indications are understood differently across countries. In addition, there are technical format requirements, within which there are three sets of standards for defining both a device identifier (DI) and a production identifier (PI), which also differ across countries.

Figure 1. UDI standards for complying with technical format requirements

Technical Formats to Comply with UDI Format

UDI Standard	GS1 Standards	HIBC Standards	ICCBBA Standards
DI	Global Trade Item Number (GTIN)	Data Identifier (DI) • Labeler Identification Code (LIC) • Product or Catalog Number (PCN) • Unit of Measure (U/M) • Mod 43 Check Character	Data Identifier (DI)
PI	Application Identifier (AI) • Manufacturing Date AI • Expiration Date AI • Lot/Batch AI • Serial Number AI	Production Identifier (PI) • HIBCC Identifier Flag • Expiration Date, Lot Number and Serial Number • Supplement Data • DI Link Character • Mod 43 check character	Production Identifier (PI) • Serial Number • Distinct ID Code/Donation ID • Expiration Date • Manufacturing Date • Lot Number
DI + PI = UDI	GTIN or (GTIN + AIs) = UDI	DI + PI = UDI	DI + PI = UDI
Alphanumeric Format	Numeric Format (DI) Alphanumeric Format (AI)	Alphanumeric format	Alphanumeric format

Source:
Proposal to introduce a Unique Device Identification (UDI) system for medical devices in Canada - Canada.ca

Taking all this into account, the final decision on how to define UDI structure for a given product is on the labeler of the device(s).

> Accounting for the type of device risk level, the physical packaging, the layers across the physical packaging, the indications that the device is used for—all this headache is on the device labeler.
>
> *Anusha Gangadhara, IQVIA*

Once the decision is made, the question arises whether a UDI will work across the globe, with different authorities and national regulatory databases. These details highlight the conflict between the primary objective of UDI being a single, globally harmonized system for identification and the reality of country-specific requirements.

"There are a lot of different threads that are pulling on organizations and that they need to weigh out: the regulatory requirements, the purchasing requirements, the cost of implementation, the data management, and ultimately how these things can be implemented," said King.

Figure 2. Differences in UDI attributes, approaches and configurations across countries and regions

Product name	Number of devices in Package	Model of the Device	Proprietary, trade, or brand name	Name of the UDI issuing agency	
Labeler name	Manufacturer Details	Contact Information	Sterilization, Latex rubber/ MRI	Intended Use	Premarket Clearance
Different size, version model and unit measure	Registration Number	GMDN	Warning, precaution & Contraindication	Custom-Made details	

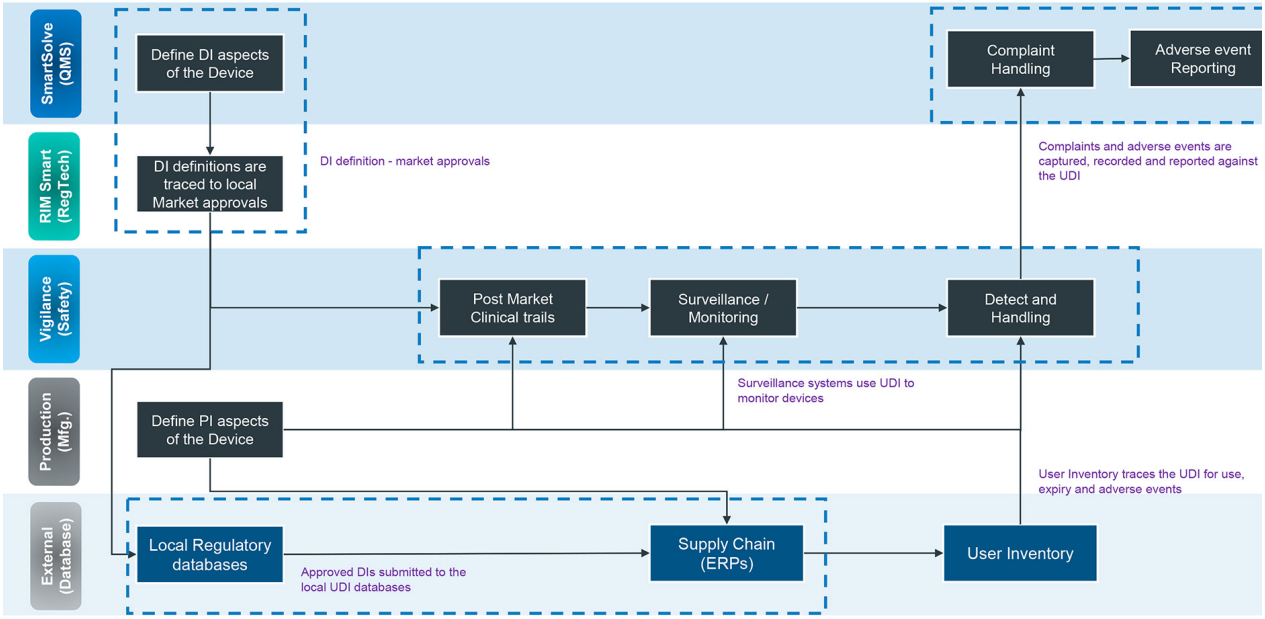
Country	Timeline	Database
China	Medical Insurance Code	Insurance Code (20 digit) is one of the key data elements for NMIM and reimbursement
EU	Basic UDI-DI	Primary identifier of a device model. References relevant Certificates, EU declarations of conformity, clinical investigations, post market surveillance
Saudi	Brand name and Device Description	in Arabic for lay person / home use devices
Taiwan	Contains DEHP	Devices required to be labeled as containing DEHP (di-2-ethylhexyl phthalate) if any
USA	Packaging Layers	Text to describe the outer packaging of the product and enables users understand higher level packaging configurations

The country-specific evolution of UDI requirements calls for a robust regulatory intelligence system.

To account for all the nuances of global and national UDI requirements, implementing UDI within MedTech companies' existing PLM systems needs close coordination among regulatory, commercial, and operational teams. Such collaboration should account for integrating UDI implementation in current product inventory and manufacturing processes with minimal changes while attending to global definitions of risk levels and of country-specific packaging and labelling standards.

A system designed to facilitate visibility into all these components and accelerate team collaboration can greatly advance UDI implementation. A bird-eye's view of a conceptual framework that may serve as the basis for such system is depicted in Figure 3.

Figure 3. A framework for placing UDI within QMS, regulatory, and post-market vigilance functions



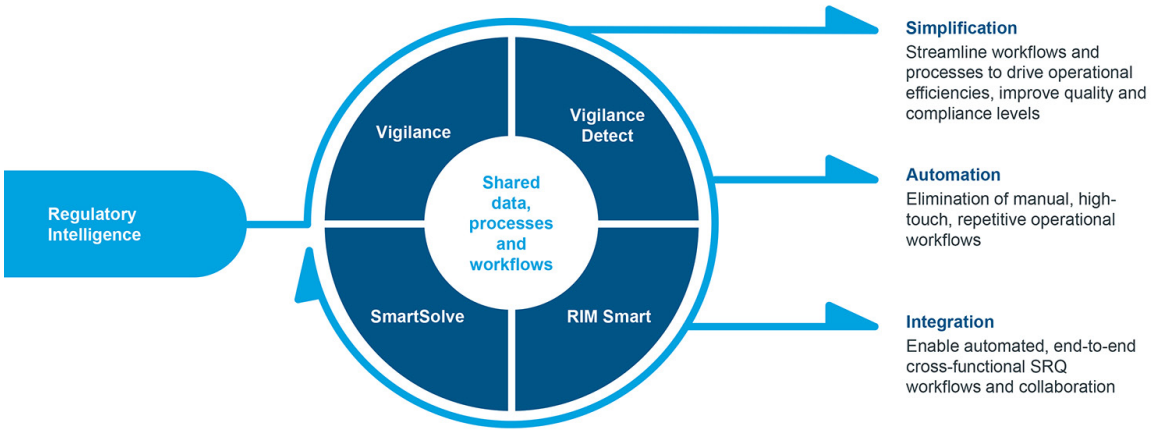
> Using UDI across your systems drives a very clean, unbroken supply chain all the way to the user, adds to positive clinical outcomes, and significantly cascades to cost savings and clean claim processes or reimbursements.
>
> *Anusha Gangadhara, IQVIA*

King noted that by capturing key UDI data fields, companies can also enhance or create datasets that can be leveraged for improving QA/RA activities. "It's a good precursor to a potential change in industry management of core QA/RA activities," he said. "When you start coding [UDI] around adverse events or clinical activities, you turn data into information and information becomes action. That action then helps drive and improve clinical performance for the products that a company sells."

IQVIA's single-source-of-truth connected intelligence system optimizes visualization of product performance.

IQVIA's safety, regulatory, and quality solution facilitates alignment and collaboration among MedTech companies' regulatory, commercial, operational, and other teams involved in UDI implementation.

Figure 4. IQVIA's interconnected intelligence system



The key successes that the system enables are UDI-related data management and data interfacing. It provides a way of gathering and storing data in such a way that UDI, which could vary across different ERP, PLM, and RIM systems, is unified and visualized in a single place. Then it interfaces that data with global databases, which may indicate a need for harmonization adjustments.

CONCLUSION

The impact of UDI integration into supply chain and clinical practices can ultimately be measured in increased efficiency, consistency, and cost savings. As the primary key for ensuring complete traceability and transparency across the healthcare ecosystem, UDI reduces data redundancy, documentation efforts, and errors while managing product information across multiple systems and processes. By mapping data, documentation, and inventory, UDI also enables the seamless integration of actual product attributes into approval submissions, thereby simplifying global operations, supply chain monitoring, and inventory management.

> When we're talking around UDI, the key to recognize is that a global UDI solution [must be] truly global; that is, bigger than America and Europe. That's part of the challenge of complexity: identifying the right data inputs at the front end of the label creation, but also making sure that those data elements carry through into global databases.
>
> *Michael King, IQVIA*

BIOGRAPHIES

Anusha Gangadhara

Business System Analyst, IQVIA

With close to a decade of technology experience in the healthcare platform and medical device industry, Anusha is part of the RIM Smart Product Management team at IQVIA. She drives the mapping of business needs to technical requirements and leads business critical engagements in defining RIM Smart Solutions for MedTech. Prior to IQVIA, she worked as a regulatory and quality engineer at Philips Healthcare and before that spearheaded global product launches at two startups—Consure Medical and Sohum Innovation Lab. Anusha holds a Master's in electrical engineering from National University of Singapore with rigorous hands-on experience in the medical device and technology development process from the Stanford-Singapore Biodesign program.

Michael King

Senior Director, Product & Strategy, IQVIA

As senior director of product and strategy within the technology solutions business of IQVIA, Michael King is responsible for ensuring that the medical device solutions have the necessary functionality to support the increasingly complex and diverse global regulations. He is particularly focused on optimising business workflows through intelligence-driven simplification and automation within and across the safety, regulatory, and quality functions.

Michael has over 15 years of knowledge and experience leading localised and global teams in regulatory affairs and quality assurance and has worked within the medical and surgical, orthopaedic, in vitro diagnostic, diagnostic imaging, dental, and urology sectors. Before joining IQVIA, he was the vice president of international regulatory affairs for a dental technology organisation and had oversight of the international product registration, adverse event reporting, and country-based quality management systems.

Michael holds a degree in Physics from Oxford University and briefly worked for a consulting firm in the telecommunications industry prior to beginning his career in the medical industry.

Jason Berning
Associate Business Development Director, Regulatory Technology Solutions, IQVIA

Jason Berning has more than 10 years of experience in Regulatory Technologies in various roles that include: consulting, product management, and sales. As an Associate Dir. of Business Development at IQVIA, Jason focuses on bringing transformational Regulatory Technology and Consulting solutions to his customers. He has worked with a wide variety of pharma companies of various sizes and is passionately optimistic about the digitalization of regulatory affairs.