CASE FOR UNIQUE DEVICE IDENTIFIER MANAGED IN PLM

The FDA requires medical device organizations to submit device information to the Global Unique Device Identification Database (GUDID) for all medical devices sold in the United States. UDI management can be done in multiple systems. Is PLM the right place to manage UDI information?

UDI Definition

A unique device identifier (UDI) is a unique numeric or alphanumeric code that generally consists of two parts. The first part is a device identifier (DI), a mandatory, fixed portion of a UDI that identifies the labeler and the specific version or model of a device. The second part is a production identifier (PI), a conditional, variable portion of a UDI that identifies one or more of the following when included on the label of a device:

- Lot or batch number within which a device was manufactured
- Serial number of a specific device
- Expiration date of a specific device
- Date a specific device was manufactured
- Distinct identification code required by 1271.290(c) for a human cell, tissue, or cellular and tissue-based product (HCT/P) regulated as a device.

The device labeler must provide the UDI in two forms on labels and packages:

- Easily readable plain-text
- Machine-readable form that uses automatic identification and data capture (AIDC) technology.

UDI Solution Options

UDI compliance requires a strategic solution that can support the two elements of the regulation for each shippable SKU:

1. Registration of the UDI "static" device identifier (D.I.) attributes (11 required + 36 additional) with the FDA GUDID.
2. Traceability assurance of the UDI "dynamic" production identifier (P.I) attributes by internal company processes (i.e. lot history, serialization, expiration data).

An effective solution needs the following components:

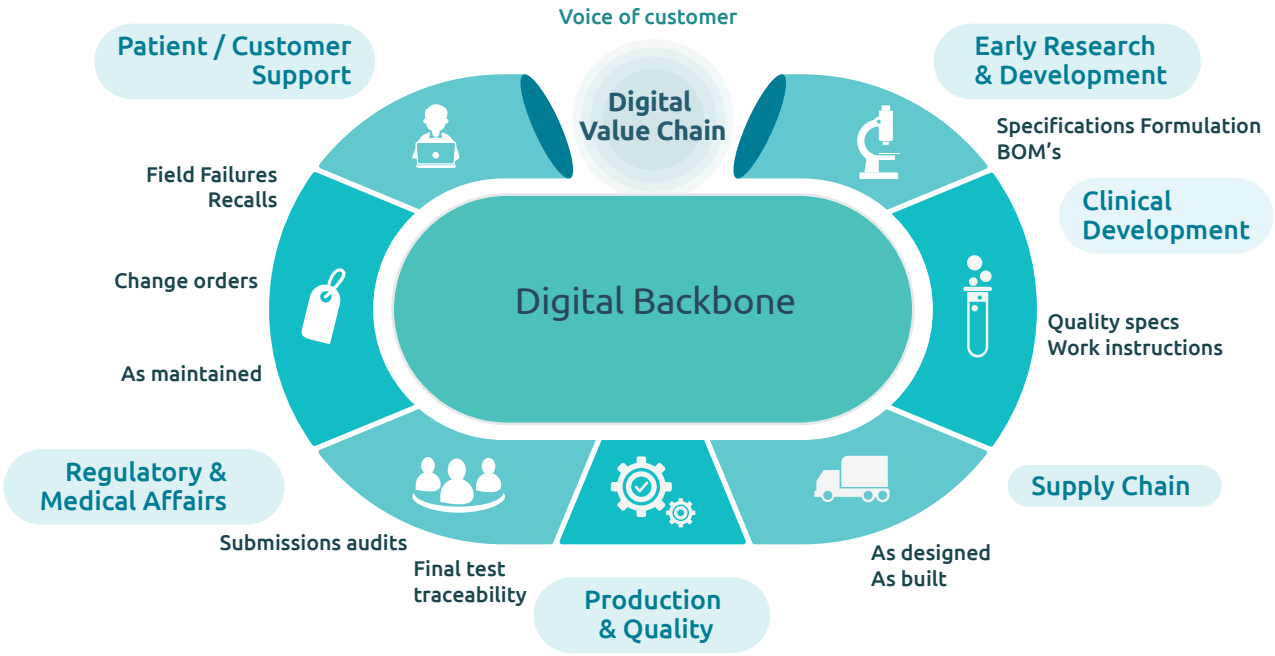
- Access to device information which is typically stored in a PLM system
- Data maintenance and ability to enrich device information to cover all 11 required and 36 additional attributes
- Access to production information which is typically managed by a combination of ERP and MES systems
- Data validation according to the requirements of the UDI databases
- Workflow for managing the approval and review of UDIinformation prior to formal submission to FDA as well as managing changes to UDI information
- Flexible data model to support changes at FDA or other r egulatory bodies
- Data exchange handling with regulator authorities like FDA
- Comprehensive reporting of UDI submission status

There are a few solution options:

- Build a stand along system which has interfaces to PLM, ERP and MES and a gateway to the FDA database
- Host UDI solution in one of the key systems, PLM, ERP or MES and pull other required information from the other systems
- Use a third party provider to manage UDI information including submissions

UDI and Quality Implications in a Digital Twin

The FDA UDI mandate was initiated to enable better traceability of medical devices throughout the supply chain and to improve the information available to manage product quality issues, which could potentially impact the patient. Other global health authorities are also enacting similar requirements with which multinational companies will have to comply.

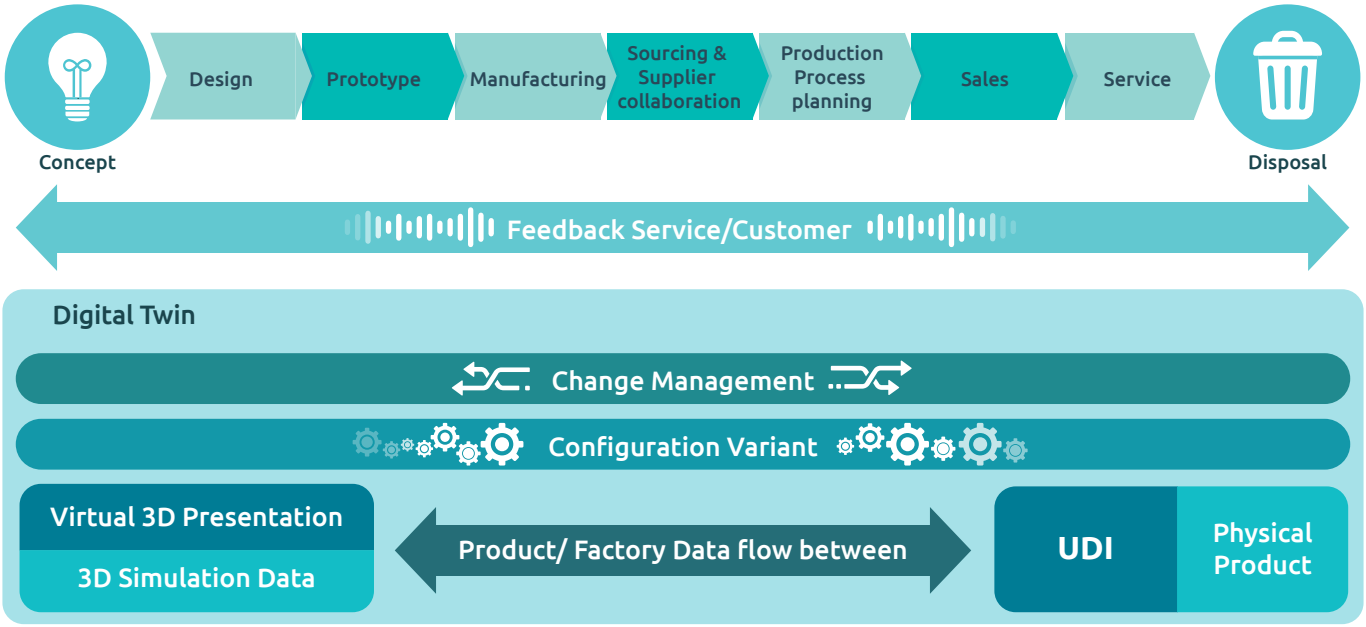


One of the three tenets of FDA's "Case for Quality" includes enhanced data transparency. The FDA expects organizations to track and submit quality-related data, including information from recall and adverse event reports and inspection results. The FDA is working with stakeholders to promote manufacturers' implementation of critical-to-quality practices during device design and production. Adverse events are a key metric tracked for quality. Companies that have proper mechanisms for monitoring and feedback based on field usage are better able to define critical performance parameters in the device design, which helps with process and supplier controls. These mechanisms also serve as a basis for continuously refining device risk assessments and assessing the baseline level of quality for new devices.

UDI becomes an important tool to track the specific incidence of a quality event and perform root cause investigation. With the advent of IoT, it is easier to capture specific details of a quality event and use UDI for tracking which device had the incident. A few years ago, the FDA launched a Precision Medicine Initiative which aims to identify appropriate treatments for individual patients. For providers to build a precise treatment plan for a patient, a piece of the puzzle will include leveraging data from UDIs to help understand trends with population cohorts that will help optimize treatments. For example, UDI can be used to identify specific device usages and where they occur globally. As a result, the data can be pulled to correlate and show patterns for specific diseases or treatments.

Closed loop quality expands the scope of PLM to power digital continuity from concept and design to service and disposal. UDI is the link between the physical product and the virtual twin in PLM.

With UDI managed in PLM, it becomes easier to correlate the virtual twin to a specific UDI or device and simulate the behavior of the physical product in context to quality incidents in the field.



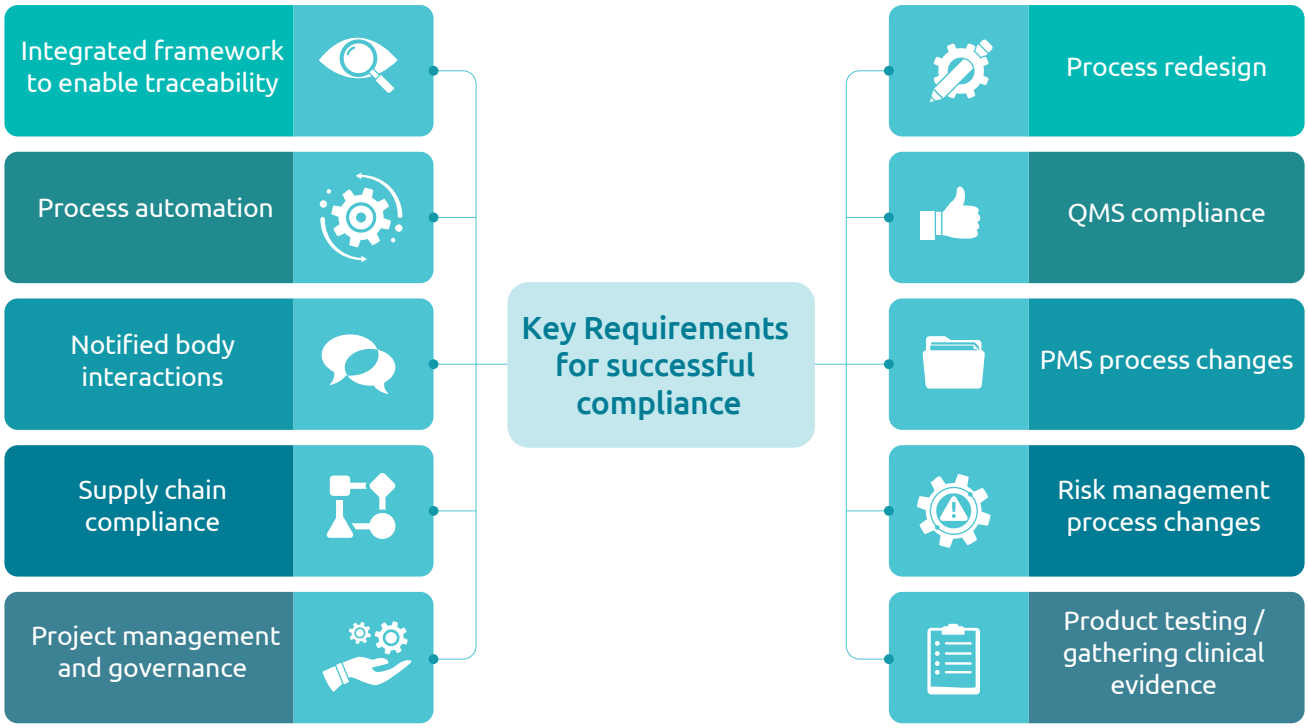
UDI and Regulatory Submissions

Organizations use different solutions for submitting device information and design history files to regulatory bodies such as the FDA.

With FDA and other regulatory organizations requiring DHF/DMR to be managed and electronically submitted, PLM systems have become the system of choice for managing design history, closed loop quality and electronic submissions to FDA.

The Medical Devices industry is constantly faced with the challenge of adhering to a variety of influencing inputs such as market drivers, regulatory constraints, and governmental constraints that are instituted all across the globe. Organizations are always assessing and addressing these inputs to ensure that their products are compliant while keeping the overarching goal to design and produce the best possible device. One such change in regulations is EUMDR which is explored in Capgemini's white paper: https://www.capgemini.com/wp-content/uploads/2020/06/PoV-EU-MDR-Implications-and-way-forward-18June.pdf. The article explores the significance of PLM for successful implementation of MDR compliance. A key element of traceability for MDR compliance is UDI managed in a central system such as PLM.

Key considerations for the successful implementation of MDR compliance



The FDA's "case for quality" initiative explores the interplay between innovation and quality. A key finding is that organizations that manage risk by driving quality organization-wide are more productive in bringing better quality products without stifling innovation.

Paper based "Design history File" (DHF) and "Device Master Record" (DMR) record keeping have traditionally been used to provide an evidence of design controls and device production controls. More often than not, DHF and DMR are compiled as an afterthought to meet regulatory needs. PLM provides a platform to help drive quality organization wide. It provides the ability to electronically track design controls and production controls as products progress through various stage gates of the product development process. Regulatory teams can now generate data driven electronic DHF and DMR packages from PLM. Engineers can continue with their innovation process while PLM captures the bread crumbs of quality processes and industry best practices embedded in the innovation process enabled in PLM.

This need for better real time electronic tracking is driving organizations to increasingly consider PLM as the system of record as well as the interface to the FDA gateway and other regulatory bodies. Extending the same interface to UDI becomes a natural progression.

Conclusion

Adding UDI to PLM extends the value of maintaining UDI electronically. The FDA developed the UDI rule primarily to promote patient safety and have better visibility to adverse events. But along the way, regulators and industry have realized there are a multitude of benefits from UDI adoption, from supply chain efficiencies to understanding what products, and more importantly, which clinically relevant attributes work best on which patients. In other words, it's not just about knowing when something goes wrong, but also about what is working at any given time in the real world, which can help providers source the right products and manufacturers to design and market those products.
The majority of the information needed for driving the value of UDI resides in PLM. Managing UDI in the same system helps better associate information for increasing the value of electronic UDI.

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Sources

(source: International Medical Device Regulators Forum (IMDRF): http://www.imdrf.org/).

https://www.capgemini.com/wp-content/uploads/2020/06/PoV-EU-MDR-Implications-and-way-forward-18June.pdf.

https://www.fda.gov/medical-devices/quality-and-compliance-medical-devices/case-quality

https://www.gs1.org/industries/healthcare/udi

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