Fact Sheet
GUDID and UDI compliance for Optical Medical Device Manufacturers

What is UDI?
Unique Device Identification (UDI) is a system to mark and identify medical devices (via bar codes) by the labeler (e.g. manufacturer, importer, distributor) within the healthcare supply chain.

What is a GUDID?
The Global Unique Device Identification Database (GUDID) is a system created by the U.S. FDA to register all medical devices marketed and sold in the US market. It serves as a repository of key master data for device identification. This key information is limited to Device Identifiers and Labeler information.

Why was GUDID established?
The FDA established its unique device identification (UDI) system to facilitate product identification and traceability of medical devices sold in the United States - from manufacturing through distribution to patient use in order to improve patient safety, modernize post-market surveillance, and foster medical device innovation. The GUDID was established to serve as the repository for all this UDI information.

What is the impact of the GUDID and UDI?
Under the FDA's UDI ruling, the labeler of each medical device labeled with a unique device identifier (UDI) must submit information concerning that device to the GUDID, unless subject to an exception or alternative.

Where does it apply?
The GUDID is based in the United States, and this regulation applies to **all** medical devices sold in the US market.

What is required?
Every "labeler" of medical devices is required to maintain UDI data and submit this information to the FDA's GUDID. Devices are grouped into three risk classifications (Class III, Class II, Class I) with differing submission deadlines. Note that for the equivalent European regulation, the responsibility for UDI submission lies with the manufacturer of a medical device.

What exactly is a 'labeler'?

According to the FDA[1], a labeler is any person who causes a label to be applied to a device, or who causes the label of a device to be modified, with the intent that the device will be commercially distributed without any subsequent replacement or modification of the label. The addition of the name of, and contact information for, a person who distributes the device, without making any other changes to the label is not a modification for the purposes of determining whether a person is a labeler.

In most instances, the labeler is the device manufacturer, but the labeler may be a specification developer, a single-use device re-processor, a convenience kit assembler, a re-packager or a re-labeler.

What is a considered a manufacturer?

A manufacturer is a person or a registered company which makes finished products from raw materials. Among the EUs three medical device directives - Active Implantable Medical Device Directive 90/385/EEC, Medical Device Directive (MDD) 93/42/EEC, and In Vitro Diagnostic Directive 98/79/EC - the definition of what constitutes a manufacturer is identical:

"Natural or legal person with responsibility for the design, manufacture, packaging and labeling (sic) of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party." In Europe, a medical device manufacturer is the entity whose name is on the label and who assumes responsibility for design, manufacture, packaging and labeling. The manufacturer must possess CE marking for its device.[2]

What is required for Optical Medical Device Manufacturers?

The FDA's UDI regulations for Class I devices require labeling, direct marking and GUDID submissions are now due on September 24, 2022. The original deadline for Class I device submissions was planned for September 2020, however, this date was postponed by two years due to COVID-19.

Note that Class I devices include spectacle frames, Plano sunglasses, over-the-counter reading glasses and many low vision devices. Additionally, for those manufacturers intending to market prescription eyewear products in the European Union, EUDAMED submission will be due in May 2022.

Further global regulations are emerging and will require both regulatory and IT expertise to develop scalable UDI compliance solution. Of course, the challenge in meeting these regulations is that product master data must be accurate, validated – and most importantly – "trusted".

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[1] https://www.fda.gov/medical-devices/unique-device-identification-system-udi-system/udi-basics

[2] https://www.emergobyul.com/blog/2008/05/are-you-considered-medical-device-manufacturer

Recommendations

Learn UDI implementation strategies to develop a scalable process for submitting product data successfully to FDA's GUDID. To optimize your process for GUDID compliance, we recommend the following four critical actions:

- Create a global Syndication Hub to submit validated product/device data that can be trusted by your healthcare providers and the FDA
- Aggregate your internal product master data from multiple sources into the Syndication Hub, for data validation and submission
- Enrich and validate the product master data based on FDA-specific attributes, code value lists and data validation rules
- Submit your validated data to the GUDID using an FDA-approved "Third Party Submitter" solution that supports HL7/SPL messaging standards and GAMP5 system validation requirements.

Innovit's UDI compliance and PIM (Product Information Management) solutions can help you overcome these challenges by allowing medical device suppliers to implement a "global system and unified process" that is fully integrated with internal systems to submit regulatory data to multiple regulatory databases simultaneously.

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