A Whitepaper from DDi

Traceability Requirements under EU MDR

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Traceability Requirements under EU MDR

Ensuring traceability at all stages of development and even post-marketing is necessary for medical device manufacturers with products in the EU. As you are aware, EU medical device regulation (MDR) would be replacing the medical device directives (MDD) by May 2021.

This regulatory shift will have strong impact on the European market as currently, over half million medical devices are functional in the EU. All companies behind these devices are to follow these enhanced rules to be compliant. EU MDR prioritizes "closed-loop traceability" and if manufacturers can achieve this then they will be highly benefitted. This helps in reducing device hazard risks that increasingly threatens Europe's aging population.

Some common areas regarding EU MDR traceability requirements have been highlighted below:

1. What are the EU MDR identification and traceability requirements for medical devices?

EU MDR emphasizes the fact that medical devices need to be traced in all stages throughout the product lifecycle. Closed-loop traceability revolutionizes the quality management system that was previously unknown.

Under EU MDR, all third-party suppliers along with manufacturers involved all through the medical device lifecycle should pass through quality audit to ensure compliance using traceability. The Unique Device Identification (UDI) is also mandatory under EU MDR to ensure proper post-market surveillance.

Lastly, the new regulation has introduced the economic operator system, which includes "manufacturers, authorized representatives, importers, and distributors. Their responsibilities in the medical device supply chain will increase from now on. This will help in maintaining traceability and device safety.

2. Why is traceability important?

In 2017 most medical device recalls have resulted from faulty designs. With patient safety as the main aim, identification and eradication of such faults is a necessity. Regulatory software can help in making closed-loop traceability simpler and can make all the pre- and post-market processes automatic. Companies working with such traceable systems will be highly benefitted through better decision-making in this competitive market.

Moreover, device traceability allows medical device manufacturers to have a streamlined audit process. Tracking allows proper data recording and documentation, which can be presented as and when requested by the auditor.

3. How to demonstrate traceability?

Modern regulatory solutions generally rely on connected processes and EU MDR regulation is the first to enact strict traceability requirements. Every EU-based manufacturer needs to have this provision to keep operating in this market.

Using a specific medical device oriented Regulatory (RIM) solution is the key to demonstrating closed-loop traceability rather than depending on separate systems. Thus taking a data-driven approach all through the product lifecycle.

EU MDR impact on Coding and Marking

Medical device manufacturers need to assign UDI code for all devices and require registering in EUDAMED. For Class III Medical Devices, May 2021 deadline marks the beginning of mandatory UDI coding. Manufacturers will no longer be able to supply their products to every EU member state without UDI codes. Fee payers and healthcare providers will not accept devices without UDI codes that are up to the required standard.

Unique codes applied to each item during manufacturing stages will provide the supply chain management system with key information, like - what the product is, where and when it was produced, its current location and how it got there. In the event a recall is necessary due to a product being faulty, the code is crucial to unlocking the so-called 'chain of custody', allowing the item in question to be traced back to its origin.

Types of Coding and Marking

Depending on the medical device and the coding surfaces involved, there are several different technologies that can be deployed for the delivery of UDIs in this sector.

1. Direct Marking

The most prominent technology for Direct Part Marking (DPM) on to medical devices is laser. While DPM is more commonly known as an industrial manufacturing application, it is most appropriate for medical device identification.

The presence of reprocessing devices throughout the supply chain can cause product items to be separated from their original packaging, which is why a permanent mark needs to be applied to the medical device. This way, a UDI code is readily available through the device distribution and use, even in the absence of packaging or labels. Medical devices such as pacemakers or surgical instruments are the kind of products that would require a permanent mark, as the UDI is designed to last as long as the device itself.

2. Primary Packaging

In contrast to Direct Marking, a variety of coding and marking technologies as well as laser can be used for applying UDI codes onto primary packaging. These technologies include Thermal Ink Jet (TIJ), Thermal Transfer Overprinting (TTO) and Print & Apply Labelling Machinery (PALM). TTO is the preferred choice for coding onto flexible, web based packaging materials. These materials and packaging applications include flexible laminated films to create pouches, sachets and bags or to lid rigid trays and apply labels to the surface of other primary packs as well as coding directly onto speciality flexible materials, such as medical paper or Tyvek®.

3. Secondary and tertiary packaging

Where larger label information needs to be printed and applied onto cases or a label is the only option due to the substrate or the shape of a product, PALM proves to be an effective alternative to TIJ and TTO. PALM can also be deployed for secondary and tertiary packaging applications. As well as the other technologies, PALM enables high resolution application of the required UDI and GS1 codes (used to encode information such as product numbers, serial numbers and batch numbers) and offers multiple applicator options which includes corner wrapping of cases.

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