Q1 PRODUCTIONS WEBINAR TRANSCRIPT:

Best Practices for UDI Implementation and EUDAMED Submissions -

Sharma Pokkuluri's Presentation

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I Got My UDI, Can I Package My Product?

You have a device identifier, so now you have your GTIN code that is for the single unit packaging. You need to raise individual GTIN numbers for different packaging that may be 10 packs of a single unit, or maybe a case and you have a pallet. You should have a different GTIN number for pallets. There are different levels which will be identified during the shipping or the distribution of the product. In all the individual cases, you need to have an individual global trade item number. Whereas the production identifier will have the DI, which has been declared that it will be the same. The product device identifier mentioned under 4 or 3 different levels of the GTINs have to be declared during the time of the product's registration and also procured from the GS1 standards.

Regulatory – USA Timelines for UDI implementation by Class

Class three products are first, which became part of the UDI system in 2013, since the final rule had been issued. Thereafter, the class 1I, and then class II and kits, but by September of 2020 the class I products have finished their transition. From September 2020, it means that the transition will have finished and all the products mandatorily will have a UDI code in the US. Simultaneously for UDI direct marking, any of the product UDI codes that have to be marked directly on the product's primary packaging is to be in place by the end of transition in 2022, and in September for the class ones.

Now at the moment, we are left with about 12 months of a time for this transition on the direct marking.

Regulatory – EU Timelines for UDI Implementation

Here you can see the EU region medical device regulations and UDI timelines, these timelines are showing the postponement of date of application for MDR and with the delays on EUDAMED. As you can see from the 25th of May, it was anticipated but we have been delayed because of the pandemic situations and the MDR certificates, which have been issued from 26th May 2020, and will be compliant to the UDI requirements.

Progress from ROW

Here you can see what the other countries have been using, there are three different kinds of systems - GS1, HIBCC and ICCBBA. There are three different organizations who are providing these barcodes, which have been added to the medical device concepts called UDI, and have been in implementation since 1999, as you can see in places like Japan. Most of the countries have been on a universal concept and accept the GS1 standards, but you can get UDI barcodes from the HIBCC, depending on your product nature, and also from ICCBBA.

You have the device identifiers which you can see from Japan, coming from MEDIS data reporting systems. Aside from the MDSAP countries, you can see going across to other ASEAN countries, and other regions of the world such as Singapore, Taiwan, or India. So the concepts have become universal, and the UDI is now effectively being used in most of the countries for the purpose of tracking and tracing the product in their supply chain, from the time of the start of the manufacturing to the end user or the patient.

Complications

Accreditation Agencies: We have three different accreditation agencies: GS1, HIBCC & ICCBBA who provide different kinds of barcodes, and they are not harmonized.

The Date Format: The length of the barcodes is different. The date formats are not harmonized, whether it is in European region or FDA region, and it should be in ISO 3166 format - which is year, month, and date.

Packaging configurations: Packaging configurations have not been clarified, as you can see the production identifier is optional. So from a GS1 point of view, it is optional, but from the European point of view, it is mandatory because ISO 15223-1/2, and they mentioned that the product expiration date and lot number are mandatory. So, these are two contradictory directions, which can cause complications.

Direct Marking: Direct marking - where the size of the product and the amount of space which is available directly on the product may be of miniature size or of massive size. Where you can print a barcode directly, or a human readable interface, that direct marketing is once again a conflict which has not been clarified in most situations.

Unit of Use: The unit of use - sometimes you may come across a bag of 100 examination gloves, then are there UDI codes for all the individual items? Or, is it just for the box of those 100 gloves? This concept has never been clarified. Obviously, the manufacturer will be confused about how to do the UDI labeling and there are special cases that you see with products like procedure packs and some of the class 1 devices.

Strategies for UDI Compliance

The strategies for UDI compliance requires the registration of the economic operator, registration of the device, and taking those registrations and aligning them with the product information, declaring the data elements, and the unique device identifiers.

I would recommend receiving clarification from a notified body or another agency, getting transparency in terms of how the certification works with your agency and with the national competent authority and how to declare that information. Go through the vigilance process of setting up the quality system, which is regarding the post market surveillance or the clinical evaluation

Thank You!

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