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Coloplast: the key to success in complying with the U.S. FDA Unique Device Identifications rule

Abstract

Coloplast, a world leader in intimate healthcare products and services, has manufacturing facilities in five different countries. As a global organisation, Coloplast is required to react quickly to changing regulatory requirements. With many new regulations on Unique Device Identification (UDI) emerging, the company focuses its work on improving its labelling processes to anticipate future UDI rules.

Introduction

Coloplast operates globally and has manufacturing facilities in five different countries. Its portfolio of 20.000 Stock Keeping Units (SKUs) is varied and covers class I, II and III medical device products[1]. In the past few years, Coloplast has focused on improving its labelling processes to meet the increasing number of regulatory requirements for labels. However, as it had several labelling systems in various manufacturing facilities, it proved to be more challenging than expected.

In September 2013, the U.S. Food and Drug Administration (U.S. FDA) published its final rule on UDI, which establishes a unique device identification system for medical devices. UDI is a unique identification that includes a device identifier, e.g. Global Trade Item Number (GTIN), and production identifiers, such as batch/lot, expiration date, and manufacturing date.

According to the rule, whenever a device must bear a UDI, the labeller will need to submit the device information to an online database administered by the U.S. FDA, called the Global UDI Database (GUDID). The latter will serve as a reference catalogue for every medical device.

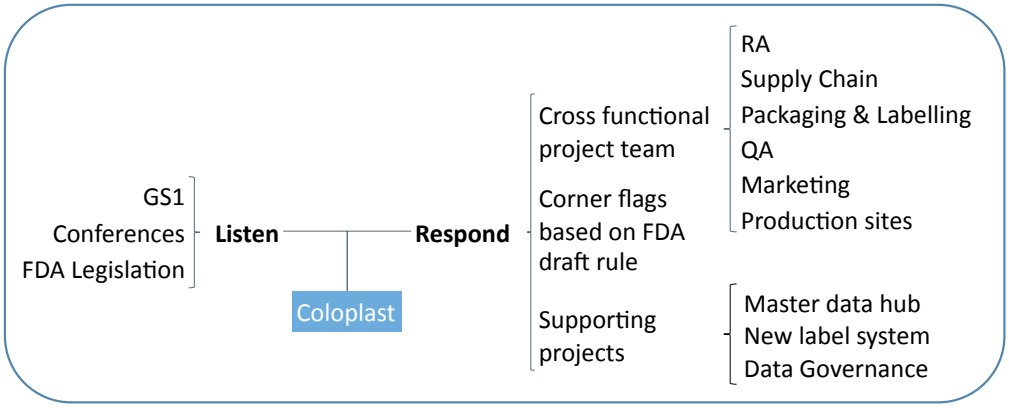
Compliance dates take effect over time using a risk-based approach starting with class III products, which have to comply with the regulation by September 24, 2014.

The road to implementation and gaps identified

In the beginning, the U.S. FDA UDI regulation was followed closely by the regulatory affairs department. It quickly became clear that, in order to comply successfully with UDI, a cross-functional team had to be established. A UDI core team was created in 2011 consisting of representatives from the following departments: Supply Chain, Regulatory Affairs, Quality, Engineering and Packaging & Labelling. During the project, the core team involved other departments when necessary.

That same year, to gain more insight into the complex UDI task, Coloplast participated in the Global GS1 Healthcare conference in Amsterdam,

Figure 1: Listen and respond to UDI requirements



1 U.S. FDA medical devices are classified into three categories: Class I, Class II, and Class III, Class III being considered the highest risk devices.

which led to a close collaboration with GS1 Denmark. Quite early in the process, it was agreed with Coloplast's management that the UDI team had to make assumptions in defining what the rule might be demanding.

The team's first task was to make an interpretation of the draft rule and identify the impact the rule might have on Coloplast's daily operations and processes. During this process, the following main gaps were identified:

- Missing or wrong bar code data carrier types on the primary packaging.
- Poor bar code symbol quality, i.e. due to the printer or the material on which the bar code symbols was printed.
- Wrong date format printed on products and packaging.
- Difficulty in extracting various data for U.S. FDA's GUDID.

Coloplast first concentrated its efforts on products sold in the U.S. knowing that further regulations were expected in other regions.

In addition to closing the gaps that the team identified, the UDI team had to ensure that the following tasks were handled:

- Make a plan for when and how to implement UDI on the various products.
- Find sources for all data elements which must be uploaded to GUDID.
- Make data extractable from Coloplast databases.
- Ensure that data is uploaded to GUDID.

New label system and change of labels

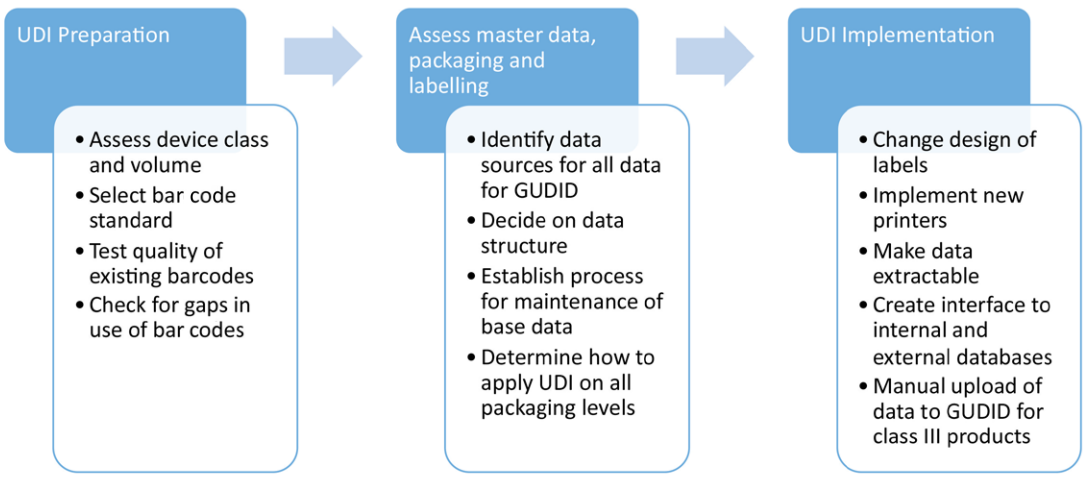
Due to an increase in country-specific regulatory requirements for labels, it had become difficult to maintain label compliance. Therefore Coloplast decided to buy a new label system that would allow them to label its products in a more agile way. The system needed to allow easy design changes and provide the means to extract some of the data for the GUDID.

One of the UDI requirements is that a bar code symbol or Radio Frequency Identification (RFID) tag must be included on the different packaging levels. Coloplast was quite far ahead already in this regard as it has used GS1 BarCodes for the last 20 years. However, Coloplast mainly included bar codes on retail and shipping levels (i.e., GS1-128 and EAN-13). GS1-128 is used internally, whereas EAN-13 is provided as a service to the retail sales chain (e.g., pharmacies).

As the GS1-128 fulfils the U.S. FDA's UDI requirements, Coloplast did not have to make any changes to the bar code on the box labels. However, the company had an issue with its primary packaging level as a vast majority of labels did not contain a bar code or only contained an EAN-13, which is not always sufficient from a UDI perspective. As many of the products are very small, Coloplast opted for a GS1 DataMatrix on the primary packaging level.

Another UDI rule requirement is the date format used for printing the production identifiers like e.g. expiration date. To be in compliance with the U.S. FDA's UDI regulation, Coloplast needed to include a new date format YYYY-MM-

Figure 2: Project plan



DD – as previously it only included YYYY-MM. The change affected the design of the labels as some were quite small. In some cases, Coloplast had to rearrange all the information to fit in the additional day on the date format.

Ensuring the right quality of bar code symbols

"Implementing a single, global system of standards, such as the GS1 System, is fundamental to enable an efficient and effective implementation of UDI"

Bianca Maria Gravenhorst Greve, Senior Regulatory Affairs Manager

The Coloplast UDI team, considering the importance of ensuring the quality of the bar codes, decided to assess its products and verify that they were GS1 BarCode-quality compliant. GS1 Denmark helped with the verification and concluded that the quality of some of the bar codes were suboptimal, mainly due to contrast issues.

Based on this result, Coloplast purchased a new bar code verifier and implemented a more thorough quality check of its bar codes. Furthermore, a standard operating procedure for how and when to verify bar codes was set up.

Data collection and submission

Coloplast needed to be able to submit all its device information to the FDA's GUDID Database for a total of 62 data elements. This was an additional challenge as the company had difficulties finding data sources from which it was possible to extract the data required. Coloplast is currently in the process of finding the most efficient solution to handle the data extraction.

The U.S. FDA provides two ways of submission to the GUDID: manually via a web form or electronically via an interface. Coloplast has 91 class III SKUs, which have to comply with the U.S. FDA's UDI requirements very soon (September 24, 2014) and has therefore opted for the web form approach.

In the long run, Coloplast's aim is to find the most efficient way to upload its data electronically as it exports more than 2000 SKU to the U.S. In order to do so, the company is establishing a master data hub that will not only be used for UDI, but also for other internal and external product-related data requirements. Coloplast realised that robust data governance processes and policies would be needed to establish a master data hub.

Benefits of using the GS1 System to comply with the U.S. FDA's UDI regulations

Implementing a single, global system of standards, such as the GS1 System, is fundamental to enable an efficient and effective implementation of UDI:

- The GS1 Standards meet the U.S. FDA's UDI requirements by enabling interoperability and compatibility internally, externally and globally.
- The GS1 identifiers (e.g., GTIN and application identifiers) comply with the U.S. FDA device identifier and production identifiers.
- GS1 Standards increase the efficiency in meeting regulation requirements.

Conclusion

The journey towards achieving UDI compliance is long and complex. However, with some anticipation and the help of GS1 Denmark, Coloplast is on its way to success. Working cross-functionally and involving all the stakeholders has helped to successfully implement the new and improved processes. Furthermore, the implementation of the new label system has been beneficial as it created a more robust and flexible process to implement UDI. New projects have emerged as a consequence of UDI e.g. the need for robust data governance, increased need for verification of barcodes and change of processes.

Coloplast is now confident that it will meet the U.S. FDA's UDI rule deadline on September 24, 2014.

About the Author

Bianca Maria Gravenhorst Greve is Senior Regulatory Affairs Manager at Coloplast in Denmark. She has been with Coloplast since 2002. Bianca has a profound knowledge of medical devices and has worked intensively with labelling systems for several years. She is responsible for constantly improving labelling processes in order to ensure global compliance and making the processes smooth and lean.

About Coloplast

Coloplast, created in 1957, is today the world's leading supplier of intimate healthcare products and services. Coloplast develops products and services that make life easier for people with very personal and private medical conditions. Working closely with the people who use its products, Coloplast creates solutions that are sensitive to their special needs.

Its business includes ostomy care, urology and continence care, and wound and skin care. It operates globally, employing more than 8,500 people.

Coloplast has manufacturing facilities in China, Denmark, France, Hungary and the U.S. and is represented in 55 countries around the world.