RESOURCES

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Case Study: IBSA | Using Serialization to Ensure Product Integrity

When counterfeiters and tampering threatened IBSA Italy's brand and reputation, they turned to their EU FMD serialization team to protect the quality and authenticity of their products. Learn how they used serialization to regain control of their image and ensure the integrity of their product. IBSA's poster, "Unique Identification Code for Dermoaesthetic Products," was one of two winning posters out of 11 featured during FutureLink Barcelona's interactive Poster Sessions.

UNIQUE IDENTIFICATION CODE FOR DERMOAESTHETIC PRODUCTS

IBSA's Internal Serialization Procedure for Medical Device Products

Authors: Maddalena Rizzi, Production Manager in IBSA Italy,
Carmen Vigorelli, Sr. Sales Manager, IBSA Switzerland

Business Challenge & Solution

- IBSA Italy manufactures and distributes worldwide a medical device class III in the Dermoaesthetic Therapeutic Area.
- After an impressive growth trend in many markets, especially in Europe, we began facing an important image problem due to non authorized sales of this product carried out by non authorized distributors, sub-distributors and cross-selling in many European countries.
- The product was being TAMPERED with, therefore causing fear of «counterfeit» and «quality issues». The end user was starting to doubt the quality of our product.
- IBSA Italy therefore needed to find a way to stop this by trying to control its product. The experience and all the work carried out for the implementation of Serialization for the Pharmaceutical products manufactured in the same production site, gave the team the idea to apply a Unique Identification Code on this medical device.

Team

- The project was carried out by the same Team that implemented the Serialization project in IBSA Italy.
- The automatic generation of the SN is carried out through the already existing software on the packaging line.
- Key People Involved in the Project: Dermoaesthtetic Business Unit Area and the Packaging Development Dept. (Manufacturing Plant).

Objectives

The main objectives of the project were:

1. To prevent the loss of control of the distribution of one of our main and most fast growing products in Europe. This product has practically doubled its turnover during the past three years therefore becoming very «attractive».
2. To prevent a reduction in sales due to this important Image Problem caused by the «tampering» of our product.
3. Protect the quality and authenticity of our PRODUCT.
4. To enhance relationships with exclusive distributors and allow them to maintain their market share and sales.

Key Activities and Resources

How it works

- The project is inspired by the EU FMD (Falsified Medicinal Directive) 2011/62, in the part of amendment to the 2001/83 art. 54 and the new MD Regulation, art. 24 of the Annex V part C concerning the UDI (Unique Device Identification).
- The aim of the project was to make the packaging of our DM compliant with the main basis of Track and Trace concepts:

Authenticity, Identification and Traceability

LABEL

1 level: complete label applied on the package;
2 level: part containing variable data in linear barcode format that allows the reading data also to the devices not able to read 2D;

3 level: tamper evident level consisting of:
a permanent part that remains impressed on the package (VOID + brand) ;
a self-adhesive part tear-proof showing the variable data in clear and in 2D Datamatrix format, removable only with tools that cause the breakage of the surface of the cartonbox , which visibly make the package tampered with (cuts , abrasions).

Resources required:

1. The Expertise and Knowhow of the already existing Serialization Team.
2. The already existing Packaging line and software which had been upgraded in order to comply with the European February 2019 deadline for Pharmaceutical Products.
3. No extra costs involved.

Outcomes

Success Metrics – Results & Feedback

- In our most important market, UK, we were able to identify TWO main companies and against whom we have taken legal action. We gained back control of most of our markets and were able to limit IBSA's image damage.
- Having gained back control of our IMAGE allowed our distributors to meet their requirements and therefore allowed us to meet the goals established for this particular product.

Recommendations

The investment made for the EU FMD has been extreme for all Pharmaceutical companies. In our case the packaging lines involved were more than 15. We needed to find a way to take advantage of this investment.

Another idea has been to use the investment made as a PROMOTIONAL TOOL.
For example, one of our pharmaceutical products (Oral Film Sildenafil) is subject to a very important black market world wide. During an important urology congress, we decided to take advantage of the Serialization Project in order to remind people how important it is to protect the authenticity of each single pack in order to ensure the quality and safety of the product.

Next Steps - Improvements

- Due to the very positive results obtained, we are currently analysing this possibility also for other medical devices which currently do not require serialization.

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