UK

DM Orthotics is using GS1 standards to meet regulations and transform their business

Like all companies who supply medical equipment to the U.S., DM Orthotics need to comply with the U.S. Food and Drug Administration (U.S. FDA) regulation on Unique Device Identification (UDI). By implementing GS1 standards in their manufacturing and ordering processes, they are able to meet these regulatory requirements in addition to making cost savings and improving efficiency throughout their business.

By Martin Matthews

Background

DM Orthotics Ltd is a world leader in the design and manufacture of Dynamic Movement Orthoses used in the management of neurological and musculoskeletal conditions. They provide to over 25 countries helping to improve the lives of people who face a range of physical challenges.

GS1 UK has been working with DM Orthotics to support their business processes and to help them meet expected regulations, both in the U.S. and in the UK.

Challenge

A challenge on a global scale

DM Orthotics has over 150 different types of product. The nature of the products they manufacture, and the individual needs of each patient, means that no two products they make are the same, with nearly every order being custom-built to the patient.

This level of personalisation makes their manufacturing process complex and labour intensive. There are also the challenges of meeting new and future regulations in two of their largest markets.

In the U.S., their largest market, the U.S. FDA requires all medical devices sold in the U.S. to carry a unique device identifier (UDI) and all information about each device be held in an U.S. FDA managed Global UDI Database (GUDID).

Orthoses
A custom-designed external device, such as a brace or splint, to support or assist movement of a weak or injured part of the body.

In the UK, the Department of Health has mandated the use of GS1 standards for all products and services supplied to the NHS.

There is likely to be further legislation in this area, including similar regulations being introduced in Europe for the unique identification of medical devices.

Solution

Understanding what's required

DM Orthotics worked with GS1 UK to understand what changes were required to their systems and processes to meet these regulations.

Cy Culpin, Digital Manager at DM Orthotics Ltd, has been working with the team at GS1 UK to define the systems specifications and other technical aspects of adopting GS1 standards.

DM Orthotics now uniquely identify their products using GS1 standards. Every product is labelled with:

- a unique device identifier; and
- production information, such as batch number and manufacturing date.

This information is represented in a GS1 barcode which allows the data to be captured and checked quickly using scanners.

Submitting product data to the FDA

The product data of all devices supplied to the U.S. must be submitted to the GUDID.

Given the highly customised nature of their product range, DM Orthotics are currently defining the best approach to submit product data to the GUDID. TrueSource, GS1 UK's datapool, fully supports the submission of data to the FDA GUDID.

Once they have a data submission solution in place, they will fully comply with the U.S. FDA regulations on UDI and will be in a good position to comply with the expected European regulations about medical devices.

Furthermore, DM Orthotics have gone beyond the need to just comply with regulations. Using GS1 standards, they are making efficiencies across their business operations.

Employee scanning GS1 barcode into the database.

Benefits

Transforming their entire operation

With changes required to their systems to meet these regulations, DM Orthotics took this as an opportunity to use GS1 standards even further, to transform their business and embed GS1 standards to automate their entire ordering and manufacturing processes.

Automated tracking

By implementing GS1 standards, their ordering system has been updated to identify each item with a unique order number and automatically generate a barcode whenever a new item is processed.

The order number relates back to the patient and the customer placing the order, which is then captured with scanners throughout the manufacturing process in the factory.

"I am confident that DM Orthotics will meet the regulations for UDI, in the U.S., and the NHS, in the UK, and thanks to GS1 standards, our business is set-up in the best possible way for the future."

Martin Matthews,
Managing Director of DM Orthotics Ltd

Real-time traceability

This has enabled DM Orthotics to gather valuable insight into the efficiencies and pinch-points along the process from an order being received to an order being fulfilled, allowing real-time improvements to be made, from staff training requirements to coping with different levels of demand.

A template for best practice

DM Orthotics have so far implemented this level of automation to a portion of their product range. This 'test and learn' approach has allowed them to make tweaks and amendments to their processes along the way and understand the benefits of using GS1 standards without disrupting their global operations. They have already seen a positive impact to their business, beyond simply meeting regulatory compliance.

Using this approach means that DM Orthotics now have a template for best practise and are planning to roll out the same level of automation, using GS1 standards, across the rest of their product range.

Now they have seen how using GS1 standards can improve the flow of information through their business, they have taken traceability a step further.

Not just products and processes, but people too

Not only are orders uniquely identified, but people are too. DM Orthotics identifies each member of staff in their factory, using GS1 standards.

Touch-screen and scanning technology has been installed throughout the factory to enable every product and member of staff to be identified at each stage of the manufacturing process. This is achieved by scanning barcodes on each product and staff ID card as an item moves along the process.

This gives DM Orthotics visibility over who's working on a particular order at a particular time.

Conclusion and next steps

- **U.S. FDA UDI compliance**
  Implementing a solution to submit product data to the GUDID, by the deadlines outlined by the FDA, will allow them to fully comply with the UDI regulations in the U.S.

- **Roll out GS1 standards to the rest of their product range**
  Using the template and best practices that have been identified through the initial phase, DM Orthotics plan to implement the use of GS1 standards across the rest of their product range.

- **Integrating their dispatch and accounts systems**
  DM Orthotics are planning to integrate their dispatch and accounts systems to the new automated processes. This will enable complete end-to-end visibility across their entire business from receiving an order, to invoicing and receipting payments.

Before implementing GS1 standards, DM Orthotics' ordering and manufacturing processes were paper-based and required substantial time and effort in manually keying and rekeying data into multiple systems.

It was difficult for them to monitor orders through the manufacturing process. The amount of manual data entry, inaccuracies of information and varying types of external order numbers, meant that orders were difficult to keep track of and manage.

The requirement to use GS1 standards has enabled DM Orthotics to make improvements to their business processes throughout their entire order and production systems, over and above meeting regulatory compliance.

By using GS1 standards, they have reduced the amount of time spent by staff processing orders and rekeying order information onto different systems. This has enabled a marked improvement in efficiency, as an order now moves automatically through the order and manufacturing systems and is identified, captured and shared through the entire process.

About the author

Martin Matthews *is Managing Director of DM Orthotics Ltd.*

Martin qualified in 1981 from Salford College of Technology as an orthotist and specialises in paediatrics and scoliosis management.

In 2009 he graduated from the University of East Anglia with a research Master of Philosophy degree investigating the effects of DMO leggings on children with cerebral palsy. He has developed the Dynamic Movement Orthoses over the past 15 years. He lectures at University of East Anglia and has written numerous scientific papers. He partners with a number of Universities to ensure continued innovation and development of the business.

About DM Orthotics

DM Orthotics was founded in 2005 by Martin Matthews. The company has grown into an international business with distributing partners in 25 countries.