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 global regulations.

Challenge

A challenge on a global scale
DM Orthotics have 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 for 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 US, their largest market, the Food and Drug Administration (FDA) requires all medical devices sold to carry a unique identifier and all information about each device be held in an FDA managed Global UDI Database (GUDID).

• 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.

“I am confident that DM Orthotics will meet all of the regulations in the US (for UDI) and the UK (for the NHS), 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
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 US 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 GUDID.

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

Cy and his team have gone beyond the need to just comply with regulations. Using GS1 standards, they are making efficiencies across their business operations.

Results

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, the company’s 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.

Real-time traceability
GS1 standards have 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. They have allowed real-time improvements to be made, from staff training requirements to coping with different levels of demand.

A template for best practice
DM Orthotics started by implementing 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 practice 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, DM Orthotics have taken traceability a step further.
Not just products and processes, but people too

Not only are orders uniquely identified, 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, which gives visibility over who’s working on a particular order at a particular time.

Next steps

Compliance with UDI regulations

Implementing a solution to submit product data to the GUDID, by the deadlines outlined by the FDA, will allow DM Orthotics to fully comply with the UDI regulations in the US.

GS1 standards in the rest of their product range

Using the template and best practices that have been identified through the initial phase, the company 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 receiving payments.

Conclusion

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.

GS1 standards have 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.