The Netherlands

Working together on a single source to achieve reliable data for medical devices

Challenge

Exchanging product information of medical devices has traditionally involved time-consuming handling of individual Excel sheets and PDF formats, with different requirements for different partners.

Approach

In the Netherlands, suppliers of medical devices and hospitals have joined together to try to standardise and automate the exchange of product information. A uniform dataset has been established in consultation with suppliers, healthcare institutions, and other stakeholders. It has been agreed that data on medical devices, including relevant certification documentation, will be shared through the Global Data Synchronisation Network (GDSN). Since February 2023, the dataset is fully integrated within the network and datamodel.

Finding a way to easily exchange consistent data on medical devices with all relevant partners.

Explaining the importance of GDSN to all relevant stakeholders

it quickly became clear that we shared the same goal," explains Paauw. Thus, the idea of developing a uniform dataset emerged. It was an intensive process in which both Paauw and Buijs were closely involved. "At first glance, it seems simple to create a list of product properties for medical devices," says Paauw. However, appearances can be deceptive. "To begin with, you need to agree on which product data is considered must-have and what falls under nice-to-have." Eventually, after good collaboration, 37 data elements were determined to deserve a place on the list.

| Manufacturer | GDSN datapool | Hospital |

Introduction

From the well-known pacemaker to the tiny screw used by a surgeon in spinal fusion surgery, it is crucial – sometimes literally a matter of life and death – to have access to up-to-date product information for the safe and effective use of medical devices. In the Netherlands, this data is exchanged through the Global Data Synchronisation Network (GDSN) of GS1.

"*For some time, we have been contemplating how to achieve standardisation in sharing product-specific data with our customers in the healthcare sector,*" says Rick Paauw, Quality and Regulatory Manager at Medtronic, an international player with a portfolio in the Netherlands of over 40,000 medical devices. "*Each hospital had its own formats, resulting in a proliferation of different lists. Besides the time it takes to fill them in, there is also a risk of errors. To bring about change, you need each other because even as a large company, you can't do it alone.*"
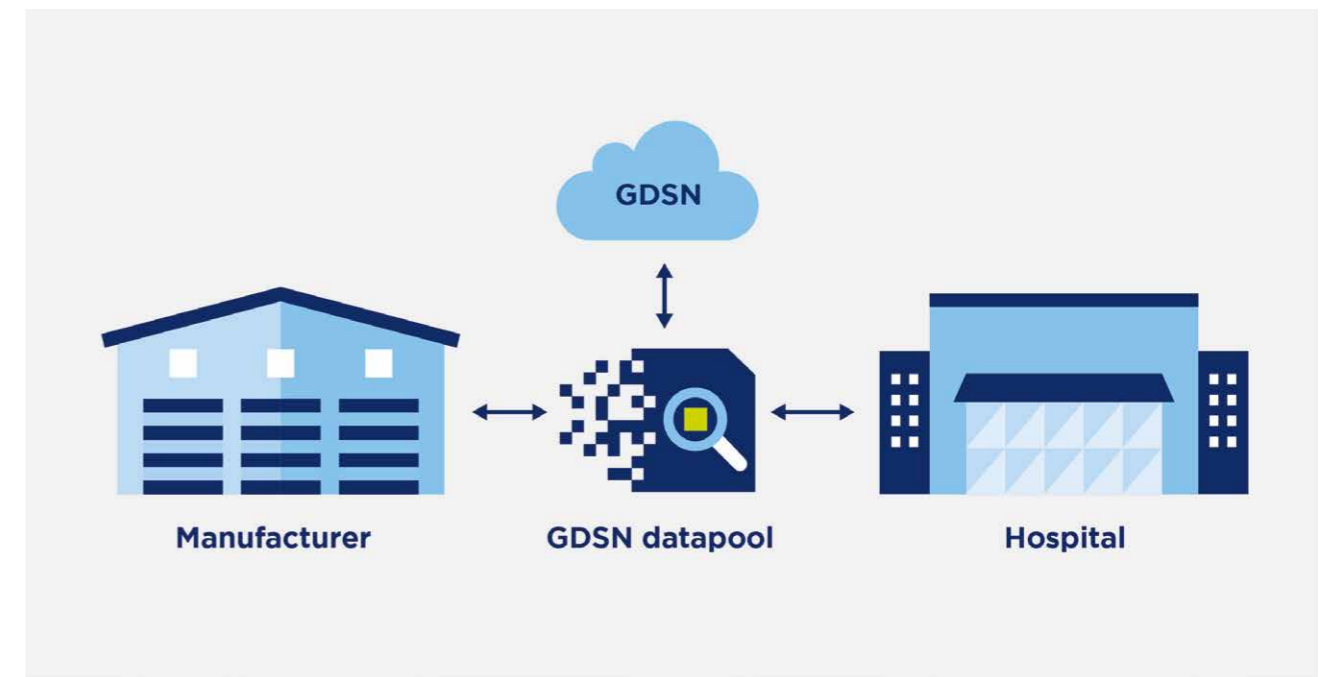
Different formats

Jolanda Buijs, board member of the Association of Experts in Sterile Medical Devices (VDSMH), understands the importance of reliable product data for medical practice. "*We want to be certain that our procedures result in a sterile medical device,*" says Buijs, who is also an accredited expert at Erasmus University Medical Center in Rotterdam in the field of sterile medical devices and cleaning and disinfecting endoscopes. "*Which disinfectant should we use? Which sterilisation method is applicable? The answers to these questions, provided by the manufacturers of the devices, are necessary to guarantee patient safety.*" This data needs to be available and continuously updated based on the manufacturer's prescribed procedure for a new device.

Effort from all parties involved

In spring 2020, a working group of suppliers and hospitals was formed to explore the collective need for standardisation. "In those discussions,

GDSN Datapool

The next question that arose was how to automate the process. The choice was made for GDSN, and that's how the request reached GS1. The implementation was feasible, and GS1 was certainly willing to contribute to process optimisation. "*The key is translating the information we want to receive into proper definitions of the data fields in GDSN. None of us are IT experts, so we greatly relied on GS1's assistance in this regard,*" says Buijs. GS1 created the data fields, and manufacturers can upload the product information into the GDSN datapool, to which 95% of the Dutch hospitals are already connected.

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> **Rick Paauw,**
> Quality and Regulatory Manager at Medtronic

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Sector-wide collaboration

With the uniform dataset, there is now one source via which suppliers provide product data to healthcare institutions and distributors, among other key partners. The next crucial step is to populate the fields with data. "*Actually, this is just the beginning,*" says Paauw.

Buijs agrees. "*If these fields are not filled, there is a chance that healthcare institutions will resort to using the old form that provides the requested data. Only if we collectively, as a sector, put in the effort, this will become a success.*"

Next steps

Implementation is the key

Implementing the setup properly takes time, and filling the dataset doesn't happen overnight, says Paauw. *"Entering the necessary data for the thousands of products in circulation is a significant task. For suppliers, especially larger ones, it's quite a challenge to gather the data internally from various areas of expertise involved in the development of a medical product. Data maintenance is also a vital aspect. Once it's in, it's not done."*

Moreover, hospital systems need to be adapted to easily retrieve the data from the database, from procurement to the operating room. *"Optimising the use of data for processes within healthcare institutions requires considerable effort."*

Product-specific data from the source

"With the dataset, we have a powerful tool to provide product-specific data directly from the source," says Paauw. For Buijs, the availability of validated information through GDSN is also an important step. With the national uniform dataset in place, it replaces the registration form for medical devices used by the VDSMH. However, not everything is entirely seamless as yet. *"We still receive Excel sheets with the familiar questionnaire from hospitals, and manufacturers haven't filled in all the fields. We need to keep educating each other and ensure that our systems are connected to generate the information from the dataset,"* says Paauw.

Conclusion

There is still work to be done, but Paauw and Buijs consider the progress made to be a real accomplishment. Optimal use of the dataset benefits all parties through time savings, cost reduction, and contributes to increased patient safety, which is the ultimate goal. In the end, the more clear and high-quality data is available, the more efficiently processes can run within a healthcare and the less work for suppliers. Paauw adds: *"You might think it's 'just' data, but the impact can be significant if the information is open to multiple interpretations, for example."*

Paauw reports that many hospitals are already using GDSN to meet the requirements of the Dutch Implant Registry (LIR). In the future, the integrated uniform dataset in GDSN is also expected to play a crucial role in meeting the stricter requirements of the Medical Device Regulation (MDR). *"If new legislation is introduced or if hospitals' data requirements change, it will be possible to add or modify data fields. That, in my opinion, is an important feature of the database offered by GS1 through GDSN. The concept is flexible and therefore future proof."*

About the author

Rick Paauw
Quality and Regulatory Manager, Medtronic Benelux

Rick Paauw is Quality, Regulatory Manager Medtronic Benelux. With his team he's responsible for activities like; Regulatory Inquiries, Tender Support, Distributor/Supplier management, Software traceability, Audits at the Medtronic sales offices in Eindhoven and Brussels. Interpretation and implementation of the MDR into the sales organisations was one of the main focus areas during the last years. Rick is also active in multiple working groups within the Benelux and board member of the RAPS Netherlands chapter, organizing congresses for Regulatory professionals, 3 times a year.

Jolanda Buijs
Board member, the Association of Experts in Sterile Medical Devices (VDSMH)

Jolanda is an accredited expert at Erasmus MC in Rotterdam in the field of sterile medical devices and cleaning and disinfecting endoscopes. Besides that, she is Board member of the Dutch Association of Experts in Sterile Medical Devices (VDSMH).

About the organisations

Medtronic is a global producer of medical devices and therapies, such as insulin pumps, pacemakers, and diabetes therapies. Perhaps best known for its revolutionary cardiac devices, such as battery-powered and miniature pacemakers, it has also introduced cutting-edge products into the industry.

www.medtronic.com

The Association of Sterile Medical Device Experts - VDSMH (Vereniging Deskundige Steriele Medische Hulpmiddelen; VDSMH) is a society on behalf of the Specialists of Sterile Medical Devices in Dutch hospitals and was founded in September 1999.

www.vdsmh.nl

Erasmus MC (university medical centre) works to provide top quality clinical care for patients with complex care needs, rare diseases, or acute needs for care and treatment. It provides distinctive, high-quality education that appeals to ambitious, inquisitive, and talented students and addresses the healthcare issues of tomorrow.

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