DIN Media

Achieving success with standards management solutions:

avasis – Digital solutions for medical technology

Medical device safety is ensured by mastering complex regulatory frameworks. avasis supports manufacturers in the implementation of standards and other regulatory documents using Nautos and ReqIF.

avasis
inspiring solutions

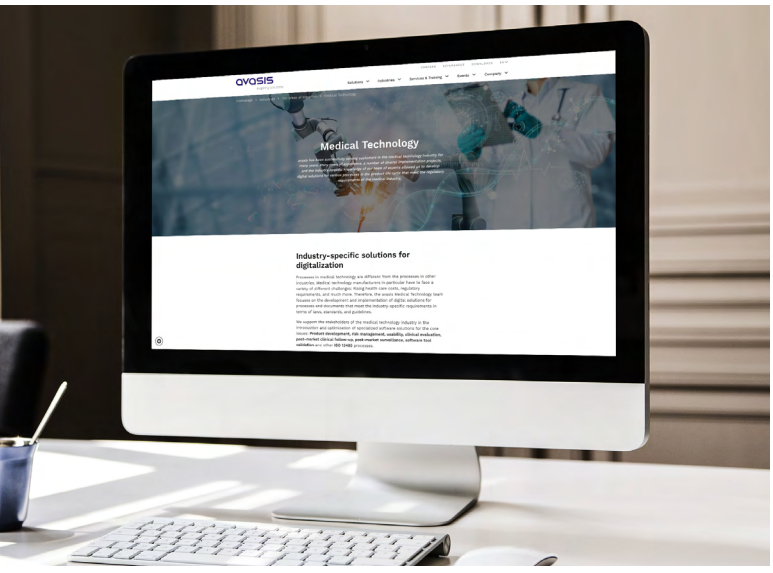
Manage. Your. Standards.

"The main benefit of our devices comes from the digitalization of processes and the automation of manual tasks. This saves our customers time and money."

Derek Crow
Product Manager Polarion Portfolio

"Our aim is to document the information about a medical product digitally. This enables the complete integration of data across different processes and software solutions."

Sarah Panten
Managing Partner, with a focus on strategic business and portfolio development



Find out more about avasis at www.avasis.biz

Sarah, how would you describe avasis?
Sarah Panten (SP): The avasis Group consists of five companies across Switzerland, Germany and Austria. The original parent company (avasis AG, Berneck) has been around for over 25 years, and it has been a long-standing partner of Siemens Digital Industries Software, a division within the Siemens Group that develops software. Siemens' vision is the "complete digital continuity" of processes in order to enable companies to work more efficiently, shorten innovation cycles and access the market more quickly. avasis solutions GmbH (ASG) specializes in software solutions for the medical technology sector and uses the tried-and-true Polarion technology from Siemens. The company was founded over five years ago by Lukas Vogler and myself together with the two shareholders of avasis AG. We both come from a medical technology background and know how tedious it is to work with Word, Excel and PDF documents.

What sets this industry apart?
SP: Medical technology is highly regulated. Medical devices must be safe for patients and users to use. Manufacturers must therefore comply with numerous laws, guidelines and standards with an enormous number of regulatory requirements for development, regulatory approval and post-market surveillance. Some of these apply to all types of medical devices, others only to certain product groups, for example X-ray devices, implants or contact lenses. It is a broad spectrum. A hip prosthesis does not need any software, whereas an ultrasound device needs a wide range of digital functions and algorithms. So we are dealing with many different types of medical devices and companies. Due to this lack of uniformity, the standards cannot cover all applications, which leaves room for interpretation. Nevertheless, all medical technology companies apply the regulatory requirements from various standards and must provide the corresponding evidence of this.

Presumably that requires a lot of effort?
SP: Imagine a huge filing cabinet with many folders containing all the information on the development, regulatory approval and post-market surveillance of a medical device – the "technical documentation". These are often thousands of pages of information that are created during the life cycle of a medical device. Each folder contains information on a specific topic such as electrical safety, biocompatibility or labelling. A manufacturer must work through the applicable standards and assess which requirements the standard specifically stipulates for the medical device under development. And some standards can run up to 800 pages!

Derek Crow (DC): As the regulatory requirements are frequently amended or supplemented by new documents, it is difficult for manufacturers to keep pace. Until recently, standards had to be split up into individual requirements using copy and paste to integrate them into the Requirements Engineering phases of product development. That is a lot of work. With solutions such as Nautos*, standards can now be provided digitally and imported directly into companies' software systems, which makes this work much easier.

Getting started with Nautos is easier than you think!

TALK TO OUR EXPERTS!
We are happy to answer all your questions about standards management.

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www.dinmedia.de/en/standards-management/nautos

And this is where your products come into play?
SP: We digitalize the processes and associated information in our products, following standardized best-practice workflows. DIN Media provides standards and associated metadata as key input. We see ourselves as an interface between the DIN Media products, the Nautos platform and our customers.
DC: This allows us to eliminate media discontinuities and import the data from Nautos directly using the digital ReqIF format. Our customers can continue to work efficiently and link pieces of information together: content of standards, specific device requirements, tests and test results. And best of all: At the end, a compliance report is automatically generated that lists which requirements of a standard apply to the specific medical device and how verification was provided. Firstly, this facilitates the regulatory approval of the device. Secondly, if changes are made in a later version of the standard, it is possible to quickly recognize how these affect the existing documentation, and which requirements or tests need to be revised.

Do your customers need to have Nautos to benefit from your software solutions?
SP: It is not absolutely necessary, but it is an advantage. How we see it, compared to other providers, the DIN Group is a technological leader with its products and services. Our collaboration with DIN Solutions has shown that we are dealing with a dynamic young team that is consistently working to optimize the entire service chain in the field of standardization for the future. This makes us confident that we have found the right partnership.

Who is your target group?
SP: All manufacturers of medical devices as well as other players in the industry such as engineering service providers, consulting companies or suppliers who develop and produce components for medical devices. Most of our customers currently come from German-speaking countries, although we also have a growing number of international customers, including some global corporations. As a result, we also work with teams based in other European countries, the USA and India.

Which standards are important for your customers?
SP: The focus is on the standards that are explicitly important for medical technology. There are around 35,000 medical technology companies in Europe, 92 per cent of which tend to be small and medium-sized. Some of these companies only focus on Germany or Europe and therefore only use German or European versions of the standards. The majority, however, work with the international versions of ISO or IEC standards, for example.

How is digitalization progressing in the medical technology industry?
SP: The large corporations have been leading the way for some years now; however, the majority of the industry is still in the early stages of digitalization. As a result of the European Medical Device Regulation (MDR), adopted in 2017, companies initially concentrated on the renewed conformity assessment of their medical devices, which was required by the regulation. This is why the industry was reluctant to launch digitalization projects until 2021. However, due to the ever-increasing complexity of regulatory requirements and the ever-increasing amount of documentation required, SMEs have now also recognized the benefits of digitalization. We have seen an increase in demand for our products and services over the last one to two years, and other software providers are experiencing a similar trend. This marks a fundamental mindset shift.
DC: In my opinion, more and more companies will want to use standards management systems such as Nautos, and the demand and interest in digital formats and automated import or direct integration of different software systems will increase.

What is the most important benefit for your customers?
DC: The main benefits come from digitalizing processes and information, as well as integrating and automating them. Media discontinuities are avoided, manual copy & paste is eliminated, and regulatory compliance can be easily checked. This saves our customers time and money.

Are there any estimates of how high the increase in efficiency will be?
SP: We know from customer feedback that they save around 30 per cent of their working time, and we continue to develop empirical data on efficiency directly with our customers.

What wishes do you have for the future?
DC: What would be ideal would be for Nautos to provide all standards internationally. But political and licensing hurdles have prevented this so far. We would also like to see a complete standardized digitalization of the standard drafting process, for example working directly in ReqIF format.

Nicola Prokop, Campaign Management at DIN Media GmbH, along with interview partner and freelance author Antje Brunnabend, express their thanks to Sarah Panten, Derek Crow, and avasis solutions GmbH.

* Nautos is an efficient standards management software from DIN Media GmbH. It supports the finding, requesting, managing and monitoring of standards and provides metadata for use.

The Nautos ReqIF converter module is a service within the Nautos platform that makes it possible to convert standards documents into the Requirement Interchange Format (ReqIF). This XML-based format facilitates the exchange of requirements between different systems.