

How Icologiq Elements helps medical devices meet safety requirements

Medicc Sports is an international organisation that supports athletes with means to deliver better performance, combined with a pleasant and more fun sports experience. In this way, every athlete can pursue their personal goals in the sport and simultaneously push their limits. Medicc Sports' development and production process falls into the Medical Devices category, meaning Medicc Sports International can use the Document Management and the Product File modules of Icologiq Elements. The use of these modules helps Medicc Sports International meet the requirements for a medical devices organisation.

In 2017, Peter Deen, IT Manager at MediccSports, was asked by the management to search for a business tool to safeguard the product development process. "I started to analyse the problems behind our product development and this is how I ended up using workflow," he says. "Then, I came into contact with Icologiq and their Elements Platform. All the basic functions that should be included in such a system for medical devices were already developed and available. The approach we chose was simple: merge relevant managed documents into a product file structure, use the workflow capabilities of the system and ensure a transparent authorization model. The bonus was that we were able to integrate our manual and deviation management into the Icologiq Elements QMS system."

The challenge in the field of product files, is in the careful monitoring of the different stages of product development, and the correct safeguarding of the completed steps in the process. A company that works with medical devices has to meet strict requirements, especially when building a development file. The system is configured from standard components, in collaboration with consultants from Icologiq. This way, we quickly arrived at a complete package that meets the requirements for recording documentation under the ISO-13485: 2015 standard. "

The advantages

The other advantage, according to Peter, is not so much in Elements itself, but in the fixed method that Elements enforces. "Because we work with a universal workflow structure, it is easy to switch from one module to another within Elements," he explains. "We can basically make this happen automatically. This is also evident from the use of forms, which is experienced as extremely useful. We used to run into the fact that we didn't always work with the latest version. This is now a thing of the past, our employees never go wrong anymore."

With Elements, you are working according to a fixed method. "This is great, because it prevents you from having a lot of different products, including a separate learning process and operation behind

each product. There is an unambiguous structure in the operation, working method and workflows, this becomes transparent as soon as one knows the product. As soon as you know how to work with Elements, you have direct access to document management, product file and QMS.”

Future vision

Medicc Sports is currently working with multiple modules from the Icologiq package. "Icologiq is in charge of the maintenance of the package, which saves us a lot of work," says Peter. "We don't have to worry that the package is not up to date, that the servers need to be updated, etc. As the entire management process is no longer with Medicc sports, we can now focus on the core business. Medical devices in particular are subject to increasingly stricter legislation, because people will have to be able to access documents more and more easily, and there is a conflict between these both interests: documents have to be easy to access, but at the same time they can't be out on the streets.”

Before the company plans to expand, they will have to grow a lot themselves. “We now have the tools to further expand and implement. This will be a long process, with a lot of work still to be done within R&D. What we will be using is the QMS part, for dealing with product complaints in a structured way. The added value of this is that everything is immediately recorded correctly: the history is easily accessible and you can run statistics. Not only is this important to the management, but it can also prevent you from making the same mistakes twice in the process of developing new products.”

About Medicc Sports

Medicc Sports International brings ultimate sports experience and medical technology together for better performance. The organisation operates from multiple companies and branches with a wide product range. Medicc Sports supplies from multiple brands and is growing fast. Medicc Sports International believes that sport should be accessible and is therefore open to all sport levels, ages and conditions.

This case study is offered to you by Icologiq BV, The Netherlands

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