



How pjur manages world-leading medical device products

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The Company



For more than 25 years, the pjur group has been a globally recognized company whose main focus is on medical and cosmetic products, centred on their core competency of skin care.

The company's product portfolio contains more than 60 premium intimate products, many having received international awards for outstanding product quality, are categorized as MDR Class IIb Medical Devices.

pjur prides itself of its high-quality standards and uncompromising strive for continuous quality improvements in all areas, products as well as processes and workforce education.

The Challenge

With this diverse portfolio of medical device products and a global reach, serving 70 countries on five continents, comes complexity and a high demand for efficient and error-free quality management.

Tracking and implementing regulatory requirements and product specifications comprises an important and significant part of pjur's development and quali-

ty process. Efficient management of these aspects is vital for serving a fast-moving market with innovative products. Handling and realization of the labelling requirements of consumer products in more than 70 countries is an even larger challenge, affecting many of the employees in the quality and the marketing/graphics departments.



**"...That was the major
reason we chose
Aligned...."**

The Solution



To address this challenge, pjur decided to look for a solution and found Aligned Elements. Aligned Elements offered the optimal environment to manage their quality and product labelling data in a clear and structured manner, with focus on easy access to control and revise data.

"The Aligned support team assisted us in adapting forms and input fields to tailor Aligned Elements to our product specific quality needs. An uncomplicated and solution-oriented approach by the Aligned team has certainly contributed to our current quality status," says Andrea Giebel, PRRC at pjur.

The immediate advantage of introducing Aligned Elements was the individualized creation of up-to-date product labels. All employees in the organization now benefit from the tool as the labelling content is easily accessible.

Aligned Elements allows pjur to efficiently control their product labels and texts, benefiting from drag & drop

functionality that makes it easy to create product label inputs. A clear user administration and rights assignment helps the organization to comply with medical device change control requirements and regulations. The pjur workforce uses Aligned Elements daily and plans to continue using the tool across departments.

"Aligned Elements ability to access to old data to compare and contrast labelling content to identify changes is a real long-term benefit. We feel confident in our ability to track and control changes over time, well in line with our high quality standards," says Andrea Giebel, and continues "We estimate that a 90% reduction in documentation errors is achieved by using Aligned Elements. This saves us a significant amount of time and money, that we now can steer towards development of innovative products instead."

In line with its high quality ethos, pjur successfully completed the first MDR audit in August 2022 and received confirmation of conformity in accordance with the MDR Medical Device Regulation (EU) 2017/745.

Aligned Elements and Medical Device Development

Aligned Elements provides Design Control management for design and development inputs & output, reviews, verification and validation activities as required by the EU MDR/IVDR regulations as well as the FDA Quality System Regulations (QSR).

End-to-end traceability, integrated version and review control, document management, and audit trail, all these things covered directly in Aligned Elements.