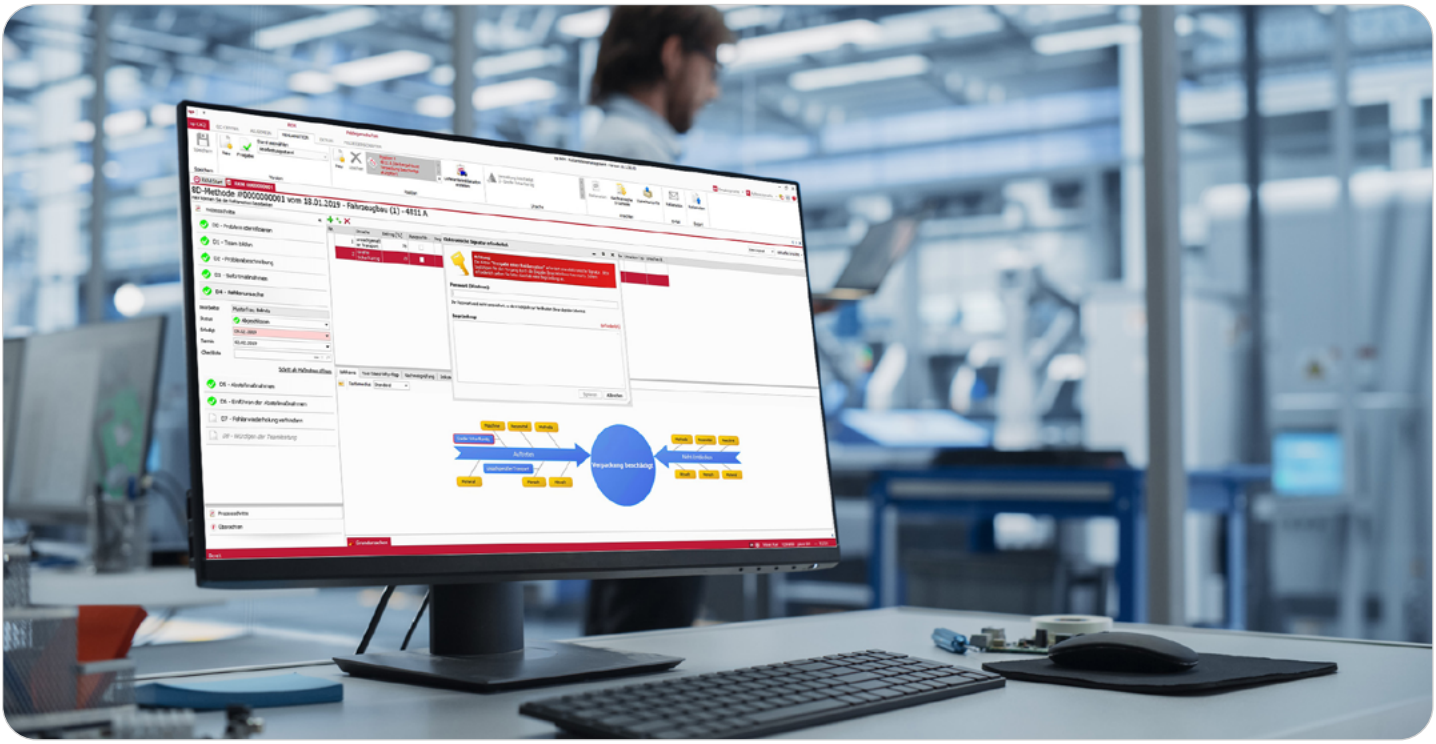
ERBE: DIGITAL QUALITY ASSURANCE IN MEDICAL TECHNOLOGY

FDA and MDR demand highest quality standards

Companies in the medtech industry must meet the highest quality requirements across all markets. They are subject to the strict requirements of the EU Medical Device Regulation (MDR), and for deliveries outside Europe there are additional requirements, above all the regulations of the US Food and Drug Administration (FDA). In order to meet these requirements, Erbe Elektromedizin GmbH from Tübingen, a prospering company with a long tradition, replaced its test cards and Excel files with a professional quality management system back in 2012. Over ten years ago, the choice fell on iqs Software GmbH from Bühl in Baden, one of the two founding companies of PeakAvenue GmbH. Since then, the PeakAvenue eQMS system "Quality Center" has consistently offered highly efficient, individual and secure solutions for the constantly changing production processes and quality requirements - for example, the replacement of the EU Medical Device Directive (MDD) by the EU Medical Device Regulation (MDR) in 2017.

When company founder Christian Heinrich Erbe developed the first constant clinical thermometer in the mid-19th century, the company had only just moved into a larger premises. Over the decades, the one-man business developed into a company with its own employees and a store selling medical and precision mechanical devices, optical products and medical supplies. After World War II, the number of employees increased; in the 1960s, the company began to establish agencies abroad.

Since 1985, the headquarters have been located in the south of Tübingen. Today, the fifth generation of the family-owned company develops, produces and sells systems for electrosurgery, thermofusion, plasmasurgery, cryotechnology and hydrosurgery worldwide - and has thus revolutionized modern surgical options. In the last ten years, Erbe has recorded a 75% increase in turnover and the number of employees has risen by 150% to around 2000, 170 of whom work in research and development alone. Erbe is one of the inventors of electrosurgery, a technology for cutting, coagulating, devitalizing tissue or sealing blood vessels. Erbe's customers include hospitals and specialist practices worldwide.



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Medical Industry – a special case

In 2009, Erbe's quality managers started looking for a eQMS system that would put all quality assurance processes on a professional basis. The focus was on the desire for an electronic signature, as required by the US Food and Drug Administration (FDA) at the time. However, other features such as the audit trail, which was only considered an "optional" requirement at national level but is now firmly anchored in the MDR directive, were also on Erbe's wish list at the time.

The decision was supported by other features of the Quality Center eQMS system: The principle of consistency, i.e. unrestricted data traffic between all quality-relevant modules, was convincing and was seen as being consistently thought through to the end within the Quality Center. The comprehensive inheritance technology for the automated transfer of data between the modules was also expected to result in significant cost and time savings when creating test plans for comparable products. And it was hoped that the automated feedback of information from Complaints Management to FMEA would enable the company to learn from errors, avoid subsequent errors and make FMEA more efficient.

Successful implementation

Erbe decided to purchase a company license that allows all Quality Center modules to be integrated into the company's own quality management system. After an extensive training and test phase, the master and transaction data was transferred from the existing ERP system via an interface. The implementation went smoothly.

Erbe has been using the following Quality Center modules ever since:

- Complaints Management (RKM)
- Failure Mode and Effects Analysis (FMEA)
- Inspection & Control Plan (PP/CP)
- Active Drawing Integration (AZ)
- Action Management (MM)
- Incoming Goods Inspection (WE)
- Inspection Data Acquisition (PDE)
- Outgoing Goods Inspection (WA)
- Inspection Equipment Management (PMV)

Increased efficiency, reduced costs

Erbe benefits greatly from the new PeakAvenue eQMS system Quality Center.

The crucial benefits include:

- Simplified inspection planning thanks to versioned management of the inspection plans,
- A simplified inspection process for the inspector thanks to digital processing and the integration of the inspection plan into the overall eQMS system,
- Simplified FMEA creation and maintenance thanks to the derivation of a baseline FMEA,
- more efficient use of FMEA by integration into the quality control loop,
- Simplified maintenance and deployment planning of inspection equipment.

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Electronic signature

Due to the special regulations in the medical industry, the requirements that Erbe and therefore PeakAvenue's eQMS software must fulfill are very high. The implementation of an electronic signature was solved by PeakAvenue in a very user-friendly way: To confirm and thus approve a process, the user authenticates himself with their user ID and password.

Audit Trail

In addition to the electronic signature, a so-called audit trail is required by the regulatory authorities. The FDA defines an audit trail as a secure, computer-generated and time-stamped electronic record that allows the history of events related to the creation, modification or deletion of electronic records to be traced. The structure and design of the Quality Center make it possible to document and archive the questions of "who changed what, when and why" and, if required - for example during audits - to retrieve them again in a readable format from any eQMS module. The employee must justify the change and sign it off - this effort is unavoidable, as this is the only way to meet regulatory requirements.

Software update and validation

Computer System Validations (CSV) are necessary on a regular basis; the software must be tested according to strict specifications. The introduction of the EU Medical Device Regulation (MDR) in 2017 also defined new requirements resulting from the regulation, which were implemented in PeakAvenue's specifications. For example, it was now important to ensure the traceability of serial numbers. PeakAvenue was able to adapt the software so it could also store these numbers. Erbe works very closely with PeakAvenue on updates and validations.

Erbe installs the software updates independently at any time. In the case of a major version update or other comprehensive software updates, the test phase, in which several Erbe employees are involved, can take up to a month. A total of two version jumps took place. Discrepancies were reported back to PeakAvenue during the test phase and anomalies were quickly rectified. Once the test phase was complete, the migration to the productive system was completed. PeakAvenue took over the migration protocol. The necessary software validation was carried out by Erbe. The delta reports that PeakAvenue provides between each service pack were very helpful in this regard. This means that Erbe can concentrate on the main changes to the software and does not always have to carry out a complete system validation.

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Customer-specific wishes

Erbe uses many different computer systems from various providers. PeakAvenue was always open to software adaptations and improvements in order to connect these optimally to the Quality Center. It was a great advantage that one and the same contact person was always available over the many years of cooperation. This person was therefore very familiar with the history and special features of the software at Erbe. Another very helpful aspect was the customer-oriented perspective, with a commitment to getting to grips with Erbe's software in order to understand it.

Many special features in Erbe's production processes resulted from the rapid technical development and constant further development of the products. PeakAvenue was also able to support the company's enormous growth excellently: The rollouts in the USA and China went smoothly and quickly.

Conclusion and outlook

The merger of iqs Software GmbH with PLATO GmbH and Isograph Ltd. to form the new provider PeakAvenue marks the imminent switch to a cloud-based web application. At the end of 2024, PeakAvenue and Erbe launched a strategic development partnership to jointly develop innovative solutions for the medical technology industry. By pooling their specialist knowledge and technological expertise, the partners are working to tailor the PeakAvenue cloud to the specific requirements of medical technology.

The plan is to move all modules step by step and complete the migration by 2026.

CONTACT

Do not hesitate –
Get in touch with us!

By phone
+49 451 930 986 0

By e-mail
info@peakavenue.com

PeakAvenue GmbH
Maria-Goeppert-Straße 15
23562 Lübeck

www.peakavenue.com

Social Media

Youtube

LinkedIn