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SAMAPLAST AG
KUNSTSTOFFTECHNIK

Customer since 2006

Validated Quality

Medical technology producers and suppliers have to submit to the high demands of European medical production standards and those of the US Food and Drug Administration FDA. In order to meet the general requirements of these quality standards for validation and for quality management purposes, Samaplast AG, the Swiss specialist for plastic die casting, relies on CAQ AG Factory Systems software solutions.

Samaplast AG products affect people intimately: the Swiss company manufactures, under the most stringent hygienic cleanroom conditions, implants for the knee, hip, and spine. Additionally, the company manufactures complementary medical products, such as dental components, catheter attachments, and medical instruments. Precision is also part and parcel of Samaplast's other field of expertise, namely technical die casting. In this area of manufacturing, Samaplast mainly produces components for optical and mechanical industries. This emphasis in manufacturing has guided Samaplast's processing of thermoplastics into plastic components since 1960.

Micro-process controlled die cast machines with 150 to 3500 kN clamping force achieve precise manufacturing of components, in 0.0005 to 1,000 Gramm dimensions, which satisfy the highest demands. Samaplast manufactures these components for global corporations, such as Synthes, Straumann, Abbott, Zimmer, and Leica.

Quality According to Medical Specifications

Due to Samaplast products' application areas, demands on quality are extremely rigorous, because people's well-being and health are dependent on these products. DIN ISO 9001:2008 and ISO 13485:2003 certifications as well as registration with the FDA (Food and Drug Administration), the agency in charge of approving pharmaceuticals in the US, attest to the highest quality criteria adherence, achieved by employing an efficient QM-system.

Samaplast's QM-system is based on CAQ AG software solutions **CAQ**.*Net*®. Samaplast used custom-created and mainly manually maintained Office applications to meet the demands of the relevant standards and those of the QM-system before the company implemented the CAQ software. As the number of necessary documents and key figures increased, this manual and print-based system proved to be more and more time-consuming and inflexible. To address these shortcomings, Samaplast began in 2006 to inquire about a state-of-the-art software solution for its quality management.

The company was looking for a system which could handle the stringent demands of the US Food and Drug Administration (FDA) concerning authorization concepts, audit trail, and release management, as well as include references relevant to areas of medical technology. FDA requirements limited the number of available software providers considerably and therefore Samaplast narrowed its search to include only those providers who had extensive experience in the field of medical technology.

Samaplast used the following criteria in their selection:

- Modular and freely scalable standard software: Depending on customer demands, modules should offer the possibility to be custom-assembled and individually configurable. This way cost-efficient and tailor-made CAQ-solutions can be realized.
- Standard software that is simple to validate with verification of suitability compliant with standards (e.g. DIN ISO 13485) and statutory demands (e.g. GMP or FDA 21 CFR Part 11)
- Risk management as well as CAPA (Corrective and Preventative Actions) with a central procedure management used to control and monitor corrective and preventative actions.
- Document management system with automatic, standard-compliant control workflow and web-based publications in Intranet and Internet
- Integrated rights and role concept combined with electronic signature and Audit-Trail functionality
- Integration into existing IT-structures (e.g. ERP or PPS systems)

After careful consideration and comprehensive evaluation of products available on the market Samaplast decided to use CAQ AG' **CAQ**.*Net*®, one of the leading software providers of validated quality management systems.

Customizable Norm

Subsequently, after a few short weeks, Samaplast installed a modular and adaptable standard software, which was then expanded incrementally according to Samaplast specifications. The first software expansion included a

document management system, followed by rejection, audit, and gauge management software. Since then, the software system has grown to be a custom-tuned system which records and documents adherence to the strict quality guidelines on two-thirds of Samaplast company computers.

Concomitantly, CAQ AG specialists and consultants of IQC AG, a partner of CAQ AG specializing in IT-system qualifications and validations in regulated environments, conducted a comprehensive analysis of the company's existing software and hardware structure. They analyzed and optimized internal Samaplast processes involved in change management, security management, and process management.

CAPA Error Management

The heart of the implemented CAQ system consists of a risk management in combination with a CAPA error management. Dealing with risks is a central task of Samaplast's company leadership. Hazards that threaten the company's existence must be recognized early and eliminated immediately. Therefore, a systematic process to identify and evaluate risks in advance must be in place. An established risk management process is also an important requisite to limit product liability and process validation. To minimize these company risks Samaplast also installed a CAPA error management system compliant with EN ISO 14971.

With CAPA error management (see explanation box) it is possible to collect, evaluate, and document efficiently deviations from standards, customer complaints, inspection monitoring, revisions, demands for changes, and the resultant procedures for corrections and preventions compliant with compulsory demands. Conventional manual, paper-based methods are slow, inefficient, and error-prone in comparison. They risk that identified defects are monitored imperfectly and compulsory requirements are not taken into account adequately. Overall, processes for deviation and complaint management become more transparent, quicker, and therefore more effective.

With the help of CAPA all potential defects in products and errors in processing are recorded and evaluated. CAPA makes it possible to analyze trends based on collected data and gives users the necessary indications to compile effective corrective action plans. The CAQ system documents and archives all information compliant with GxP starting with deviations in production to customer claims to concisely applied actions with subsequent evaluation of effectiveness. CAPA accompanies product and processing quality from manufacturing to distribution to customer delivery, in short, along the entire value added chain.

Ahead of the Competition

In addition to CAPA error management the CAQ system provides for traceable and standard-compliant documentation of all quality-relevant processes, data, evaluations, and documents. All information can be attained with just a few mouse clicks from a central database and therefore create transparency which would have been inconceivable with traditional isolated software solutions. After just a short time obvious improvements became apparent that by far exceeded expectations. In the past, complex datasets could only be evaluated within limits with Excel or other Office applications. Analysis was time-consuming and not always meaningful. **CAQ***.Net*® compiles comprehensive, meaningful quality reports and evaluations. With **CAQ***.Net*® Samaplast has a high-performance analysis tool and can recognize system errors very early on and therefore evaluate and avoid risks.

While in the past it could take weeks for the company to recognize the error system and implement remedial actions after an error occurrence, now this can be done within a few days. Immediate results allow for instantaneous actions and hence lead to significant savings and image improvement in the eyes of the customer. Moreover, with detailed and comprehensive information the company can evaluate and securely negotiate liability and guarantee risks.

With **CAQ***.Net*® Samaplast was able to drastically reduce time-consuming routine actions, such as logging audit trails, applying modifications and revisions, controlling actions and their status, and copious release procedures. Samaplast could eliminate redundant manual double acquisitions of data by adding the ERP system Abacus into the CAQ software. Additionally, they no longer have to add QM-data, acquired elsewhere in paper format, laboriously into the quality management, and instead can enter it directly into the CAQ system. This saves time, costs, and eliminates errors during input.

Validated Compliance with Standards

Samaplast's implementation of its new CAQ system was an essential tool to realize re-certification of ISO 9001 and ISO 13485. Currently, they are completing the final steps of software validation in compliance with medical regulations; the so-called installation qualification (verification of successful installation) has been completed successfully and the "operational qualification" (verification of function) is scheduled. Due to CAQ software's modular system Samaplast has scheduled an expansion of the system to include **AuditTrail***.Net*, which allows complete retracing of all changes in the CAQ system, as well as **Success***.Net*, a central balanced score card for all Samaplast identification numbers.

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