Measurable and Reproducible Processes in the Cleanroom

Quality Management Software

The food, pharmaceutical, and medical industries place the highest demands on product safety. Parts that Pöppelmann manufactures for this sector are injection molded or thermoformed under cleanroom conditions. In order to certify for the required cleanroom class, the plastics processing company relies on software by CAQ AG.

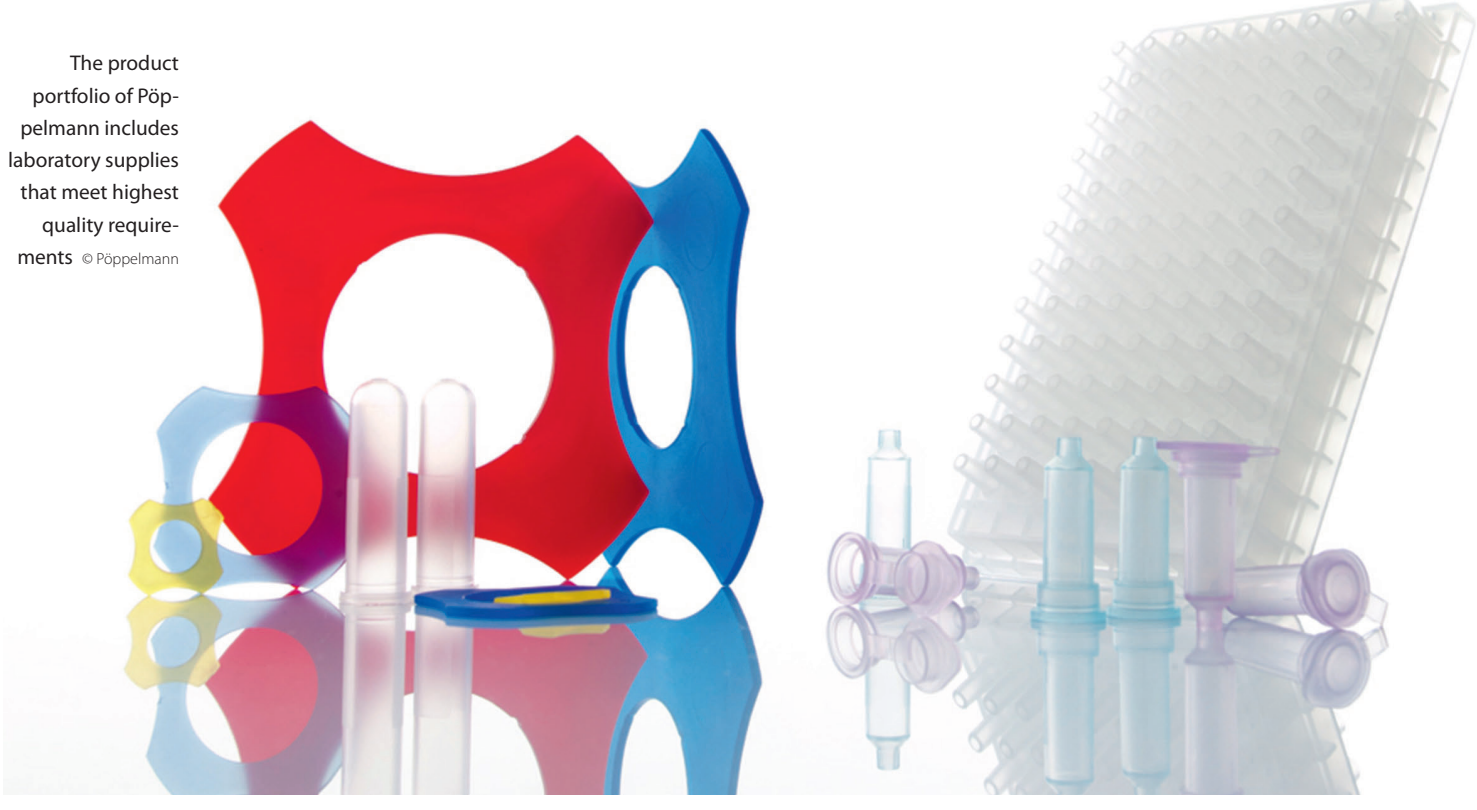
Pöppelmann GmbH & Co. KG has in the more than 70 years of its existence become one of the leading manufacturers in the plastics processing industry and the company's product portfolio includes a total of four divisions (**see Box p. 8**).

The Famac division occupies a special position with regard to standard requirements and official regulations to be complied with. It is a manufacturer of components and packaging for the food, pharmaceutical, and medical products industries and is therefore subject to the highest requirements for product and user safety. Certified to DIN EN ISO 9001, ISO 13485, and BRC Packaging, among others, Pöppelmann's Famac division manufactures parts using injection molding and thermoforming processes under cleanroom conditions in accordance with DIN EN ISO 14644–1 Class 7, GMP Class C.

Goodbye Excel, Goodbye Paper

Today, the Famac division is supported in terms of quality assurance by CAQ AG's holistic CAQ.Net software solutions. One of the reasons for implementing CAQ.Net was that previously there was no dedicated software for QM processes. Procedural and work instructions were managed on paper, and training management was accomplished with a non-validatable Excel solution. In general, too many isolated applications were in use at Famac, which, in the absence of interfaces, led to redundant, incorrect data. Due to a lack of user rights structure and audit trail, the legacy system, which consisted in part of HTML programming on the intranet, was generally not validatable and prevented the fulfillment of standards and customer requirements with regard to the validation of computer-based processes and the guarantee of data security and data integrity.

The use of CAQ.Net software at Pöppelmann began in 2015 with the introduction of the modules for document management, process management, and training management in connection with the central quality control module. In 2018, the modules for incoming goods inspection, production inspection, com-



The product portfolio of Pöppelmann includes laboratory supplies that meet highest quality requirements © Pöppelmann

plaint management, and gauge management were added, as well as audit management and supplier management in 2019. This was followed in 2020 and 2021 by the solutions for gauge capability testing, change control, initial sample inspection, and KPI visualization.

Step by Step Expansion of Quality Management Instruments

During the successive rollout of additional modules, the company was able to draw on the experience and concepts gathered during the initial implementation of CAQ.Net in 2015 as well as the expert know-how of those responsible for computer software validation (CSV) in accordance with ISO 13485 and GMP.

ISO 13485 and GMP? Successful Validation Requires the Correct Approach

When it comes to validation, you cannot just run off blindly – you have to know exactly where you want to go and have a clear approach. In terms of specifications, documented evidence, VMP, RA, plans or reports, Pöppelmann first had to define what the (GMP-) critical operations and processes were and how they would be tested and validated before going live. Instructions and tutorials had to be drafted describing workflows and system configurations and containing work instructions for all modules and workflows as well as technical reports on configurations (system settings, etc.). Since there was to be no user authorization without proof of training, clear qualification requirements were defined for user groups, which could conveniently be monitored directly with CAQ AG's training and qualification management module. Finally, a decision had to be made regarding an update strategy. The company chose a frequency of one update per year, including regular update evaluations, risk analyses, and relevance assessments, as well as continuous requalification with new, comprehensive plans and tests. CAQ AG supports this strategy by regularly providing complete documentation of all changes and enhancements made to the software modules. In the context of validation, there »

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Cleanroom conditions according to DIN EN ISO 14644–1 Class 7, GMP Class C apply in production © Pöppelmann

One Company — Four Divisions

Since 1949, the company **Pöppelmann GmbH & Co. KG**, with 2500 employees at five production sites in three countries and 700 injection molding machines, thermoforming lines and extruders, has become one of the leading manufacturers in the plastics processing industry. Pöppelmann's solution portfolio is divided into four divisions that operate principally on an industry-specific basis:

- The Kapsto division is one of the world's leading manufacturer of caps and plug, according to company statements
- K-Tech is a supplier primarily to the automotive industry
- Teku provides plant pots, trays, and individual solutions for commercial horticulture
- Famac is a manufacturer of components and packaging for the food, pharmaceutical, and medical device industries

was still the issue of the user rights concept. In the course of the validation, Pöppelmann had to develop a concept that regulated in detail who from the staff is allowed to do what, when and how in the software. The decision was made to divide the software into viewer, user, key user, and admin/subject admin.

Who's Who: The User Rights Concept

The designed user rights concept – including single sign-on (LDAP) – was transferred to all individual CAQ.Net software modules in the company using the cross-modular System.Net system settings control module:

- The **Viewer** is a guest user of a module. He can start the module and view contents but has no editing rights.
- The **User** is a user of a module who requires specific training/qualification. He may access an application but has no configuration rights.
- The **Key User** is a specially trained user with additional user rights. He can e. g. edit module-specific libraries.
- The **Admin/Subject Admin** is an employee with administration rights. In total there are two system admins and one subject admin per module.

Is He Allowed to Do That?

The need for a well-thought-out user rights concept becomes clearly evident in the case of inspection planning, inspection data acquisition, and SPC at Pöppelmann. While only three trained inspection planners create and monitor the approx. 1850 active articles as well as article variants and family inspection plans in inspection planning, the subsequent inspection data acquisition is of a much different order of magnitude. Around 150 trained employees and inspection data recorders gather inspection data at 20 measuring stations on the production shop floor itself and at dedicated quality assurance/quality control (QA/QC) sites.

For this purpose, six measuring machines, three tension-pressure machines and various hand-held measuring devices are used. The order control for the inspection data acquisition is carried out by means of an interface to the ERP and PDA system and regulates both the fully automatic registration and updating of the inspection orders as well as the assignment to the individual measuring stations at production and QA/QC levels. The distribution of user rights distinguishes here, for example, in manual inspection data acquisition between the "IDA" user group in production, which only has rights for data acquisition, and the "IOP" user group in QA and QC, which has more extensive rights for order logoff and inspection order processing.

Intelligent Software Facilitates Standards-Compliant Processes

Today, Pöppelmann has a holistic, validated software solution at its disposal, which is characterized not least by an intelligent user rights concept, a uniform system interface, and a high degree of networking and integration into the existing system landscape. Through secure and valid workflows and processes, as well as the avoidance of redundant data, the CAQ solution creates the highest levels of data security and accompanying trust in production-wide processes and quality management. The detailed validation process thus created intelligently implemented software that consistently enables standards-compliant work in accordance with ISO 13485 and GMP. In addition to consistent audit security, this also leads to increased product quality and associated customer satisfaction. ■