Reference

Qualification of an injection moulding plant and validation of the injection moulding process

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Validation of an injection molding process & qualification of an injection molding system

for HEMA Formenbau und Kunststoffverarbeitung GmbH

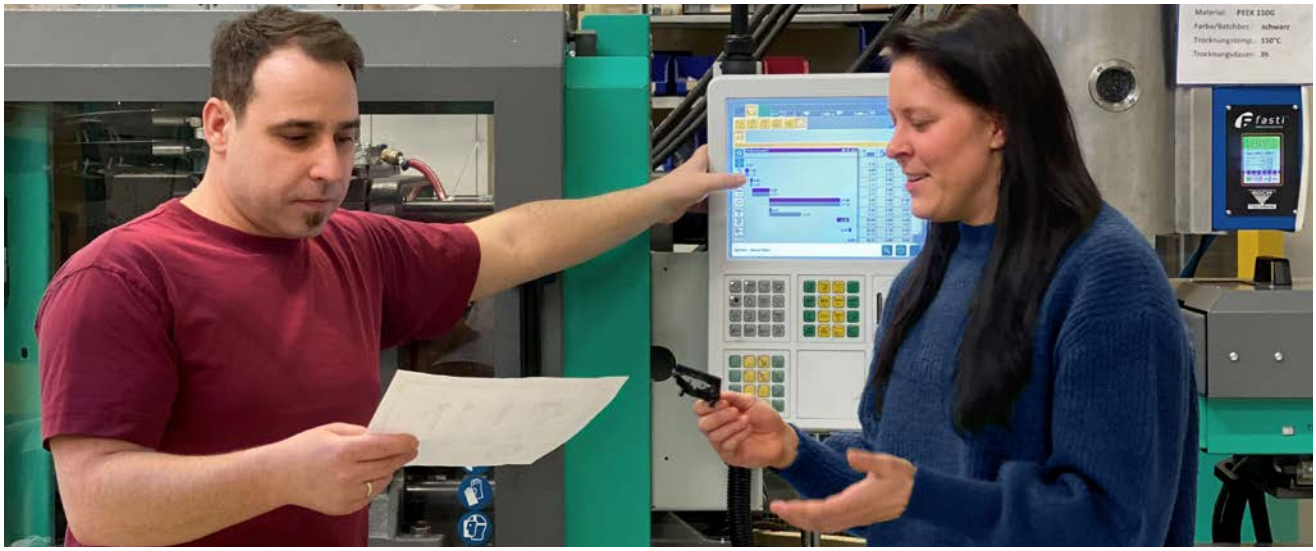
HEMA Formenbau und Kunststoffverarbeitung GmbH, based in Jena/Thuringia, was founded in 1990. On 2,400 m² of hall space, the medium-sized industrial company produces injection molded parts for various industries. These include companies from the automotive, medical technology, the photographic, optical and electrical industries.

The company specializes in the production of fine parts in small series. The range of services includes mold making of injection molds and die casting tools. State-of-the-art machinery with special high-performance injection molding machines guarantees customers high-quality products that can be quickly deployed.

The goal

In accordance with DIN EN ISO 13485:2016, manufacturers of medical devices are required to provide evidence that their suppliers have qualified their equipment and validated their production processes. This obligation also extends to suppliers in supplier management.
HEMA is a supplier of a well-known manufacturer of medical products and has been asked by the manufacturer to qualify equipment for production and to validate the associated processes.

The objective of the order placed by Testo Industrial Services with HEMA was the retrospective qualification of an injection molding system and the subsequent validation of the customer-specific injection molding process for two components of a medical product. The exercise of the interface function between the supplier HEMA and its medical technology customers was a particularly exciting challenge.



The scope

The company HEMA is a specialist in injection molding technology and mold making. Additional requirements for qualification and validation arise from the medical technology industry in accordance with the DIN EN ISO 13485:2016 standard. With Testo Industrial Services, HEMA has chosen a competent service provider in the field of qualification and validation in the environment of medical device manufacturing.

The following points were essential for the project execution:

- Pragmatic processing and documentation structure that fits HEMA‘s specialization.
- Fulfil regulatory requirements and internal requirements of the medical device end user.
- Best practice approach that can later be transferred to other processes.
- Develop a scalable company-specific documentation format for future validations.
- Performing the interface function between HEMA and the end customer.

Special features

- Pragmatic implementation of the requirements and specifications of the end customer (medical device manufacturer) to the supplier HEMA.
- Interface function of the Testo Industrial Services team to the medical technology end customer and HEMA.
- Consulting and conception.
- Mediation and exchange of medical technology Expertise between the Testo Industrial Services team and the HEMA team.
- Best Practice Approach: Development of a scalable company-specific documentation format for future validations.

Services of Testo Industrial Services

- Creation of a validation master plan
- Carrying out a risk analysis (FMEA)
- Preparation and execution of the installation qualification, functional qualification and performance qualification
- Process-related implementation of the validation
- Final summary and evaluation of the validation in the validation report

The result

- Development of a pragmatic regulatory compliant documentation approach.
- Pragmatic and process-based conceptualization of validation.
- Best practice approach to creating company-specific documentation templates.
- Completion of project-related qualification and validation documents „Just in Time“ within a tight timeframe.
- Project support and monitoring by experienced validation experts.
- Smooth coordination of the implementation of the medical technology manufacturer‘s requirements in the customer‘s production environment.

Interview with Frank Juhe, Head of Plastics Processing at HEMA Formenbau Kunststoffverarbeitung GmbH

Testo Industrial Services: *Mr. Juhe, HEMA has never been in the situation of having to validate your manufacturing processes?*
Frank Juhe: In fact, as experts in injection molding in plastics manufacturing, we supply customers from a wide range of industries. With the exception of our customers in the medical technology sector, we have not yet had to meet this requirement.

Testo Industrial Services: *What were the particular challenges in this validation project?*
Frank Juhe: Above all, the transfer of knowledge between our customer with regard to validation and our core competence in injection molding was the core task and the largest challenge. Testo Industrial Services was convincing as the ideal interface to achieve a good result for all sides.

>> The validation engineer mastered our project with great knowledge and competence. Structured approach to work and high flexibility yielded excellent results. More joint projects will follow. <<

Testo Industrial Services: *How did you find Testo Industrial Services as a partner for the project?*
Frank Juhe: Since we did not have any expertise in this area ourselves, after research I found Testo Industrial Services GmbH as a possible cooperation partner. The combination of expertise in the area of qualification and validation, as well as the focus on medical technology, seemed to be a perfect fit for us.

Testo Industrial Services: *What was the course of the project like?*
Frank Juhe: Already in the first conversation, I was convinced by the company‘s appearance and professional competence in validation for medical devices. After further discussions between Testo Industrial Services, our customer and us, all parties had a good feeling. And in addition I had the impression that Testo Industrial Services can not only validate in the Big Pharma environment, but can also perform a validation pragmatically and process-related. Professional competence and collegial cooperation brought our project forward quickly right from the start.

Testo Industrial Services: *How would you describe the overall cooperation with Testo Industrial Services?*
Frank Juhe: It was a trusting one from the beginning, goal-oriented and pragmatic cooperation.

Testo Industrial Services: *Did the commissioning of Testo Industrial Services result in concrete benefits for HEMA beyond the validation of the manufacturing processes?*
Frank Juhe: Yes definitely! We now know precisely what specific requirements our customers in the medical technology sector have. It was also very valuable for me that Testo Industrial Services „thought outside the box“ during the project and supported me in creating GAP analyses.

Testo Industrial Services: *: Were you satisfied with our performance and how do you rate the professional qualifications of our employees?*
Frank Juhe: I was highly satisfied with the cooperation. All the requirements set by us and our customer were met in full and completed effectively and quickly thanks to a very structured way of working. The on-site employee distinguished herself through very good expertise and high flexibility and thus delivered excellent results for our end customer.

Testo Industrial Services: *: Would you choose Testo Industrial Services as your service provider again for a new project?*
Frank Juhe: We have already discussed the cooperation for the next two years. During this time, all validations will be carried out in-house by Testo Industrial Services - so yes, we would.

Be sure. testo

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