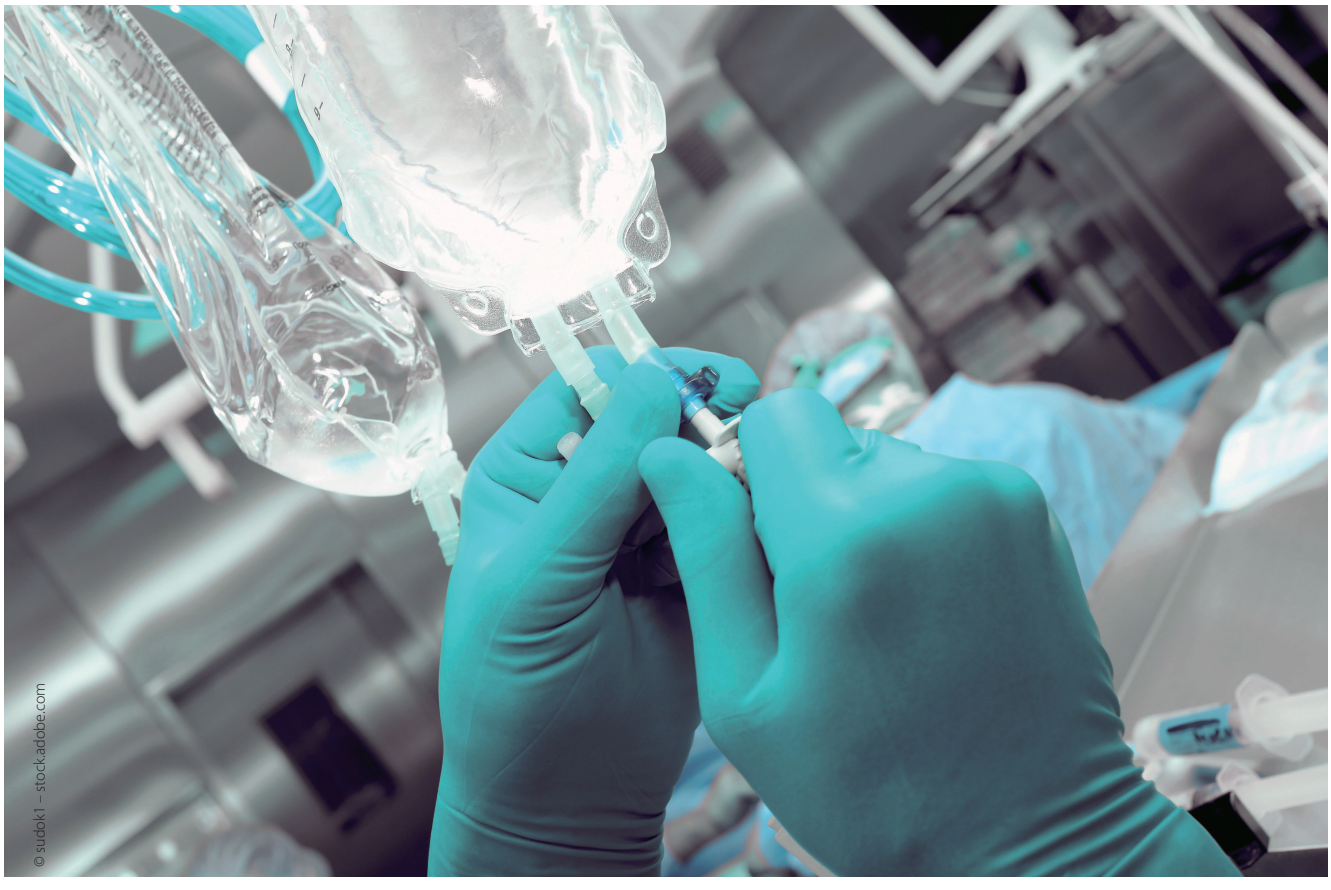
VDI ProValiMed Guideline Project Launched

Making Converters Fit for the Manufacture of Medical Devices

In particular, for component manufacturers, also called converters, the validation of processes under the new Medical Device Regulation is a challenge – whereas the product manufacturers of medical devices already have ways of approach worked out for that. The ProValiMed 2023 initiative sets guardrails with the help of a new VDI guideline. The aim is to use the guideline to create a generally agreed consensus in the sense of "good practice". As a guideline for action, it defines framework conditions for processes of manufacturing plastic components for medical devices.



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Safety of users and patients are indispensable requirements for medical devices. In addition to clinical evaluation and testing of usability, the validation of product properties and manufacturing process in the development is therefore of particular importance (**Fig. 1**).

International regulations, such as the recently revised Medical Device Regulation MDR 2017/745 [MDR17] of the European Union with regard to increased requirements for patient safety, call for validation of the manufacturing processes as part of the development process. The MDR defines safety as an essential performance requirement for the medical device. The requirements for the validation of the process are not explicitly defined. However, for technical documentation, specifically for the design and manufacturing information, the regulation requires „complete information and specifications, including

the manufacturing processes and their validation, their adjuvants, the continuous monitoring and the final product testing." (MDR 2017/745, Annex II, pt. 3b). Further explanations for validation are still open. Standards describing quality management systems for medical devices, such as ISO 13485 [ISO16], on the other hand, elaborate on the concept of validation in more depth: „The organization shall validate any processes for production and service provision where the resulting output cannot be or is not verified by subsequent monitoring or measurement and, as a consequence, deficiencies become apparent only after the product is in use or the service has been delivered." (ISO 13485, 7.5.6 Validation of processes for production and service provision).

This assessment is also made by the Experience Exchange Group of the Bodies Notified under the Medical Devices Regulation (EK-Med), a national body of the Central Authority of the Federal States for Health Protection with regard to Medicinal Products and Medical Devices. Sterilization processes, cleaning processes, aseptic filling, packaging processes for sterile products, coating processes, injection molding, soldering, gluing, welding are named as processes to be validated [EKM07].

AiF Project "ValiData" Delivers First Solutions for Injection Molding

It is clear that validation of the process is required, but the regulations deliberately do not include explicit requirements for validation and place this in the hands of the manufacturers placing the product on the market. The AiF project "ValiData" aims to provide an initial approach to validation specifically for the injection molding process. The Institute for Plastics Processing (IKV) Aachen, Germany, is currently investigating methods for validating injection molding processes for medical technology through process control strategies as part of a joint industrial research project [AIF20].

The product manufacturers of medical devices have meanwhile developed their own strategies and approaches to validation, adapted to their products and manufacturing processes aligned with the Notified Bodies. This marks an individual approach that is customary in the industry, but also results from the fact that standards and guidelines for orientation have not yet been available for this topic.

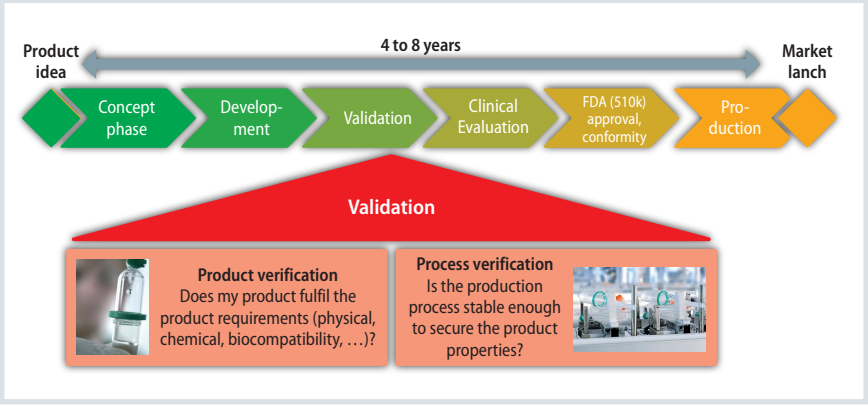

Fig 1. Validation as an integral part of the medical device development process.

Source: B. Braun Melsungen AG; graphic: © Hanser

In particular, small and medium-sized converters respectively producers of components who act as suppliers for various product manufacturers are faced with major challenges against the background of the growing requirements for process validation. After all, they have to organize their own manufacturing processes accordingly and establish a validation process that conforms to the regulations. Process validation requires both time and capacity resources. It must be planned and taken into account at the right time. The documentary effort involved in validation should not be underestimated. Different views on the contents and procedures within the scope of a validation between customers and suppliers sometimes not only cause friction and discord in the project process, they can even lead to a considerable delay.

The need for a framework guideline for plastics processing was recognized by the VDI technical working group "Plastics in Medical Technology". In April 2021, the VDI guideline project 2023 "Validation of plastics processing for medical – ProValiMed" was launched. The aim is to develop a guideline that provides guarding rails and framework for the validation of manufacturing processes for plastic components. This should enable converters, i.e. component manufacturers, in particular to design their own validation processes based on it. The guideline focuses on the injection molding process, although it can also be applied to other plastics processing methods such as extrusion, film production and welding processes. In this way, it should also be possible for manufacturers previously unfamiliar with the sector to align their own processes accordingly with the requirements of medical technology in order to gain a foothold in the industry. Another important aspect is that customers can refer to these guardrails. Often the product manufacturer who brings the final »

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References & Digital Version

You can find the list of references an a PDF file of the article at
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product into the market is not an expert in plastics processing. He does not have to be. For both sides, it is therefore important to avoid unnecessarily overshooting the mark due to lack of knowledge.

25 Experts Structure the Guideline Piece by Piece

The working group consists of about 25 representatives of product manufacturers, producers (converters) of plastic components, universities and machine manufacturers as well as experts from statistical data analysis. Together, they started last year to design the structure of the guideline and to fill it bit by bit with content. The guideline addresses the various aspects of validation for component producers and manufacturers (**Fig. 2**).

In a first step, the roles and responsibilities of the actors are to be defined. The section "Regulatory requirements" describes the context of the topic of validation in relation to the legal requirements. The concept of validation is based on a risk-based approach with regard to the use of the medical device, which is presented in a separate chapter. The methods of statistics and test specifications form the statistical toolbox of validation, terms such as sample analysis, AQL values or process capability are thereby explained. The procedure for determining process limits and validation strategies, for example for similarity consideration and analogy conclusions for the validation of comparable processes up to recommendations for action for revalidation or the procedure for changes to the process (Change Management) also mark up an important part of the guideline. Further topics are the handling of process data and the documentation for validation.

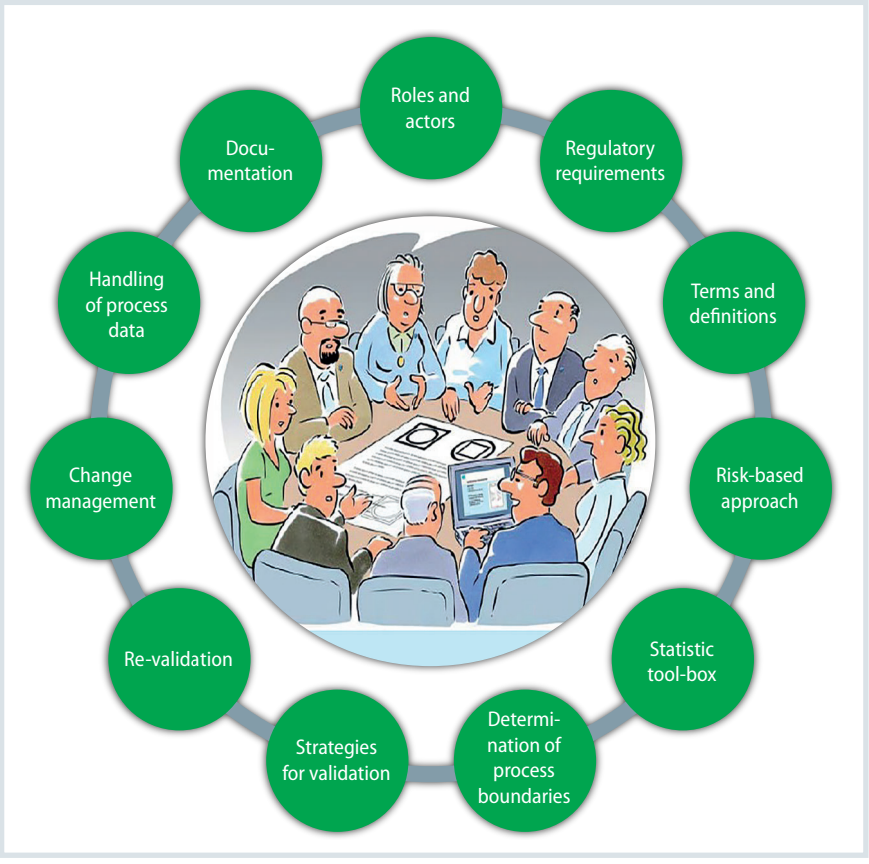

Fig 2. Thematic fields of the VDI Guideline 2023 "ProValiMed".

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The validation of the medical device itself is not the subject of the guideline work described, as this is the responsibility of the manufacturer. The focus of the guideline work is rather to be placed on the development of validation concepts for the manufacturing process of the components with regard to the aforementioned procedures and thus to address in particular the manufacturers of plastic components such as medium-sized processors respectively converters but also manufacturers of medical devices.

What is the roadmap for the future? Now that the structure of the guideline is in place, the various topics are currently being worked out in a joint dialogue. The working group does not see itself as a closed circle; other interested parties who would like to contribute their expertise on the topics are highly welcome to contact the working group via the authors of this article. A draft, the so-called "greenprint", which will be presented to the public for discussion, is expected in early 2023.

Ultimately, the resulting guideline should contribute to the standardization of the procedure in process validation for plastic components in order to save cost and time in the validation process through coordinated validation concepts and the associated documentation, thus contributing to safe products. ■

Technical Regulations: from the "Greenprint" to the Guideline

VDI guidelines are technical regulations that set quality standards in a wide range of technical fields. For this purpose, technical experts meet in guideline committees and develop guidelines on technologies, processes, materials and procedures on a voluntary basis. The Association of German Engineers (VDI) e.V. is responsible for coordination and publication. The bilingual German/English guidelines are considered to be particularly practical. A guideline is first published in draft form as a so-called "greenprint". This is followed by a commentary phase in which everyone has the opportunity to address comments and notes to the technical committee. After evaluation and, if necessary, consideration by the expert committee, the final version is published as a "white paper". In the meantime, more than 2200 guidelines have been produced, which are widely used in the industry.