White Paper

From device design to industrialization

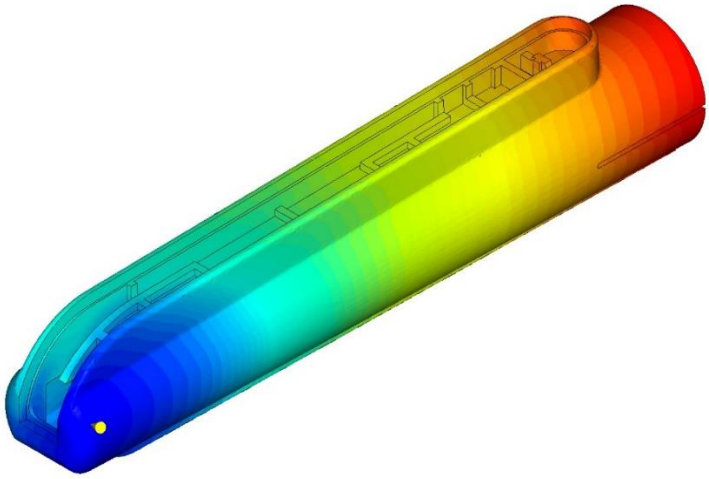
Secure development and fast time to market thanks to digital twins and dedicated prototyping

Product development in the pharmaceutical and medtech industry ties up time and resources: an important reason for manufacturers to keep development cycles as efficient as possible. This is best achieved with a partner who brings both extensive know-how in development, design, and manufacturing as well as knowledge of the latest techniques to the table – from simulation of the initial idea using digital twins to prototyping and series production.

What do you need to consider when in the process of developing a new medical device? One of the core aspects is the time component: the longer the process, the more cost-intensive the market launch. This is because the future product goes through several iteration and optimization steps, especially during development. If this process is only initiated when using the real tool, the costs will increase enormously. Good Design for Manufacture and Assembly (DFMA) from the very beginning and the efficient use of digital technologies can help. You should not only consider all necessary requirements for a feasible, but also for an efficient solution – especially during the concept phase and the constructive elaboration of the CAD design. Since DFMA implies the consideration of possible effects on the device, simulation should ideally be used already in the design phase – long before moving towards the tool. This makes it possible to ensure that the design is suitable for injection molding, e.g., by checking for filling problems and weld lines. In addition, steps considered in the DFMA include material choice, mold layout, the injection molding process, assembly, and automation. This makes it possible to check at an early time whether a design can be manufactured at all and also reduces risks and development time significantly.

Higher quality thanks to digital twins

After the concept has been created via CAD, the ideal next step is a more advanced simulation of the injection molding process using a digital twin. The latter connects the real with the digital world: by capturing and incorporating real-time data, it mirrors the current state and is able to simulate technical options for the future state. The digital twin allows users to detect potential problems early, thus creating the basis for optimization. In device production via injection molding, the simulation virtually represents the filling process. This makes it possible to determine the optimal parameters for the subsequent production of the molds and for achieving optimal part quality. The virtual prototypes make clear whether, for example, injection points need to be adjusted or wall thicknesses need to be optimized. The simulation also shows if, for example in multi-cavity molds, the filling of the left and right parts of each cavity is not perfectly balanced. In addition, alternative designs can be tested, for example designs in which the diameter of the two outer hot runner canals is changed.



The result of this virtual process development is an ideal definition of the gating point, heat distribution in the mold that is as uniform as possible, and perfect demolding. This makes it possible to determine an ideal process window. Thanks to injection molding simulation, the digital twin provides helpful approaches for designing the mold concept in the best possible way at a very early stage, and for determining an efficient injection molding process. This type of simulation is an integral part of mold specification and qualification at Sanner.

Virtual prototyping saves time and money

The biggest advantages when using digital twins are time and cost savings: the simulation of molds with different plastic materials allows users to quickly define which material is most suitable for a particular article and which part design guarantees the functioning of the article. Tool changes can be tested virtually in advance. This eliminates the need for time-consuming material tests and saves the time otherwise needed for test runs on injection molding machines. Any problems that may arise, such as air inclusions or difficulties with shrinkage and warpage, can be identified and rectified in the digital twin even before the actual molds go into production. The permanent virtual optimization of the mold construction makes it possible to reliably produce conform, high-quality parts.

Simulation also pays off from an economic and ecological point of view. By utilizing a digital twin, it becomes possible to identify where cycle times and material usage can be reduced, leading to a positive impact on the environmental footprint: products become more sustainable and material scrap is reduced. Used correctly, simulation leads to a significantly lower error rate. It avoids expensive and time-consuming tool corrections, allows for faster sampling with less scrap and waste, and supports a shorter time to market as well as more efficient production with better cycle times.

The importance of prototyping

Virtual and real prototyping go hand in hand in the scope of effective and efficient product realization. The results from both approaches influence the design of the tool. The earlier in the development process optimized prototypes and samples of individual items are produced with simulation, the sooner the tool concept can be reviewed and adapted for the later manufacturing process, including the design and functionality of the end product.

The first 3D-printed samples provide a feel for the handling and appearance of the mold, later injection-molded samples can successively be used for development verification and validation. The findings from the prototype molds are incorporated into the design of the mold concept for series production. However, real prototyping is primarily concerned with the product, not the mold, whereas injection molding simulation is used to design and optimize the manufacturing process. Modern device CDMOs have multiple technical solutions in their

portfolio when it comes to prototyping – from 3D printing to additively manufactured mold inserts and aluminum and/or steel fabrication, depending on the development status and the complexity of the product. The following criteria are decisive:

- Selecting the appropriate prototyping method to draw the best possible conclusions in the respective development steps and be able to further minimize risks.
- Optimizing the component design from a process technology point at an early stage and making it ready for later design transfer and scaling for large-scale production.
- Taking into account the required number of parts needed e.g., for tests or clinical trials, when selecting a prototyping method.

Rapid prototyping and rapid tooling

Prototyping option 1: 3D printing

3D printing shows its strengths especially when it comes to evaluating different concepts – and offers the first opportunity after the virtual prototypes from the CAD to test a device or component in real haptic and optical form. Here, the focus is on prototypes in the sense of ‘works like’ and ‘looks like’, often even viewed separately at first. Moreover, the focus is on understanding the dimensions, the accuracy of fit and at least partial functions. To implement this method, Sanner uses two different 3D printing processes.

The FFF process (Fused Filament Fabrication) is a classic filament printing process based on thermoplastic plastics and is particularly suitable for larger components. The plastic filament is fed through a heated nozzle, usually with a diameter of 0.4 mm, by an extruder and thereby melted. A layer thickness of at least 0.1 mm is required to prevent the molten material from deforming during the cooling process. This process is ideal for jigs, fixtures, and large prototypes in the 300 x 250 x 300 millimeter range. The material is significantly less expensive than the one used in the SLA printing process described below. In addition, the latter also requires more extensive protective measures and eventually also more rework due to liquid resins and solvents, depending on the area of application.

SLA printing (stereolithography) is particularly suitable for medtech applications, as it also allows biocompatible materials to be processed in accordance with DIN ISO 10993. The materials used by Sanner have similar, although not identical mechanical properties compared to the original materials (plastics). This simplifies the verification of different product properties. In particular, more complex parts can be used for optical and tactile measurement. The development of processes and assembly concepts can thus be planned more effectively, which significantly accelerates this development step. Prototypes can sometimes be produced and tested within a day. If the 3D printed samples produce the desired result, the next step can e.g., consist in investing in an aluminum tool to obtain samples made from the original material for further tests.

Prototyping option 2: Sanner Flexible Change Mold System

The materials used can have a significant influence on the functions of some products, making the use of samples made from the original material obligatory. Additively manufactured mold inserts offer a cost-effective and rapid solution to get first samples made from the original material. Standardization of the master molds allows different part sizes to be produced flexibly. First, development and design experts review the component design as well as the intended function and use of the parts to be manufactured. The mold inserts are then designed, adapted in terms of processes, and additively manufactured. The result is available within a few days, sometimes even on the very next day: fully functional mold inserts made of highly temperature-resistant and rigid plastic that can be integrated into the company’s own master molds.

Tests with parts close to serial production made from the original material can be conducted at an earlier stage, as the prototypes possess properties similar to the final product. This enables the acquisition of more accurate and reliable results compared to, for instance, 3D-printed samples not made from the intended series material. In this way, the development

process takes up a shorter time and defects can be eliminated at an early stage. As early as in this phase, Sanner works with the customer to develop an optimal tool concept that can be scaled for the ramp-up and series. If required, the same inserts can be fabricated from aluminum according to the results from the additively manufactured tool to achieve a longer service life and hence more sample parts.

Use case: Babyplast and Sanner Flexible Change Mold System

The Sanner Flexible Change Mold System uses a Babyplast injection molding machine. This makes it possible to produce plastic injection-molded parts from small batch sizes cost-effectively. Babyplast injection molding machines can process most thermoplastics, standard types and engineering plastics, as well as LSR.

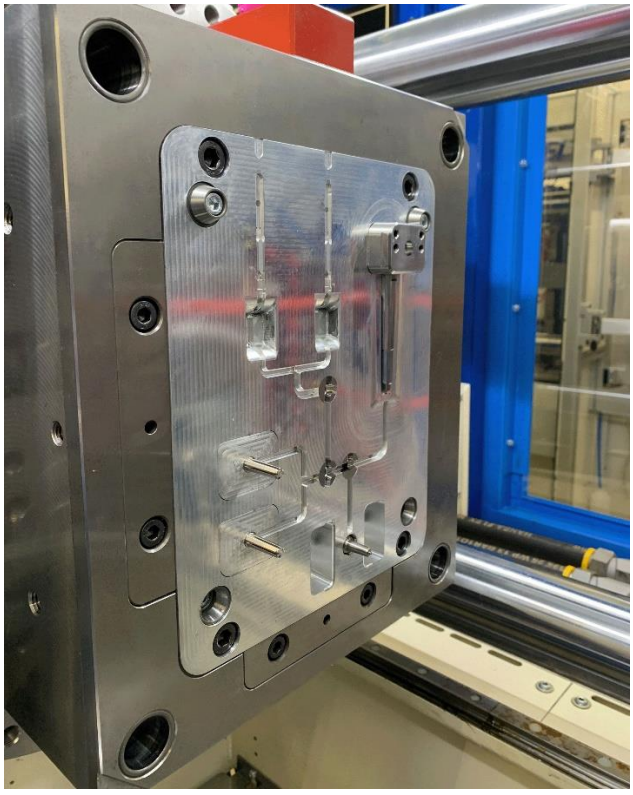
The additively manufactured mold inserts can be easily integrated into the master mold to produce prototypes – even according to cleanroom requirements up to ISO class 7. The design of the additively manufactured mold inserts is already very close to the series mold, for example with regard to the injection point. This makes it easier to define material properties for series production. Part prices are lower thanks to the low machine hour rate. Smaller molds and shorter setup and assembly times provide additional flexibility.

Sanner is planning to also use the Babyplast injection molding machine at the new production site in Bensheim to manufacture small components in the grey or clean room. This will enable development experts to test mold concepts during the real injection molding process directly on site.

The Sanner Flexible Change Mold System also allows the mold inserts from the Babyplast machine to be used in a large Sanner master mold. This means that, depending on the requirements of the manufacturing process, parts can be produced using the same inserts on different machines. In addition, the large master mold allows for the use of larger inserts for parts that can no longer be filled on the Babyplast machine due to their low shot weight.

Prototyping option 3: pilot tools made of aluminum and steel

Tools made of aluminum and steel can be used as a further option or as a last step before series production. However, they are not yet designed for large-scale production. Aluminum is lighter and faster to process than steel. While steel used to be significantly cheaper, material costs for aluminum are now almost at the same level. In clinical trials, the use of aluminum or steel molds is particularly relevant, as the prototypes are required to have exactly the same functionalities as the final product in order not to falsify the results of the trial. Moreover, the production process must be transferable.



If high quantities are required, the use of steel tools is preferable. In terms of time, however, both aluminum and steel are by far inferior to the previously described solutions. This also applies to the cost of such a prototype tool. If improvements need to be made during prototype production, e.g., in relation to the injection point or the mold concept, implementation times until the improved prototypes are considerably more time-consuming and ultimately more expensive for both variants.

Best Practice: Using 3D printing, simulation and aluminum tools for clinical trials

Solios diagnostics GmbH is developing RapidoDX, an innovative rapid test system using lateral flow (LF) immunoassays. The company pursues an all-in-one platform principle that enables simple and safe sample and test handling without additional components and processing steps and is applicable to all common LF assays.

Sanner initially took over an existing design. It soon became clear that the product would have to be specifically revised for use in series production – an important reason to cooperate on development with a suitable CDMO partner who thinks and develops with DFMA in mind right from the start.

In this case, wall thicknesses were optimized, draft angles and threads were adjusted. The first samples were 3D printed. Since the material used had similar properties as the material planned for series production, it was possible to shed light on various aspects with the 3D-printed prototypes to ensure an ideal lateral flow.

A bio-based plastic is being considered for scaling up to final industrialization. Questions such as ‘Are the holding functions for the test strips optimal?’, ‘Is the test strip supported and exposed in the right places?’, ‘Is the degree of bending optimal?’, and ‘How high are the operating forces?’ could be answered.

Cuts to the 3D sample verified the individual aspects inside the device. The optimized 3D prototypes served as proof of concept on the basis of which an aluminum tool was produced to obtain samples for a clinical study.

Tool competence as a deciding factor for a device CDMO

As a CDMO with many years of mold expertise, Sanner uses modern approaches such as 3D printing or additively manufactured mold inserts to produce prototypes that come close to the final device in terms of their functionalities. Coupled with injection molding simulation, issues such as filling problems, air inclusions or warp can be avoided, cycle times can be optimized, and ideal process windows defined. This contributes decisively to a faster qualification and market launch of the new device and significantly reduces development risks. Basic requirements for this are profound expertise in product and process development as well as an in-house mold technology.

When it comes to manufacturing the mold inserts, a company like Sanner benefits from many years of expertise in precision and multicomponent injection molding, as well as in mold technology – including and especially in high-volume production. As a CDMO for customized pharmaceutical packaging and medical products, Sanner has been supplying customers with injection-molded components and assemblies for decades.

In addition, Sanner can provide important impulses for the manufacturing process beyond prototyping: with its standard-compliant stage-gate process (Sanner IDP Process®), the company ensures that all important factors are taken into account right from the start in accordance with ISO 13485. Sanner combines many years of experience in the pharmaceutical and medical technology sectors with expertise in the design and implementation of complex, high-quality applications. For this purpose, development and project engineers accompany customer projects from the initial idea through development and prototyping to series production – precisely customized to the respective project and with open and team-oriented communication.

Authors

Marco Arras
Senior Project Engineer | Tooling Expert
m.arras@sanner-group.com

Felix Hartmann
R&D Engineer
f.hartmann@sanner-group.com

About Sanner

Sanner was founded in 1894. Headquartered in Germany and leveraging its best-in-class manufacturing facilities across Germany, France, Hungary, and China, Sanner has developed from a global market leader for desiccant closures and effervescent tablet packaging into a sought-after provider of customized solutions in the areas of medical devices and diagnostics, pharmaceuticals, and consumer healthcare. Today, Sanner supplies its products to more than 150 countries globally and has over 600 employees. Since November 2021, GHO Capital, a leading specialist healthcare investment advisor, holds the majority shares of Sanner. Together, GHO and the fourth generation of the Sanner family will continue the successful growth and create intelligent healthcare solutions for a better quality of life.