A holistic process for customized solutions

The ideal packaging solution in six steps

How an individual development process helps to implement increased requirements for drug packaging – quickly, efficiently and sustainably

Especially user-friendly test strip dispensers, breakage-proof dual-chamber syringes, child-resistant tablet packaging, or even the 'intelligent' primary packaging with RFID codes or NFC functions – medical packaging requirements are increasing continuously. To ensure a fast and reliable market introduction of new products, the appropriate packaging concept plays a crucial role.

The road to the ideal packaging is a long one. It starts with the design and leads all the way to reliable large-scale production. How can all the requirements be reconciled? How can drug manufacturers, who have already invested a lot of time and money into the development of a new medication, bring their product to the market quickly? Which characteristics must a pharmaceutical primary packaging solution fulfil to be both smart and efficient, without sacrificing product safety? And how can the packaging performance for stability tests and a smooth approval process be ensured? The following example of a child-resistant packaging provides valuable insights.

Example: CR packaging

CR functions are becoming more and more frequent in the requirement specifications for new packaging solutions. CR stands for 'child-resistant' and aims to protect children from the accidental ingestion of medication. In the U.S., around 60,000 children are treated after inadvertently swallowing medicine every year, while in Europe, approximately 3,000 children die from the consequences of mistakenly ingested drugs. According to the World Health Organization (WHO), drugs stored at home pose a particularly high risk. Consequently, this topic ranks high on pharmaceutical producers' requirement lists for medical packaging. The Sanner IDP-Process® shows how a modern and efficient packaging concept can be developed.

The holistic development process comprises six phases. IDP stands for ‚Idea. Design. Product.‘. Developments are managed and individual packaging solutions are realized all the way from the idea to serial production. Based on many years of experience, the Sanner specialists know exactly what is needed and develop individual primary packaging concepts and medical devices for large-scale production in close collaboration with pharmaceutical manufacturers.

1. Concept phase

In the concept phase, the Sanner specialists develop different approaches based on customer demands, whilst already taking into account the criteria for subsequent serial production. The concept phase also includes a first, rough cost estimate, as well as a detailed examination of the regulatory requirements and the patent situation.

In the CR packaging example, the focus is on the child-resistance of the tablet dispenser. The FlipTop’s click sound ensures that the package is completely closed. Moreover, an

appealing, modern design with user-friendly haptics is also required. Furthermore, a tamper-evident function ensures manipulation safety. The tablet dispenser is intended for 50 tablets, which must be protected from moisture. For this purpose, a desiccant is integrated into the packaging – one of Sanner's core competencies.

All materials must meet the requirements of the European and the U.S. pharmacopeia (USP); according to ICH, the product must have a shelf life of at least 24 months. This is only possible, if the container is absolutely tight and has the right climatic conditions inside.

So that the customer understands exactly how Sanner intends to implement the packaging solution, first sketches are created in CAD and explained in detail. Already during this first phase, the customer can choose between several possibilities, all of which fulfill the given requirements.

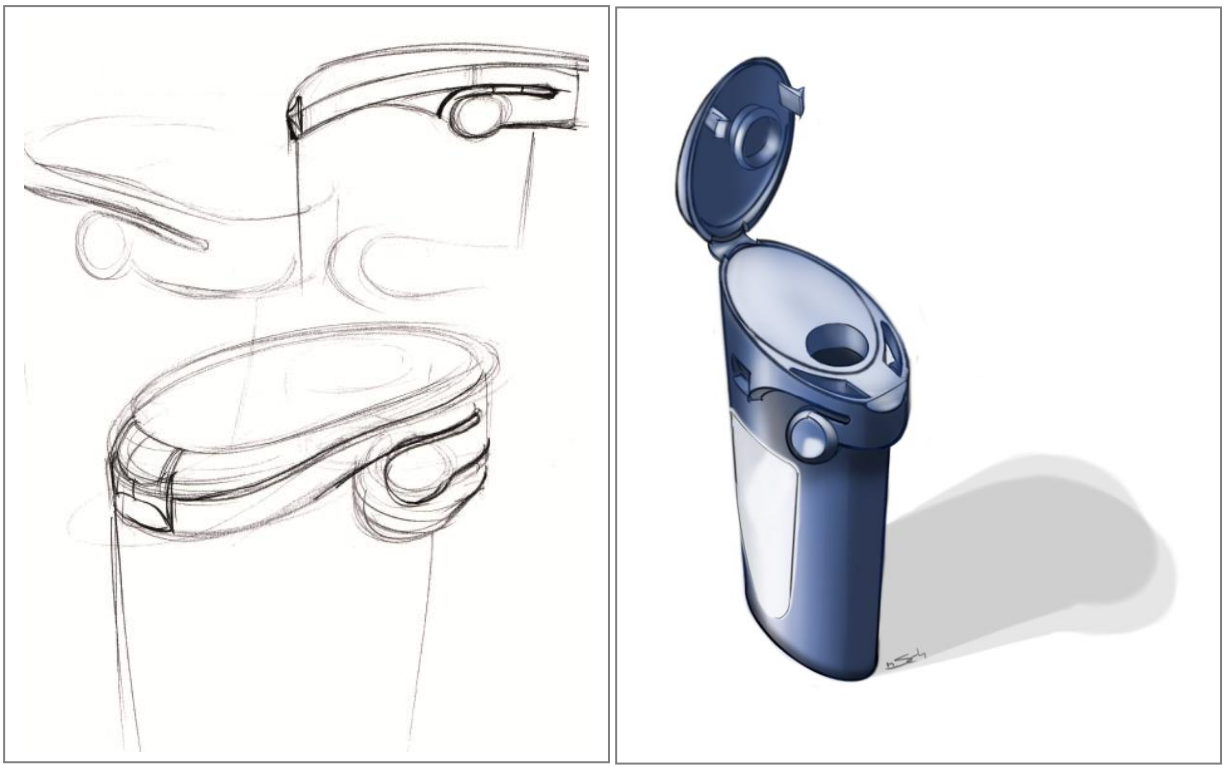


Image 1: first sketches and CAD drawing of a CR packaging solution

2. Design phase

The selected product concept is developed in further detail during the design phase, while the manufacture of close-to-production product samples is prepared. To demonstrate the basic functionalities of the concept, the customer receives a detailed elaboration of the CAD data, as well as a physical 3D model. In parallel, the material is selected. In addition to the technical properties, the suitability of the material in accordance with regulatory requirements and its long-term availability are of particular interest.

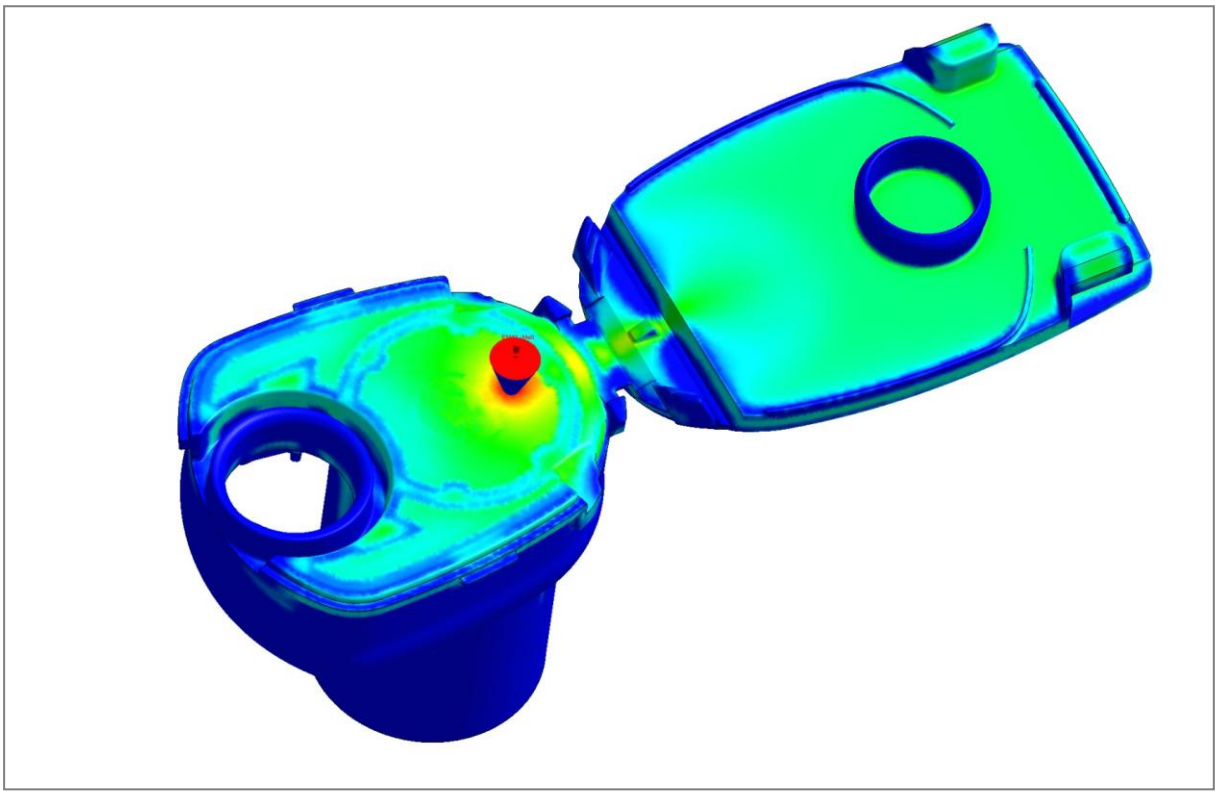


Image 2: mold-flow analysis of a close-to-production sample

The tool engineering for near-serial product samples is particularly important during this phase. By means of mold-flow simulation, the Sanner engineers analyze the filling of the cavities and the temperature conditions in the planned tool in order to achieve an optimum quality. This way, the number of subsequent approval loops can be reduced, leading to considerable time and costs savings.

During this phase, the basis of the production concept for later serial production is also established together with the customer. For the pharmaceutical manufacturer, it is advantageous to cooperate with a partner who has extensive experience in large-scale production with different technologies. These include injection molding, two-component injection molding, injection blow molding technology or in-mold labelling, as well as desiccant processing.

To ensure the best possible climate for the product, Sanner evaluates the packaging using the Atmo Guard System® and determines the type and optimum amount of desiccant. All aspects of moisture ingress in the interaction of product, desiccant and packaging are taken into account. The CR tablet packaging consists of two parts – the container for the tablets and the bottom part, which contains the desiccant.

Risk assessment has a key function during the design phase. To get the packaging solution ready for the prototype phase, an FMEA analysis is used to carefully check whether the design meets all requirements. A viable and validated packaging design is thus created in close cooperation with the tool manufacturer.

3. Prototype phase

In the third phase of the process, the necessary equipment for the manufacture of near-serial product samples is realized. This equipment forms the basis of the fabrication tools required for large-scale production. It is also the phase, where final changes to equipment and packaging design can be carried out without major costs and time loss. The multi-cavity production tool can only be manufactured once series maturity is reached.

In the case of the CR packaging, a steel tool with one cavity for the container, the FlipTop closure and the dosage opening, as well as one for the bottom part are produced. Dimensional adjustments and functional optimizations for the CR function and the click sound during closing are performed on the product pattern. Permeation tests ensure the required tightness, which has great influence on the drug's shelf life of at least 24 months.

Detailed consumer tests provide information about the handling and – in our example – the correct function of the closure according to US 16 CFR 1700.20 and ISO 8317.

The prototype phase is the most critical and complex phase of the entire process: all requirements must be finalized and tested. Correspondingly, good project management on the part of the packaging solutions manufacturer is very important, as is the close cooperation with the customer during finalization. Stability tests can only be performed if all quality requirements and deadlines are adhered to. This results in a tested and approved product design for the successful transfer into serial production.

4. Industrialization phase

The industrialization phase mainly consists of the production, installation and qualification of serial production equipment, as well as the definition of parameters for a smooth and efficient production process; if required, also under cleanroom conditions.

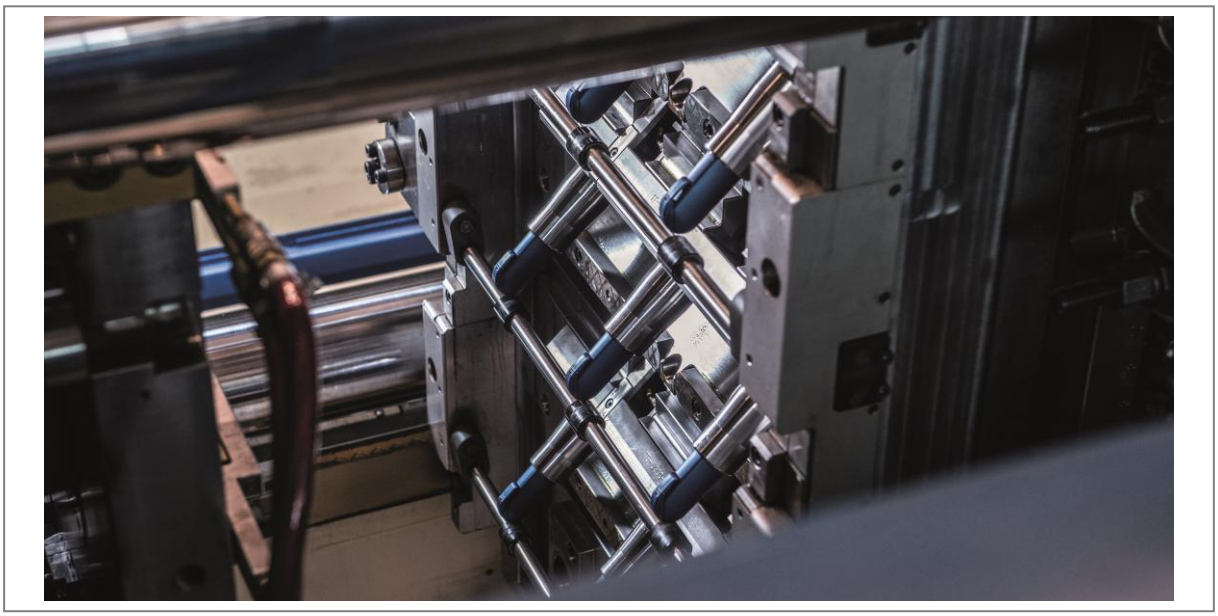


Image 3: production of child-resistant packaging at Sanner in Bensheim, Germany

For the CR tablet packaging, Sanner produces manufacturing tools with 16 cavities designed for an annual capacity of around 20 million containers and bottom parts. To ensure a consistently high product quality and an efficient production process, the manufacturing tool

is subjected to a comprehensive qualification process in accordance with cGMP guidelines. These include the design qualification (DQ) for the construction of the injection molds and the approval (FAT) of the tools at the manufacturer's site, followed by installation qualification (IQ) and operational qualification (OQ), which includes the process determination and definition of the process window by means of statistical test planning (DoE - Design of Experiments).

5. Implementation phase

In the implementation phase, the production processes are validated and all necessary documents for packaging approval and registration are finalized. During performance qualification (PQ), the manufacturing equipment generally produces three validation batches in order to prove its performance in permanent operation. According to a testing plan especially developed by Quality Management, the Sanner experts inspect all relevant functionality parameters, such as test dimensions or desiccant weight. If the final inspection is successful, constant product quality, and consequently a timely market entry of the pharmaceutical product, is ensured.

6. Roll-out and production monitoring

In order to ensure the quality of product and processes during and especially after the market launch, continuous control of serial production is indispensable. The individual In-Process Control (IPC) inspection plan defines test criteria and intervals. In addition to the attributive and variable tests of the CR tablet packaging, it is also necessary to test the functionality of the CR closure or the FlipTop at defined intervals. Sanner continuously monitors and safeguards the functions of all production equipment through preventive maintenance.

Throughout the entire product life cycle, the Sanner IDP-Process® provides for the highest quality, especially in large order volumes. All test results, as well as the operating data are integrated into Sanner's own MES, ensuring continuous traceability. This reliability is also reflected in the complaint rate and OTIF level: per ten million delivered parts, Sanner records less than 0.5 complaints throughout the entire manufacturing process and the supply chain

right through to the arrival at the customer's site. In addition, more than 98 percent of all deliveries arrive completely and on time, thanks to professional process and production management.

For the customer, it is also important to be closely involved in the development process. High transparency and open communication in all project phases is crucial for everyone to be informed about the current status at any time. Thanks to professional project management and profound expertise, the six-stage Sanner IDP-Process® creates a successful tailor-made packaging solution with a focus on quality, time and cost-effectiveness – because Sanner knows exactly what customers need.

The Sanner IDP-Process® at a glance

Concept Phase

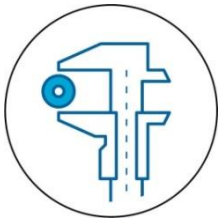
Tell us what you need!

We will develop creative packaging concepts and medical devices in line with regulatory requirements, which are transferable to large-scale production.

Design Phase

Take a pick!

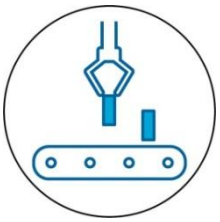
We will specify your favorite concepts based on a validated product design.



Prototype Phase

Challenge us!

We will qualify and test the required equipment and close-to-production product samples in a close cooperation between your and our experts.



Industrialization Phase

Get ready for the real thing!

We will manufacture, install and qualify the production equipment and define the parameters for a smooth and efficient production process.

Implementation Phase

For your approval!

We will establish a robust and fully validated manufacturing process, and prepare the required documentation. Once you give your approval, everything is set for a fast and reliable production start.

Roll-out Phase

Conquer the market!

While you get busy selling, we make sure that consistent product quality is maintained through continuous control of serial production.

For more information visit: http://www.sanner-group.com/en/idp/