White Paper

Higher safety for pre-filled syringes

How small changes in component design can make the big difference

Although predictions vary significantly, one thing is certain: the market for pre-filled syringes is growing at a rapid pace. Apart from Covid-19 vaccines and highly effective new biopharmaceuticals, the handy devices are also used in ophthalmology, orthopedics, and aesthetic medicine. What unites all endeavors to optimize pre-filled syringes is the need for absolute safety from design through to actual usage. Here, small changes in component design can make the decisive difference.

The Covid-19 pandemic has increased the need for pre-filled syringes above the predicted average. Further reasons for the growing demand are the ongoing boom in the development of new biopharmaceuticals, as well as the rising life expectancy and the increasing demand for self-medication to treat chronic diseases. What's more, the devices are also used in ophthalmology, orthopedics, and aesthetic medicine, for instance in therapies based on Botulinum neurotoxin (Botox) or hyaluronic acid. In these sectors, a trend towards individualization is especially apparent. Even small changes in design or components can change the user experience for doctors, patients, and pharmaceutical manufacturers alike.

Different industries – one solution

While there are many good reasons to change the design of pre-filled syringes, one is most important: making syringes safer to use for all parties involved. Oncology medicine must be easy to administer for doctors; insulin should be easy to use in self-administration for all patients; and aesthetic medicine also does not forgive the slightest safety flaw in administration. However, there are subtle differences in the different industries, which require a stronger individualization of pre-filled syringes. Hence, it is advisable for pharmaceutical producers to combine their glass or plastic syringes with individually adapted components,

which increase not only customer and patient orientation but, above all, safe usage. All these different requirements can be met with a simple recipe: individualization.

For example, Botox or hyaluronic acid therapies require convenient handling and dosage safety, both during treatment by a doctor and in patients' self-medication. At the same time, patients are looking for appealing products, which transport their lifestyle and make the treatment a unique experience. Inaccurate (self-)treatment of wrinkles or lip filling can quickly become the nightmare of any public person, dermatologist, or plastic surgeon. In orthopedics, on the other hand, hyaluronic acid is used for treatments in rheumatology or arthritis. Most often, orthopedic injections are performed by physicians. To avoid injuries during treatment despite the high viscosity of the substance, they require devices that are designed as simple and yet as safe as possible, allowing for easy administration.

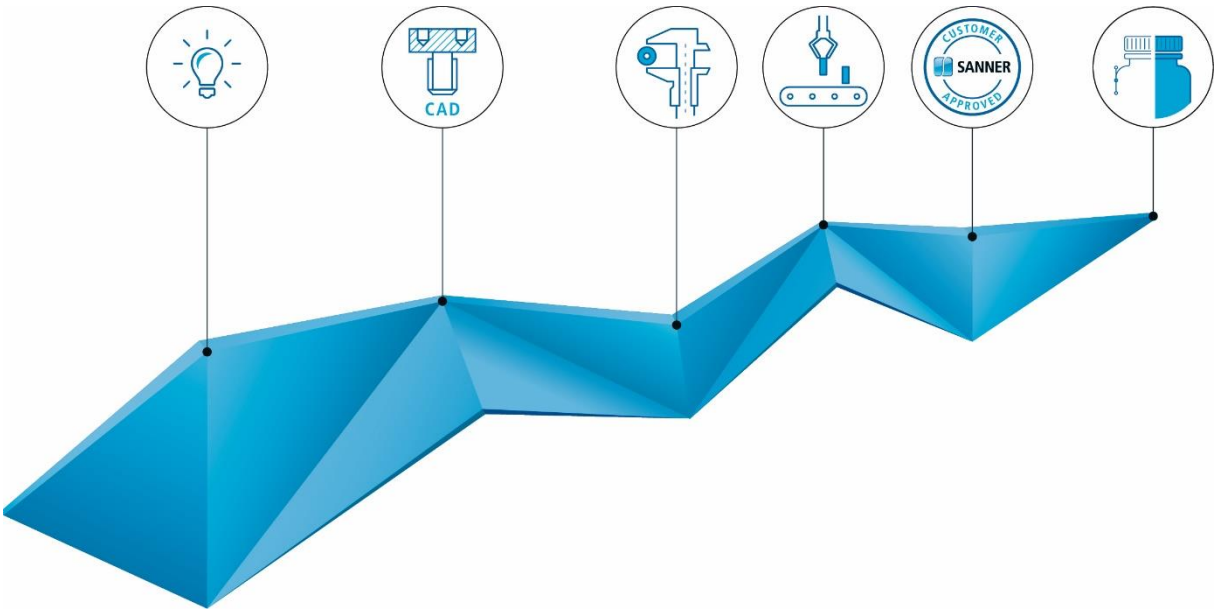
Individualization with many benefits

The possibility to individualize pre-filled syringes are manifold. Most importantly, individualization not only benefits the end users, but also pharmaceutical manufacturers. As far as safety and handling aspects are concerned, the design of individualized syringe components focusses on ergonomics. However, optics also play an important role: while end users, especially in the aesthetic field, prefer to undergo their expensive treatment by means of a high-quality and visually appealing device, pharmaceutical companies primarily want to set their products apart and gain a competitive advantage. They can apply the brand name or logo, use different colors or indicate dosage strengths. Moreover, regional traceability, safety, and information requirements can be met with simple but effective means.

From a technical point-of-view, a sophisticated design of syringe components such as the thread, can ensure fast and safe processing on filling lines and simplify the packaging procedure. Thousands of pre-filled syringes can be filled and assembled on high-speed lines – provided the single components such as backstops and rods are perfectly compatible. An exact design and compatibility with common filling systems is crucial for high process efficiency, which, in turn, is decisive for pharmaceutical manufacturers, especially in view of the high time and cost pressure in the pharmaceutical market.

A six-step approach

Individualized and safe solutions require high packaging and processing expertise, combined with industry knowledge and design know-how. In addition, this kind of individualization must be backed by a specific process that enables not only detailed product specification, conception, and development of individual solutions, but also does this under competitive conditions. How can all these requirements be reconciled? Which characteristics must a pre-filled syringe solution fulfil to be both convenient and efficient, without sacrificing patient safety? The answer lies in a holistic development process that encompasses several phases – from the development of a first idea through product design to large-scale serial production.



The concept phase

At the beginning of this multi-stage development process, different approaches are developed based on customer demands, whilst already considering the criteria for subsequent serial production. This phase should also include a first, rough cost estimate, as well as a detailed examination of the regulatory requirements and the patent situation. Moreover, first sketches of the proposed solutions are created, giving pharmaceutical companies the option to choose between several possibilities, all of which fulfil the given requirements.

The 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. In parallel, the materials are selected in line with regulatory requirements and long-term availability. Tool engineering for near-serial product samples is particularly important during this phase. By means of mold-flow simulation, the engineers analyze the filling of the cavities and the temperature conditions in the planned tool 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 should also be established.

The prototype phase

The third phase of the process contains the realization of the equipment needed to manufacture near-serial prototypes. This equipment forms the basis of the fabrication tools for large-scale production. Novel additive manufactured tool inserts even make it possible to produce the prototype in the final material – a competence that is highly sought-after and currently still hard to find in the market. These tool inserts can be manufactured quickly, they feature the same characteristics as the final product, and deliver more precise and reliable test and qualification results. Moreover, they make it possible to identify and correct design errors at an early stage, thus speeding up the development process significantly.

The prototype phase is the most critical and complex phase of the entire process: all requirements must be finalized and tested. Good project management and the close cooperation with the customer are crucial during finalization. Quality 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.

The industrialization phase

This 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. The manufacturing tool is subjected to a comprehensive qualification process in accordance with cGMP guidelines.

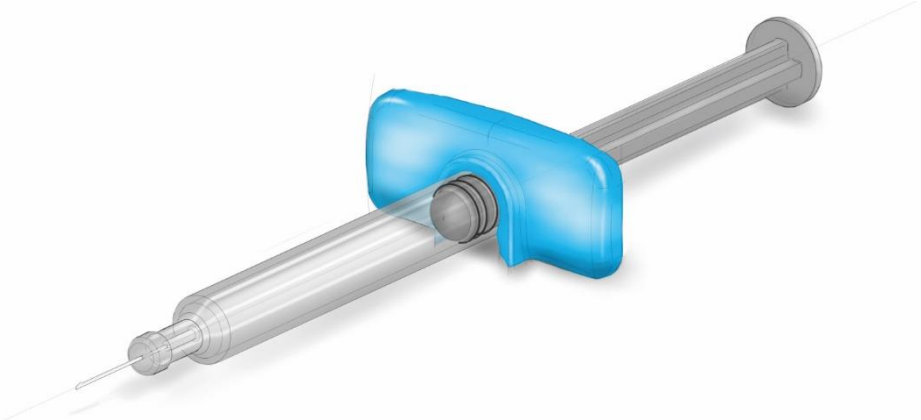
The implementation phase

Next, it is necessary to validate the production processes and finalize all necessary documents for approval and registration. According to a testing plan especially developed by Quality Management, all relevant functionality parameters are inspected. If the final inspection is successful, constant product quality, and consequently a timely market entry of the pharmaceutical product, is ensured.

The roll-out and monitoring phase

To ensure the quality of product and processes during and after the market launch, continuous control of serial production is indispensable. An in-process inspection plan defines test criteria and intervals. In addition to attributive and variable tests, the functionality of the syringes and components are tested, and production equipment is monitored.

Best practice: finger rest enlargements for syringes



As a CDMO, Sanner supports companies in the development of syringe systems, including prototyping – or translates their own design into an efficient production concept. Safety, functionality and design are equally important, as a practical example shows: ergonomically shaped finger rest enlargements with a non-slip grip lead to greater safety and ease of use of pre-filled syringes. The ability to rotate the syringe barrel in the support enlargement allows the syringe needle to be optimally aligned, so the syringe does not have to be applied several times. For a better grip and even more safety during injection – especially for aesthetic treatments or in cosmetic surgery – Sanner also manufactures the finger rest enlargements in two-component injection molding with the smallest shot weights.

Tailor-made syringe components

Throughout the entire product life cycle, a multi-phase process can ensure the highest quality, especially in large order volumes. Integrating all test results, as well as the operating data into a Manufacturing Execution System ensures continuous traceability. Thanks to this kind of close-knit quality control and professional process and production management, complaint rates can be kept under 0.3 complaints per ten million delivered parts, while OTIF levels rank high, with a rate of over 99 percent of all deliveries arriving complete and on time.

The close involvement of the drug manufacturer in the entire development process is extremely important to achieve satisfying and efficient results. High transparency and open communication in all project phases keep everyone informed about the current status at any time. Thanks to professional project management and profound expertise, a multi-stage development process creates safe and successful tailor-made pre-filled syringe components with the required focus on ergonomic handling and patient safety and cost-effectiveness.

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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 Partners LLP, 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.