Smart Medical Devices

Form follows (smart) Function

“Smart” is one of today’s buzzwords. Not only cars, refrigerators and other everyday objects, but also packaging and medical devices such as inhalers or insulin pumps have become more intelligent in recent years. However, the development of a smart medical device is complicated, if not to say highly complex. Due to strict regulations and complex requirements, many different skills are required – from product design to manufacturing and processing to risk management. This whitepaper provides an overview of the requirements and uses concrete examples to show how “Form follows (smart) Function” can be implemented in practice.

Medical devices achieve their main intended effect by physical means. They are typically used when drugs alone cannot achieve the desired effect. In addition to pacemakers, this includes implants, products for injection, transfusion and dialysis as well as human medical instruments, apparatus, dental products, dressings and laboratory diagnostics.

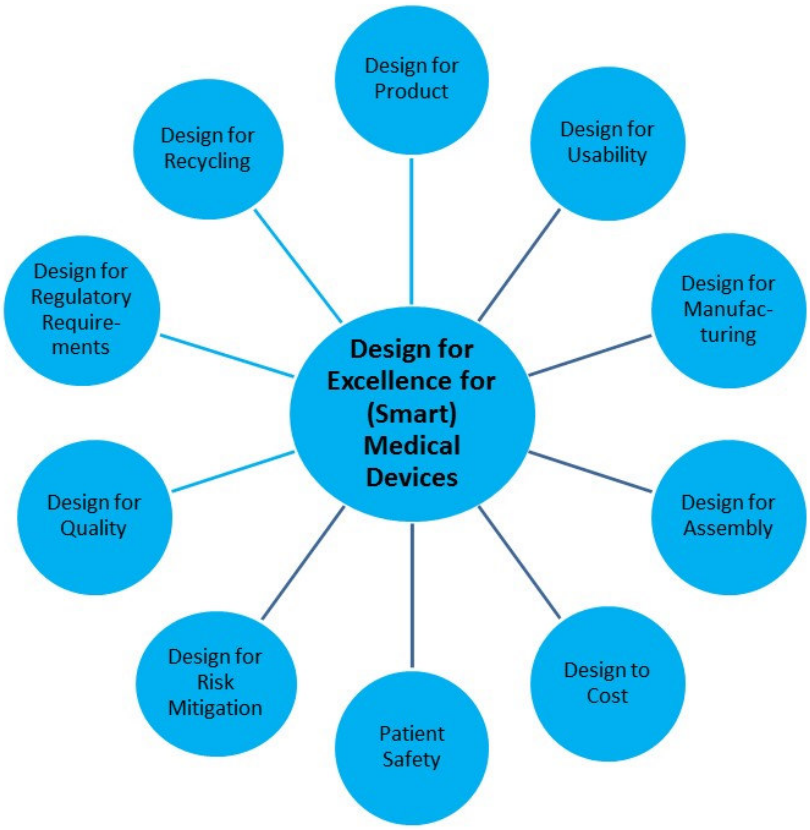
There are also intelligent, so-called smart medical devices. They support patients with certain functions, such as reminders or dosage, and thus increase therapy adherence. The collected data can be stored on the device or transferred to a cloud. With a connection to digital interfaces, doctors can perform direct data analyses. In addition, smart medical devices support telemedicine, make it easier to evaluate clinical studies and facilitate traceability. Products range from smart tablet boxes to intelligent tablet dispensers, for example for pain therapy; from electronic dosing systems such as medical pumps for fine dosing to retrofittable add-ons that equip inhalers or injection systems with connectivity and additional functions.

There are three basic strategies for implementing connectivity in medical devices:

- **Device add-ons** to retrofit an existing product
- **Device upgrades** for existing product designs without affecting the core functionalities
- **Built-in devices** that are designed with built-in, intelligent functions from the outset

Competencies for the development and manufacture of (smart) medical devices

The development and production of medical devices is complex, as the following diagram shows. Many different competencies build on each other or go hand in hand. Fulfilling and observing all these competencies forms the basis for product success.



The development of a medical device always begins with requirements management, which must be taken into account in the first development phase, the Design for Product.

Design for Product

The product design phase requires practicable creativity and know-how. Product designers develop concepts based on numerous customer requirements. From the very beginning, they consider the factors functionality, patent situation, manufacturability and costs for medical devices, which can later be transferred to series production. They physically convert the results into CAD models. The product design defines all other characteristics of the medical device.

Design for Usability

User-friendliness and ergonomics are important quality features of medical products. They make a decisive contribution to correct use and acceptance, which ultimately improves the therapeutic success. Hence, special attention is paid to the usability design of the device, and to a well-balanced relationship of usability and functionality. The goal is to minimize the risks of application errors, ensure patient safety and create the required conditions for the highest possible level of adherence.

Design for Manufacturing

“Design for Manufacturing” describes the development of parts and components and how these can be optimally manufactured in the subsequent production process. The product must be optimally designed regarding the planned production and assembly conditions, quality and costs. Especially in the case of plastic components, product and process development must go hand in hand. Material selection, tooling and injection molding technology, as well as the smallest possible number of components, functional integration and simple assembly (see Design for Assembly) are considered from the very beginning in order to create the basis for an efficient and safe manufacturing process as early as possible.

Design for Assembly

Depending on the product type, Design for Assembly should be an integral part of the Design for Manufacturing phase. Product and assembly steps must be optimally coordinated. Design for Assembly describes the optimized product design including product structure for the subsequent assembly process. The assembly concept (i.e. a partially vs. a fully automated assembly) depends on the number of parts to be assembled.

Design to Cost

Cost management is a central component of the product creation process. It should be determined at an early stage during the development and design of technical solution options to achieve an optimal cost-benefit ratio and keep follow-up or modification costs low. Particular attention must be paid to the optimum use of materials and to keeping the number of components as low as possible, while optimizing cycle times in the production process. In the case of smart medical devices, electronic components can also boost manufacturing costs and should therefore be analyzed in detail.

Design for Patient Safety

Patient protection, patient well-being and patient benefits are important issues in the development, production and application of (smart) medical devices. In general, patient safety is understood as avoiding, preventing and/or improving undesirable outcomes or harm from healthcare interventions.

Design for Risk Mitigation

To ensure this patient safety, product risk management in accordance with the international standard ISO 14971 with a focus on user and patient safety is a central element in the development of medical devices. Most of the usability requirements listed in the European Medical Device Directive (MDR) also refer to basic safety and performance criteria. By means of risk management, manufacturers must ensure the safety of their products and eliminate or minimize handling risks, provided the product is used properly.

Design for Quality

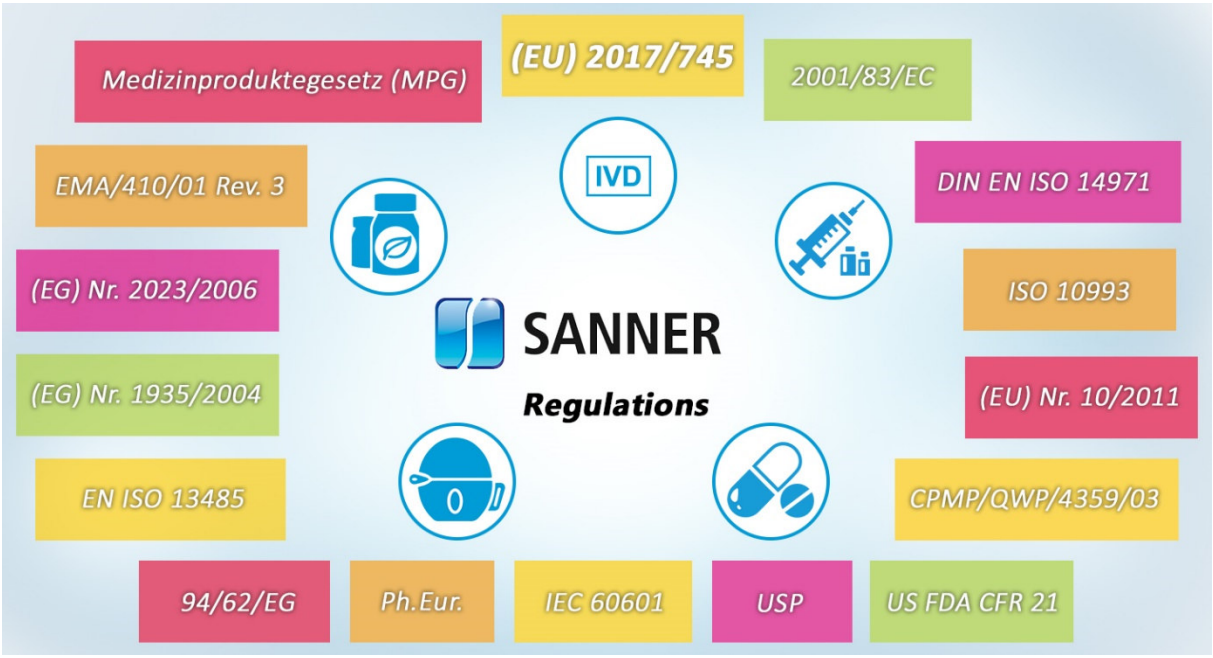
Process safety and speed, as well as safety aspects and risk mitigation play a major role in the development and implementation of testing concepts. Fast, precise and fully automated error detection is essential during the testing process. While an inspector used to examine the parameters with the naked eye at each station, this can now be done with video assistance systems that are integrated into the production process. These systems compare the actual results with the specifications from the CAQ system almost in real time.

Design for Regulatory Requirements

How regulatory requirements need to be fulfilled depends strongly on the specific product. Smart medical devices are categorized as “active medical devices” and are subject to the same strict documentation requirements as all other medical devices. This includes risk analysis and risk assessment to prove the safety and performance of a clinical evaluation, as well as a comprehensive quality management system. The following diagram below provides an exemplary overview of possible regulatory requirements.

EU MDR 2017/745 applies for European developers and manufacturers of (smart) medical devices. Moreover, several guidelines and harmonized standards can be consulted to fulfill the (essential) requirements regarding safety and performance. The required documentation and

declarations of conformity are created during the development and manufacturing process. They must always be kept up to date by the manufacturer of the medical device.



The main components required to minimize the risk when using a medical device comprise a stable and established product development process with standardized validation and qualification procedures, as well as a risk analysis according to ISO 14971. A certified quality management system is a central competence of a medical device manufacturer. On a global level, the requirements for a QM system such as those of 21 CFR 820 (US) and ISO 13485:2016 must be taken into account. Moreover, many further regulatory requirements are directly linked to quality management for medical devices.

Quality standards are also crucial for electronic assemblies. Hence, it is indispensable for many manufacturers of plastic components to work with the right partners who, amongst other things, are able to meet the regulations for medical electrical equipment (e.g. IEC 60601).

Design for Recycling

Environmental aspects, i.e. disposal, recycling, retrofitting and rechargeability, play a central role in development, especially when electronic components are built into medical devices. This makes it possible to maximize the proportion of recoverable and recyclable materials and to develop products that facilitate the dismantling and recovery of recyclable materials.

All these factors are required for the optimal development and production of a smart medical device, with varying emphases depending on its complexity and design. In Design for Excellence or Design for X, the X stands for a variable, which makes a development successful only in optimal interaction with the others.

Best Practice Example 1: Add-on device for Inhaler

The example of an add-on device for a DPI (dry powder inhaler) shows the challenges that can arise when developing an intelligent medical device and which aspects of Design for Excellence must be taken into account. First of all, the following question regarding the integration of electronic components had to be answered: where and how are the electronic components positioned and attached in order to ensure their functionality and to make the assemblies reproducible for large quantities?

Different boards with different sensors are installed during the Design for Manufacturing stage. Then is the inhalation process recorded correctly and visible for the patient. This makes it possible to avoid over-dosage or under-dosage, and to maintain both usability and patient safety.

The position of the sensor is also crucial in terms of Design for Risk Mitigation: to further minimize the risk for patients, impairments that could, for example, arise from the user's grip are prevented. This is only possible if the sensor is always in the exact same position, regardless of which inhaler the add-on is attached to.

Since different inhalers have different manufacturing tolerances, a flexible tolerance compensation is essential. In our example, the optimal position of optical sensors for detecting the opening of the inhaler cap was determined so that an optical signal is only triggered when the inhaler is fully opened.

In line with Design for Manufacturing, the simplest possible tool geometries were realized when fixing the boards, to minimize subsequent cycle times. In this example, the main board is fixed by attaching it to fixing pins. The board can be easily clamped when the outer shell is mounted. The later (design for) assembly was also taken into account. In this case, the optimum solution

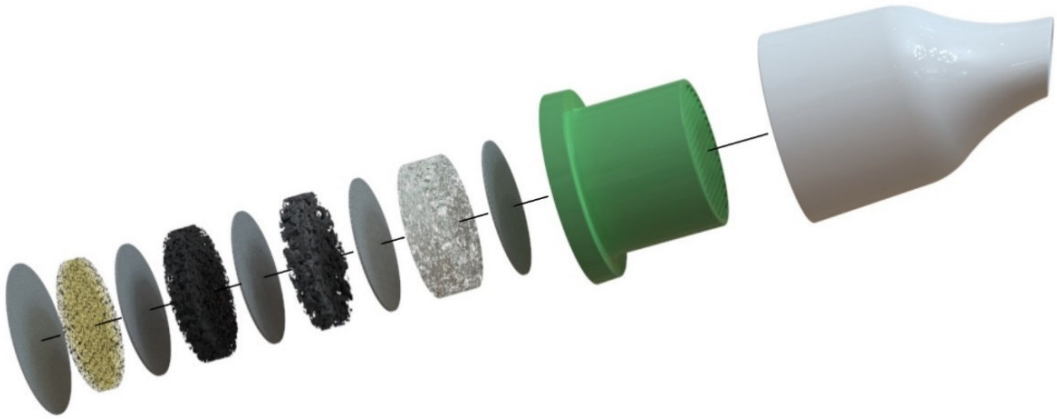
consisted in a pre-assembled assembly group (battery with holder), which is placed in the bottom of the add-on to facilitate the assembly steps and cabling.

Best Practice Example 2: Mouthpiece for inhaler

Another example that illustrates the complexity of medical device design is a mouthpiece for a state-of-the-art measuring device for determining inflammatory activity in chronic respiratory diseases. A successful product and usability design of the two plastic parts of the mouthpiece combines a high degree of user-friendliness with the necessary functionality. A first-class Design for Manufacturing and Design for Assembly resulted in a multi-stage production and assembly line, which assembles a total of eleven individual components.

The injection-molded mouthpiece is filled with different media and components in several stations. It is sealed several times, packed in individual bags and then packaged in variant-specific sales packaging. Altogether the assembly process consists of 23 individual steps. The biggest challenges for the assembly are a product-specific feeding of the different parts and filling media, the exact dosage (accurate to 1/100 gram), as well as the exact positioning and welding of the components and filter materials.

In this example, the Design for Assembly was successfully implemented. It ensures a multi-stage and precise assembly of large quantities at high speeds with high reproducibility and maximum quality throughout the entire process chain.



Regarding Design for Quality, a fully integrated and automated software-supported 100% inspection of each work step was implemented. 15 camera systems inspect for presence, correct execution and completeness, while six weighing stations check the correct quantity. What's particularly important about these steps: there is no need for subsequent testing on the finished assembled part. This conserves resources, saves time and costs.

Many years of experience and comprehensive expertise

Smart medical devices require not only high development competence, but also efficient and professional manufacturing and quality control capabilities. A good concept alone is not enough; the proposed solutions must be designed to make them ready for series production. Only a manufacturer with many years of global experience in implementing even highly complex products and projects can meet these complex requirements.

Rapid prototyping (e.g. 3D printing) and the production of functional prototypes with high dimensional accuracy help to optimize functions on the real component quickly and in a time-saving manner at an early development stage. In addition, a flexible team of engineers, project and quality managers, as well as compliance experts is needed to coordinate all Design for Excellence process steps.

"Form follows (smart) Function" is Sanner's claim. First and foremost, the design must optimize the product's functionality, ensure adherence, patient security and compliance. In addition, features such as usability, assembly, cost optimization etc. must be fulfilled.

Last but not least, "smart" extensions of medical devices can lead to a decisive competitive advantage, while representing the future of modern medicine.

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About Sanner

Based in Bensheim, Germany, Sanner GmbH was founded in 1894 and is now in its fourth generation as a family-owned enterprise. Sanner develops and produces high-quality plastic packaging and components for pharmaceutical, medtech, diagnostics and healthcare products. As the world's leading manufacturer of desiccant closures and effervescent packaging, Sanner produces four billion plastic parts each year for standard and customized packaging solutions. With 575 employees in Germany, China, Indonesia, India, Hungary, France and the U.S., the company generated annual sales of approx. 85 million euros in 2019.

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