Challenge – innovative medical technology

Ways to develop innovative medical products despite the enhanced requirements of MDR/FDA

senetics – from innovative idea to the market

Are you looking for a certified development service provider, consulting for regulatory affairs and a biological laboratory for your new medical device? senetics accompanies you with interdisciplinary competence from the innovative idea to the market-ready product – as we provide innovation out of passion!

New regulatory requirements by MDR and IVDR

Continuous progress in medical technology also requires a regular adjustment of the legal requirements for the products. As a result the MDD, AIMD and IVD, as well as known as directives 93/42/EWG, 90/385/EWG or 98/79/EG are replaced this year. However this can harm innovation, if many of your own resources are spent in the regulatory affairs. By June 2020 at the latest, all medical device manufacturers will have to integrate the new regulations. Some of the numerous adjustments affect the technical documentation, marking, specifications of clinical evaluation as well as the classification of certain products. On this occasion you can rely on external support by senetics.

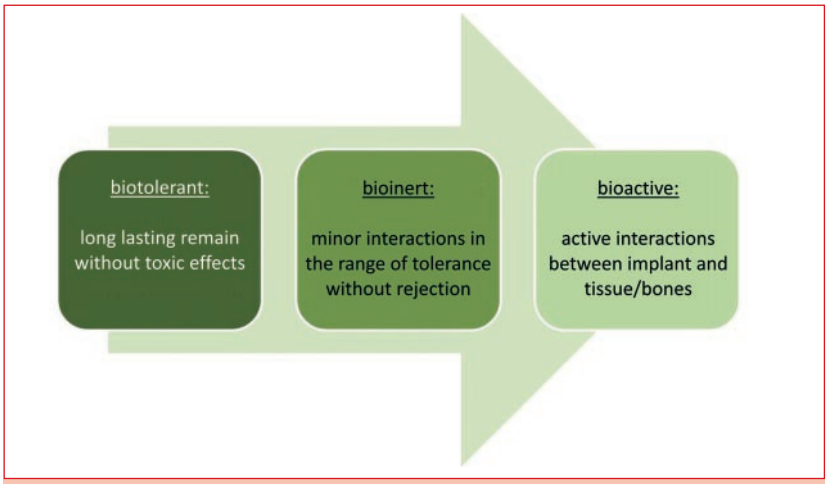
Furthermore, cosmetic products are now included in the surveillance. In addition, there is a new classification system for in vitro diagnostics, which significantly increases the number of IVDs monitored by notified bodies. Disadvantages result largely from the increased effort both in regulatory as well as personal area. We support both major and medium-sized companies.

The first step towards the adaptation to these regulations is a gap analysis of the existing QM system with the new requirements as well as the regulatory framework. Afterwards a roadmap is established on how to supplement the gap in conformity with standards. Doing this we can support you in many ways. We have many years of extensive consulting experience and offer a wide range of training on all important requirements, such as: The EU conformity assessment procedure, the FDA approval, the maintenance of their technical documentation, and the conduct of clinical trials or evaluations.

Smart clothes – convenient monitoring

At least since the development of flexible smartphones, the so-called Smart Flexibles have been heavily discussed. Interesting for medical technology are textiles for measuring different parameters of the human body. The combination of clothing and sensor is particularly interesting for the fitness area. In addition to the most varied functionality tests, there are also risks to be considered. A major problem here is the

Team senetics in front of the new company building ■



Classification of substances depending on their interactions ■

continuous skin contact in case of excessive perspiration. Therefore the material must be biocompatible. Depending on the nature of their interactions with the human body, biocompatible substances are additionally divided into bio-inert, biotolerant and bio-active. A wide range of tests in accordance to DIN EN ISO 10993 are carried out at senetics to determine whether and which interactions a material is taking with the human body. This includes various in vitro and in vivo tests. We would be glad to advise you which biological tests are required by law and which are useful for your product. The following tests are recommended for smart clothes:

- tests for in vitro cytotoxicity (DIN EN ISO 10993-5)
- tests for irritation and skin sensitization (DIN EN ISO 10993-10)

However, the successful biocompatibility test is only the starting shot for a series of different tests, up to the finished product. Using the example of a jersey for real-time measurements during training, a possible test scenario is explained. It is not sufficient to carry out simple long-term tests on lifetime, accuracy and reliability. All environmental influences affecting the product during its lifetime must be determined and their effects assessed. The combination of technical- and biological development and test labs can be used to simulate a wide range of environmental conditions and test their impact. In a jersey for measuring different health parameters during training, these influences are numerous. They start with the normal aging, as well as a regular contact to sweat and cleaning agents. However irregular burdens such as rain, mud, cold or heat must also be considered. senetics is your partner for a variety of standard-conforming tests, both general test methods such as bioburden or endotoxin testing, as well as customized test procedures.

Profit maximization through time management

As in almost all areas the guiding principle "time is money" also applies to medical technology. For one thing this is conditioned due to the ongoing costs. On the other hand, constant innovation and market competition require the fastest possible product introduction to maximize profits. An important step towards time and cost savings is process optimization. This includes the reduction of suppliers. Therefore senetics is your all-in-one shop. Our development and research area is the interface between technology and biomedicine. Close cooperation between the three pillars of development, testing and regulatory affairs, we offer the necessary know-how in addition to the technical development to the legal requirements, regulations and biological as well as medical connections. Especially in the case of novel product developments, the data situation from already approved medical products with comparable technologies is often only limited. Therefore, it is often necessary to carry out clinical tests, in addition to a clinical evaluation, which demonstrate the functional capability of the developed system. In addition, we carry out a technology analysis for you as well as a predevelopment and feasibility study.

New location Ansbach

We moved to our new, innovative location in Ansbach at the turn of the year. The resulting expanded development, manufacturing and laboratory capacities enable us to process your customer orders even better and faster thanks to the higher number of employees and structurally better placed subdivisions of the company. Through short distances between the laboratories and the office even interdisciplinary orders can be processed quickly with the usual high quality. We would like to invite you to look at the new home of senetics healthcare group GmbH & Co. KG personally and to get an impression of our competent employees. ■

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