

rock solid
medical
engineering.

SELEON. TURNING IDEAS INTO SUCCESSSES.

Founded in 1998 as a spin-off from the University of Freiburg, seleon gmbh is today a broad-based engineering service provider in the field of medical technology specialising in product development, production, licensing and risk management.

Highly skilled employees deliver our clients' goals. These include physicists, engineers and information technology experts – all with many years' experience of interdisciplinary life sciences projects. An experienced team of project managers works closely with our clients, accompanying them over the entire product development process – from design to series production.

seleon has excellent personal contacts with the research community. This means that we can call on experts from all kinds of disciplines for advice for your project, and have access to the best contacts for carrying out studies and tests.

Talk to us if you want to turn your ideas into successes – we look forward to taking on your challenges.



DIN EN ISO 9001:2008

DIN EN ISO 13485:2007

21 CFR 820 (QSR/FDA)



COMPETENCE³

INNOVATIVE AND EFFECTIVE PRODUCT DEVELOPMENT.

The strong pressure to innovate in medical technology requires that new products are developed rapidly. seleon offers you reliable developments using skilled and experienced project teams and can come up with new products in a short space of time. You gain a decisive advantage that helps you safeguard market opportunities. **COMPETENCE³**

seleon medical engineering has a clear goal: to turn your ideas into products that are at the very pinnacle of innovation on the international stage. Our experience of even the most diverse technologies allows us to master all fields of application in the discipline of medical technology. Both in the hardware and the software sector. From components to complete equipment.

Thanks to the specialist knowledge of our interdisciplinary development teams and our professional project managers, seleon gives you the opportunity to harness the following key advantages: cut costs, gain time and ultimately get the best possible result for your success. Our services in this domain include:

■ Development process

- Research/concepts
- Feasibility studies
- Design drafts/studies
- Specifications/requirements catalogues
- Functional samples
- Prototypes
- Transition to series production

■ Areas of development

- Mechanics/mechatronics/design
- Electronics
- Firmware/software
- Process technology
- Product testing/product documentation
- Project management
- Quality management

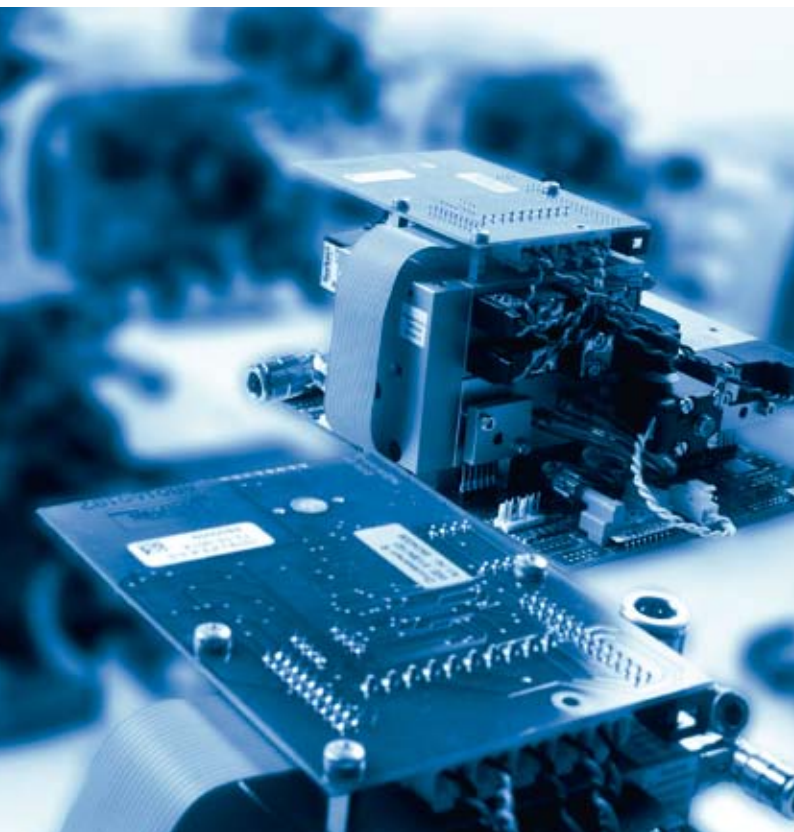
MEDICAL TECHNOLOGY PRODUCTION TO INTERNATIONAL STANDARDS.

The production of sophisticated and standards-compliant medical equipment requires technical expertise and first-class expertise in production and logistics processes. Profit from seleon's efficient and highly skilled production department and in-depth experience. We guarantee you maximum quality and adherence to deadlines. **COMPETENCE³**

Whether it be a custom-made production of small and medium series, zero and first series, prototypes and special systems, whether it be ready-to-sell products or global shipping to the customer: with seleon, you are choosing a partner that adjusts perfectly to your needs on every level.

Thanks to flexible production capacities, we can manufacture your product in a short space of time with the standard of quality you require and in accordance with the joint quality assurance agreement. Certifications, together with the observance of Good Manufacturing Practice (GMP) guidelines, ensure that your product is manufactured in a safe, secure and standards-compliant way. Our services in this domain include:

- Production
 - Batch production
 - Zero series
 - Small series
 - Series
- Production of special systems and design samples
- Provision of production and testing equipment
- Quality management



COMPETENCE³



COMPETENCE³

INTERNATIONAL LICENCES AND RISK MANAGEMENT.

The extensive requirements set down by the licensing authorities, along with guidelines, legislation and standards, are often the biggest hurdle to the launch of medical technology products. seleon's extensive expertise does away with any expensive delays and unnecessary distractions. Use our knowledge to your advantage. **COMPETENCE³**

An important part of the development process is obtaining the licences required to sell your product. We have comprehensive experience with obtaining product licences in Germany, on the European markets, North America and other non-European markets. Our services in this domain include:

- Organisation/moderation of the risk management process and the usability-orientated development process/usability engineering
- Performance of clinical evaluations based on literature as per MEDDEV 2.7.1 and the organisation of clinical trials in Germany and abroad
- Compilation and submission of product documentation
- Taking care of communication with the licensing authorities
- Taking care of tasks relating to market monitoring/vigilance as per MEDDEV 2.12-1

DESSAU.

THE HOME OF DEVELOPMENT AND PRODUCTION.

Our branch in Dessau was founded in 2000 and, alongside mechanics, electronics and software development, also offers all conceivable facilities for the production of components and equipment. Engineers from various disciplines and our production team carry out development and production projects here on behalf of our clients. Our Quality Management and Regulatory Affairs departments are also based in Dessau.



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HEILBRONN. MANAGEMENT AND DEVELOPMENT.

seleon gmbh's headquarters were moved at the end of 2007 from Freiburg to Heilbronn, where we also moved into new company premises in 2010. Heilbronn is where the management and administration departments are based, along with our hardware and software development facilities and Quality Management and Regulatory Affairs departments. Engineers from various disciplines carry out development projects here on behalf of our clients.



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BASIC TECHNOLOGIES.



RESPIRATION TECHNOLOGY

With seleon, you can utilise extensive expertise in the humidification, heating, administration and mixing of gases for respiration. Our portfolio of products spans the entire domain of housings and equipment holders, control mechanisms and sensors, valves, compressors, fans and pumps.

CARDIOLOGY

seleon sets standards in this field. Two examples: with the stent coating machine, we developed a global innovation for clinical research. We supplied an oximeter for one cardiac catheter measuring station that allows the local oxygen saturation of the blood in the heart chambers to be determined in situ during the procedure.

DISPOSABLE MEDICAL PRODUCTS

Whether it be CPAP masks, masks for neonatal respiration or tube systems for syringe drivers: we draw up complete product concepts, offer design studies and develop products to series production stage. Disposables and equipment from a single source.

MEASUREMENT AND ANALYSIS OF PHYSIOLOGICAL DATA

seleon also has an excellent reputation in the analysis of data and management of complex systems. This includes, for example, the evaluation of pressure and flow signals in respiratory therapy, the capture of trigger signals from ECG data for the synchronisation of CT images and the analysis of tremors for the diagnosis of Parkinsonism.

EQUIPMENT FOR HOME-BASED THERAPY

The variety of devices used for home-based therapy has grown markedly in recent years. We take care of the development of products for our customers that are designed especially for the challenges of home environments. Intuitive to use, quiet, robust and maintenance-free.

MEDICAL LASER TECHNOLOGIES

seleon has worked in the fields of medical technology laser products and phototherapy equipment for many years. Our clients come from the disciplines of dermatology and dentistry, for example.

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