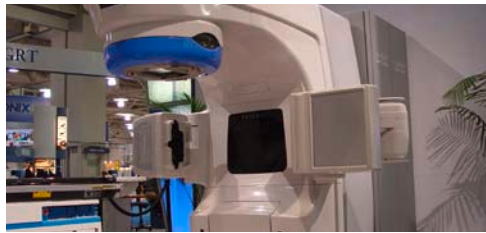


Medical Products have to be developed according international regulations. Zühlke has long-standing experience in the development of multi-disciplinary medical products using a systematic development process.



Consulting Development Integration

# Development of Medical Products

## Licence requirements

To successfully licence new medical products on the international markets, researcher and developers must consider country-specific guidelines when setting up the quality department and development processes. In the European market, there is the process-orientated standard DIN EN ISO 13485:2003. The FDA requirements for medical products in the American market are specified in document 21 CFR 820. Also important is risk management according to ISO 14971.

## Standards-driven development

The standards in medical technology contain particular requirements for development. Among others, risk management, reviews, verifications, and validations are included as well as change control. Our wide-reaching system development process covers these requirements and ensures the hardware and software development conforms to regulations, inclusive of the required documentation.

In consultation with you we work following our

own or your company's quality management system. As an ISO 13458 certified development partner, we implement multidisciplinary products, and test systems – from the very first idea to the finished product. We gladly bring our experience and know how of the regulatory environment in the form of consultation, coaching, training and reviews into your internal project implementation.

## Your benefits

- The experience and know how of Zühlke specialist, combined with compliant system development processes and quality management guarantees an innovative product development in a regulatory environment
- The know how transfer to your team during the project is secured through training and coaching

## Project examples in the area of medical products

- Development of injection equipment for intraocular lenses
- Development of a digital camera for colour measurement in the medicine
- Development of eye operation equipment based on laser
- Cost reduction of cataract operation equipment
- Numerous reviews of different medical products

Come to use with your ideas for new products. We will convert them together with your team or deliver the product ready for manufacturing.



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