



## DEVELOPMENT OF A NEW TYPE OF EYE LASER

Pantec Biosolutions AG, a medtech company in Liechtenstein, is developing an advanced eye laser (class IIb) for a US start-up which integrates a new treatment method for presbyopia. In several stages, device prototypes will be developed for preclinical studies, usability evaluation, and eventually clinical validation for obtaining FDA approval. The implementation of this complex development project involved collaboration between konplan and other development partners.

### From concept to verification

konplan supported Pantec in the early concept phase by jointly developing GUI workflows and wireframes. For implementation of the corresponding GUI, konplan coordinated numerous activities with other development partners. In addition to activities related to formative usability evaluation (IEC 62366), konplan supported the other development partners in generating compliant documentation (IEC 62304) and worked together with Pantec Biosolutions to develop a documentation and verification concept for creating the evidence documents necessary for market approval.

### Preclinical successes and satisfied customers

Using the prototypes that were developed, preclinical feasibility studies were successfully performed. These studies allowed precise calculation of the most important product requirements and an efficient start to development of the clinical prototype. The compliant project documentation produced deficiency-free audits. In conjunction with the verification process, an accurate roadmap for the upcoming development stages could be defined.

### Result

- Functional GUI for preclinical studies
- Intuitive touch control
- Audit-ready documentation

### Methodology & Technologies

- .Net Framework WPF (Rich GUI)
- .Net Core (Web Simulatoren)
- Akka.net Actor Model Toolkit
- MS Azure Cloud (Devops & Services)

### Scope of Services

- Requirements engineering
- GUI concept, architecture & development
- Documentation & verification concept
- Documentation according to IEC 62304



29 months



4 employees – konplan



Analysis & idea generation, conception, development

### Customer

