



# OUTSOURCED MEDICAL DEVICE SOFTWARE LIFE CYCLE PROCESSES

**Software development and maintenance, in particular for medical devices, demands for highly skilled personnel, continuous training on technologies and regulatory aspects as well as maintenance of compliant and up-to-date development processes.**

**More and more companies outsource this activities to specialized companies like ISS AG, Integrated Scientific Services.**

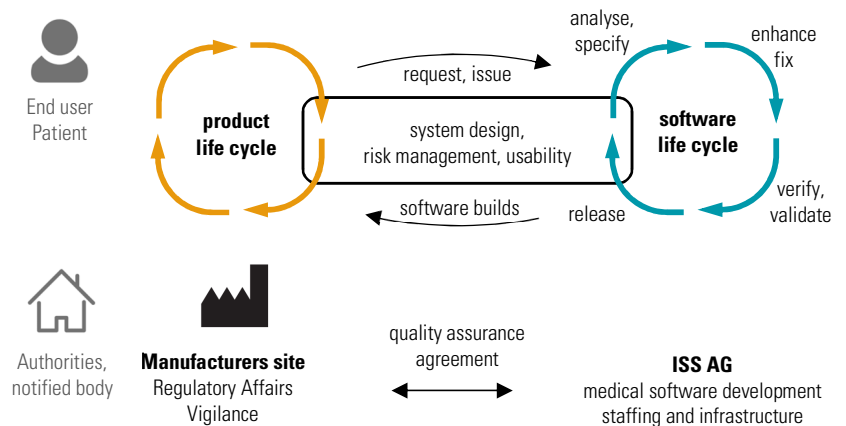
## Your benefits

In case developing and maintaining medical device software is not the core competence of your company, outsourcing this activities enables you to stay focused. Regulations and the notified bodies often judge software as a substantial risk, demanding for high quality and structured, sustained evidences of the quality of the software as well as established software life cycle processes. Incidences like software security flaws or failing to adapt software to a new generation of hardware justify this evaluation.

## Our service

### Software life cycle management

We develop and maintain medical device software – every day. Since we have implemented the necessary processes, our customers can outsource not only the development, but the whole software life cycle management including technical documentation, issue tracking, maintenance processes and software release as needed. Our ISO 13485 certification, scoping medical software development, allows us to demonstrate compliance to authorities and notified bodies of our customers on behalf of state-of-the-art standards and regulations like ISO 13485, 21 CFR part 820, IEC 62304, IEC 82304-1, ISO 14971, IEC 62366-1, IEC 60601-1-x as well as guidances and technical reports. Together with our customers, we define the interactions of the processes as needed by our customers by means of a quality assurance agreement.



### Software technologies

We have a strong track record on both, embedded medical device software and software as a medical device, particularly in the following fields:

- Intel, ARM and TI architectures, PCs and microcontrollers, Linux, Windows, Keil RTX5
- Signal- and image acquisition and processing software, numerical software
- Motion control software, real-time software systems
- Multi-Touch Human Interfaces on Linux (Qt) and Windows (Qt, C#, .NET WPF)
- Web Applications, Web Technologies and Databases

### Assignment of rights of software

IP for mandate development (source-code, documentation, etc.) will go to the customer.

## Your contact

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