Fraunhofer Institute for Experimental Software Engineering IESE

Software is a part of our lives. Embedded into everyday equipment, into living and working environments or modern means of transportation, countless processors and controllers make our lives simpler, safer, and more pleasant. We help organizations to develop software systems that are dependable in every aspect, and empirically validate the necessary processes, methods, and techniques, emphasizing engineering-style principles such as measurability and transparency.

The Fraunhofer Institute for Experimental Software Engineering IESE in Kaiserslautern has been one of the world’s leading research institutes in the area of software and systems engineering for more than 20 years. Its researchers have contributed their expertise in the areas of Processes, Architecture, Security, Safety, Requirements Engineering, and User Experience in more than 1,200 projects.

Under the leadership of Prof. Peter Liggesmeyer, Fraunhofer IESE is working on innovative topics related to digital ecosystems, such as Industrie 4.0, Big Data, and Cyber-Security. As a technology and innovation partner for the digital transformation in the areas of Autonomous & Cyber-Physical Systems and Digital Services, the institute’s research focuses on the interaction between embedded systems and information systems in digital ecosystems.

Fraunhofer IESE is one of 72 institutes and research units of the Fraunhofer-Gesellschaft. Together they have a major impact on shaping applied research in Europe and contribute to Germany’s competitiveness in international markets.
SOFTWARE-BASED SYSTEMS FOR HEALTH AND QUALITY OF LIFE

The domain of medical systems faces particular challenges: The market demands innovative products in less and less time, which constantly increases the complexity and networking of the systems. Yet, absolute reliability and safety of the systems and the (embedded) software are required. There is hardly any other area of our daily lives where computer technology is so close to humans, and consequently, mistakes can have very serious effects.

Our software and systems engineering approach supports you all the way from the elicitation of requirements on the medical product to validation. Together with our customers, we develop innovative solutions for software development that efficiently fulfill the requirements of IEC 62304, DIN EN 60601-1-4, and ISO 12207, and provide assistance in systematically implementing them in daily practice. We integrate future-oriented methods and techniques that ensure quality requirements (e.g., in accordance with ISO/IEC 9126) efficiently and economically. Safety is the top priority in this respect. We use new methods to support you in performing risk management according to ISO 14971 for software, and to use techniques such as Failure Mode and Effects Analyses (FMEA) and Fault Tree Analyses (FTA) for analyzing software safety. Custom-tailored quality management approaches (e.g., similar to ISO 13485) are defined as supporting processes.

Your benefits:
- Higher safety of the software and thus of the medical devices
- More efficient development and faster time to market
- Reduction of the development and quality assurance costs
- Measurable quality

EXAMPLES OF APPLIED RESEARCH MADE BY FRAUNHOFER ISE

Especially in the area of medical systems, every effort has to be made to prevent both hardware and software system errors to the greatest extent possible. Therefore, the effort for testing during development is enormous and accounts for a major portion of the overall costs. For ATOMOS MedizinTechnik GmbH & Co. KG in Lenzkirch, Fraunhofer ISE developed an adapted system-testing methodology and requirements inspection techniques. Both techniques were successfully introduced in custom-tailored training events. Thus, defects can already be found in early development phases, and can be corrected with relatively minor effort. B.Braun AG in Melsungen and Stryker GmbH & Co. KG are other companies that benefit from Fraunhofer ISE’s know-how in the area of Usability Engineering.

COMPETENCE IN SOFTWARE AND SYSTEMS ENGINEERING

Fraunhofer ISE provides support for manufacturers of medical systems during all phases of software and system development.

SOFTWARE DEVELOPMENT

Requirements Management
Domain standards such as IEC 62304 require an appropriate design of requirements and specification documents during development. We support you in eliciting requirements and in developing suitable requirements specifications as well as in managing the requirements.

Usability Engineering
With our approach Usable Software Products Based on Innovative Requirements Engineering, we support you in ensuring that usability is considered during development, and in integrating it into the software and systems life cycle.

System and Software Architectures
We support you in the specification and implementation of future-oriented architectures and in the evaluation and re-structuring of your existing software architecture, taking into account special constraints such as runtime behavior or memory requirements.

Software Product Lines and Reuse
Systematic reuse, for example in the form of software product lines, helps to decrease a product’s time to market. With our PULS® approach, we support you in defining and introducing the idea of software product lines, and in defining suitable and safe reuse concepts.

SOFTWARE QUALITY MANAGEMENT

Risk Management
Standards demand a lifecycle-wide risk management process, especially also for software. We support you in the standard-conformant implementation of ISO 14971 requirements by defining and implementing a risk management process for software and the corresponding documentation that is adapted to your context.

Safety Analyses
We support you in selecting and using adapted techniques such as FMEA, FTA, or more recent processes such as component fault trees. In particular, we make these processes applicable to software in medical devices.

Development Processes
We support you in the standard-conformant definition (e.g., IEC 62304, ISO 12207, V-Model), structuring, documentation, and implementation of development processes and in the selection of methods, tools, and techniques that are suitable for passing certification procedures.

Static Quality Checking Techniques
Together with you, we define appropriate and innovative processes for verification in parallel to development.

Testing of Distributed Systems
We support you in modeling and planning test processes, in developing test cases, and in evaluating system quality.

Model-based Testing and Test Automation
We support you in the design and introduction of model-based testing techniques for embedded software, focusing in particular on test automation aspects.

Quality Management
We support you in defining, structuring, and establishing a standard-conformant quality management system for your software development in the style of standards such as ISO 9000-3 or ISO 13485, or the FDA Quality System.

Software Measurement Systems
Through the use of defined metrics, which we derive in a systematic manner adapted to your demands, quality aspects can be expressed in concrete statements.