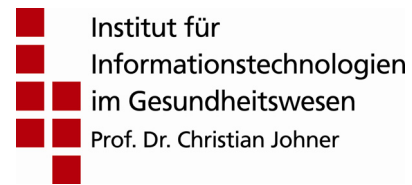




Developing Medical Software Compliantly

Institut für IT im Gesundheitswesen,
Freiburg/Konstanz, Germany

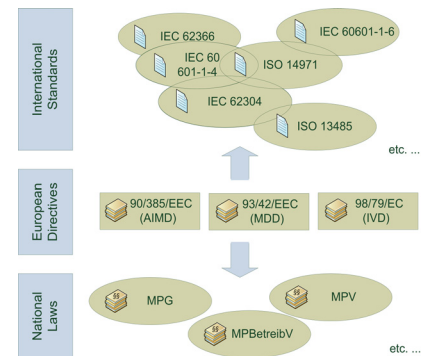
In cooperation with: Method Park, Erlangen and
Polarion, Stuttgart, Germany



BACKGROUND and BASICS

Manufacturers of medical devices need to be compliant to a lot of regulatory requirements. As software is often a part of it or is sometimes even a medical device in its own rights, these requirements apply to software development as well. Currently not many tools provide specialized support for that.

The Institute for IT in Healthcare tries to build bridges between regulatory affairs and practical software development by establishing knowledge and techniques to bring those things closer together.

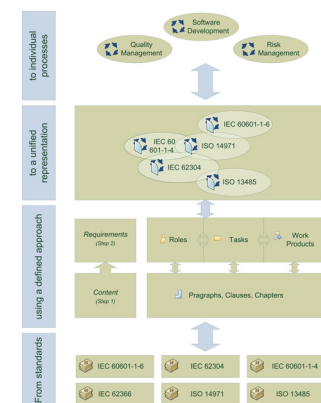


CONCEPT and SOLUTION

The key to develop and proof compliance is a bi-directional traceability from standards to the “real world” and vice-versa. Three things are necessary to achieve that:

- Ways to define and build models of the real world
- Techniques and procedures to transform regulatory requirements into those models
- Tools to support this

We are using commonly used standards as meta models, commercial tools for modeling and our own experience to develop procedures and techniques to combine all this.

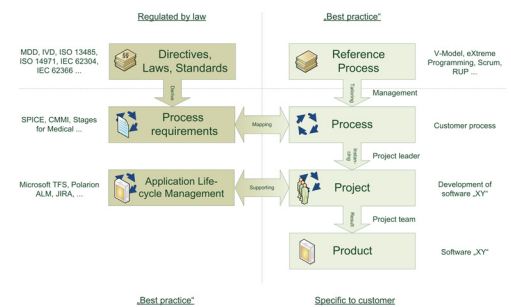


STATUS and OUTLOOK

In cooperation with Method Park, we have merged all relevant European standards into a single, uniform BPM representation and are currently working on relevant FDA requirements. This so-called “Unified Reference” is part of “Stages for Medical”, Method Park’s Business Process Modeling Suite.

In addition to that, we are working on ways to transform regulatory requirements into Application Lifecycle Management tools. We are currently building the “MedPack”, an extension to Polarion’s ALM application.

For both projects, we are looking for proof-of-concept customers to test and enhance our approaches and products in live scenarios and real medical projects.



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