



# GHTF 2006 Conference

Technikzentrum Lübeck GmbH  
PQM - Integrated Project- and Quality-Management for Medical  
Technology

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## Introduction

Large R&D-projects, with many different parties taking part, often suffer from the problem of an efficient implementation of an innovation accompanying project- and quality-management. Technical project development does not directly integrate the legal and regulatory affairs requirements which causes time and resource consuming feed back loops to create and approve all necessary documentations. This is especially true for R+D in universities either as direct product development or collaborative contributions to industry.

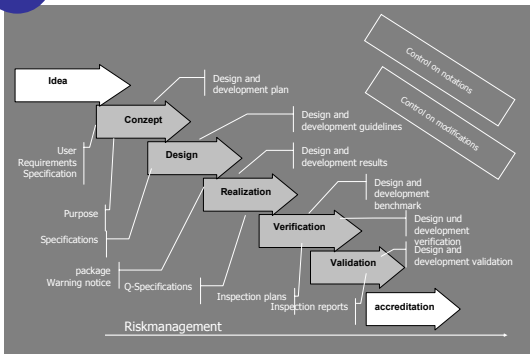
## The idea

- A joint project of companies with university institutes and clinics works on a project- and quality-management scheme that aims besides other aspects to
  - integrate the use of development and project management tools for user requirements specification, risk-analysis, medical evaluation, usability testing etc.
  - assist the optimal coordination of the communication between different developments or project parties with focus to the quality-gates in the development-process
  - minimize the documentation efforts, but considering the compliance with regulatory affairs by using standardized documents

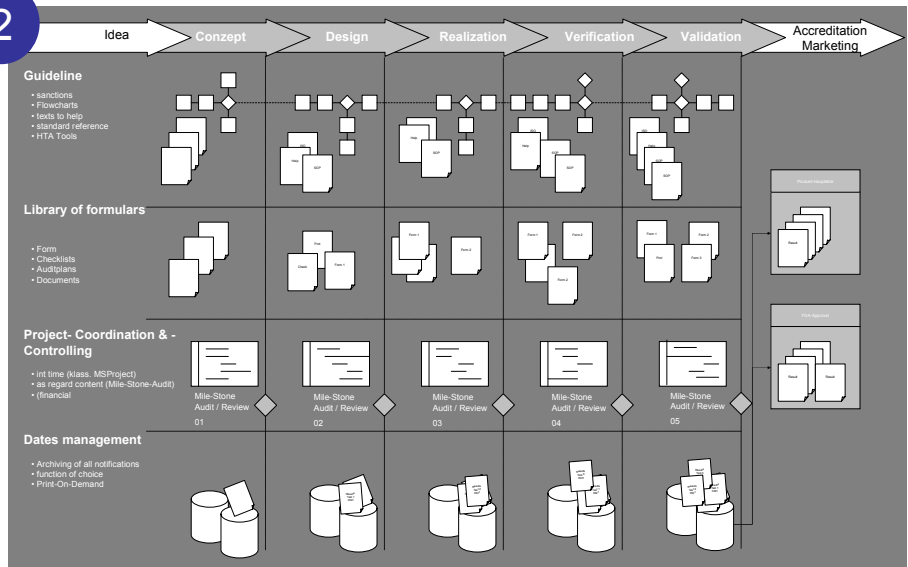
Own development activities and first implementations have been started within a large R&D-project concerning liver surgery technology (simulation, navigation, smart instruments).

## Process of product development

1



2



## Method

On the basis of the logical connection from processes for development, risk-management, evaluation and the activities for usability the involved R&D-personal and other users will be assisted to get results that meet all the different quality requirements. The assistance is offered via SOPs, explanative hints and supporting tools as well as standardized templates for the documentation. The guided integration of technical development and quality management requirements up to clinical and health impact assessment should make medical product development more efficient and safe in terms of regulatory affairs fulfilment.

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