



Increasing the process efficiency for creating documents for CE/FDA approval

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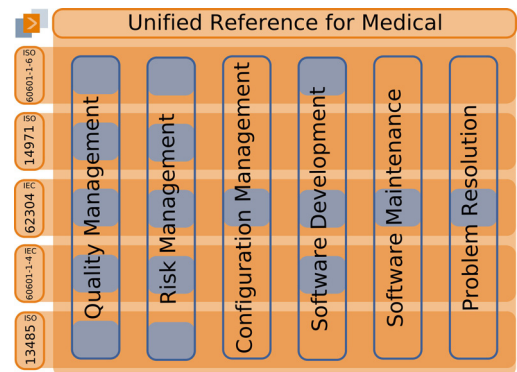
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BACKGROUND and BASICS

- We can already support you reaching conformity with major medical standards
- Not only small startup companies struggle to get approval for their medical devices/software
- There is complex documentation needed to show compliance with the essential requirements to get CE marking or to create a 510 (k) to get FDA approval – don't be afraid!

Competences of Methodpark:

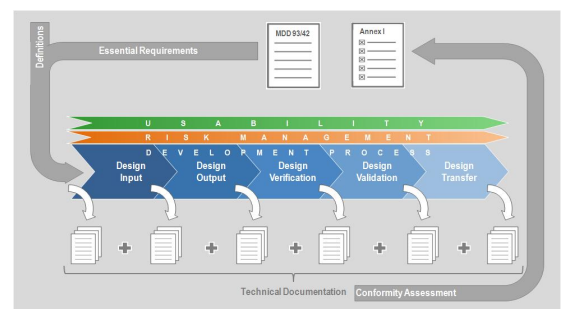
- Knowledge and experience of processes and their compliance to standards and laws for medical devices/software



To easily achieve conformity with medical standards

CONCEPT and SOLUTION

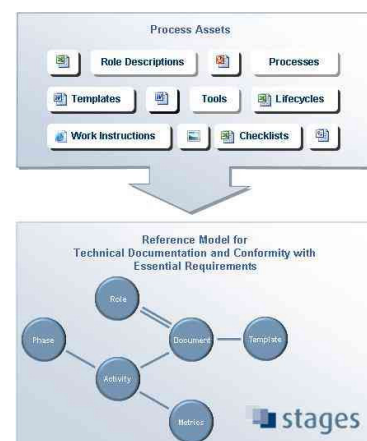
- Getting the approval for medical devices should not be handled as a separate process
- Documents will be created following a workflow during the development process
- We can support you by integrating the regulatory needs into your development process to create documents at the right time with the proper content
- Target is to reduce time to market by getting the approval in time!



Getting medical approval – easier than you believe!

STATUS and OUTLOOK

- The framework for process modeling and compliance mapping already exists (Stages) and is implemented at many customers
- Merge of relevant standards for CE- Conformity of medical software in one Unified Reference for Medical exists
- Specifics for FDA compliance (Guidelines) are getting realized soon
- Bundle with support and consulting for technical documentation and approvals is ongoing
- We look for partners for an evaluation side of our solution



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