Startup of a Requirements Engineering process in the MedTech environment: Risks, opportunities and side effects.

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Agenda

- Tecan
- Environment / starting point
- Risks of RE process startup
- Journey through 5 prototyping steps
- Side effects and outlook
Startup of a Requirements Engineering process in the MedTech environment

- Head office in Switzerland, >1100 employees
- Development sites in US, DE, and AT
- Market leader in lab automation
- Products and OEM-instruments in Biotechnology, Pharma, Diagnostics, Life Sciences, Forensics, etc.
Lab automation - sample to result

Sample Preparation

Consumables

Lab Automation

Detection

Analysis
A MedTech analogy…

Product

Package insert

Regulatory Body

User
…with MedTech species…

CEO

Product Manager (PM)

Project Leader (PL)

Developer (Dev)

Quality Engineer (QE)

System Tester (ST)
...their tribal structure...
…and MedTech projects

CEO

Project A

PM

PL

DEV

EST

Project B

Project C
...and that is particularly significant. Which are the opportunities and risks in the introduction of RE???
RE startup risks – we did encounter

- **Complexity**: “I don’t want another process”
- **The wrong thing... at the wrong place**: “We are SCRUMies where RE’s write user stories.”
- **High costs**: “I already pay for 20 SW developers, 3 HW engineers and 15 testers, RE is simply too expensive”
- **No value**: “Ahm, what do you guys produce again...???”
- **No change**: “Hey, project managers can write the requirements by themselves.”
- **Inefficiency**: “Send the bullet list from our brainstorming session to the project leader for cost estimation”
What was our Vision?
1 RE on our RE Process

- Analyze company and project environment
- Understand needs of projects and organization
- Identify key persons in projects and company
- Small steps forward
Ongoing project – fire extinction

- Release driven Requirements Engineering (agile)
- Tool-supported traceability of requirements to task (reporting)
- Standardized requirements / UML support
- Establish change management
3 Extend RE to system level

- Requirements engineering process on product level
- Develop system processes as framework
- Details by Use Case specifications in combination with mockups
Startup of a Requirements Engineering process in the MedTech environment

RE delivers value

Process

UC Specs

Customer

Team Tecan (RE, PL, PM)

Mock

Design

Specifications

Prototype

Development Partner
RE Process Guideline

1. Project Kick off meeting
2. Business Processes
3. High level Use Cases
4. Activity Diagram
5. Product Requirements
6. Use Case Specifications
7. Mockups
8. Specifications
9. UI Prototype
10. PRD Refinement
Management by **Agile RE**

- Task from: projects, start up and improvements
- Team commitment and transparency
- Continuous improvement cycle
- Bottom up target setting
Review of RE startup risks

✅ **Complexity**: Integrated in existing process by intuitive and efficient RE tool change

✅ **The wrong thin… at the wrong place**: Scalable RE process on system level that works across projects and disciplines

✅ **High costs**: Demos of success stories using a “Best practice project”

✅ **No value**: We use efficient, intuitive and extendible methods

✅ **No change**: Consulting of projects, training on RE process to RnD members, management presentation, etc.

✅ **Performance**: Agile RE task management process

☐ **Inefficiency**: Tool support (ongoing)
All done?
Side effects and outlook of RE

Established RE process…

- …provides sprint and project structure for SW
- …is offered as service for workshops and moderation
- …supports the innovation (business opportunity) process
- …provides framework for build up of Usability Engineering
- …more focus on prioritization and value definition
- …initiated a Global Tecan Traceability Tool Project
Thanks a lot for your attention!

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