

Tools and Processes for Regulated Software Development

Fantasy Football for Medical Devices

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June 25th, 2019

Fantasy Football for MD development

Premise: If you were the in charge of a brand new MD product,

and you had complete control,...

what tools and processes would you choose?

(virtualized "team" of tools and processes)

The Product:

Blank page software development

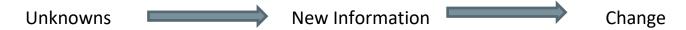
Replacement technology – infusion pump for home

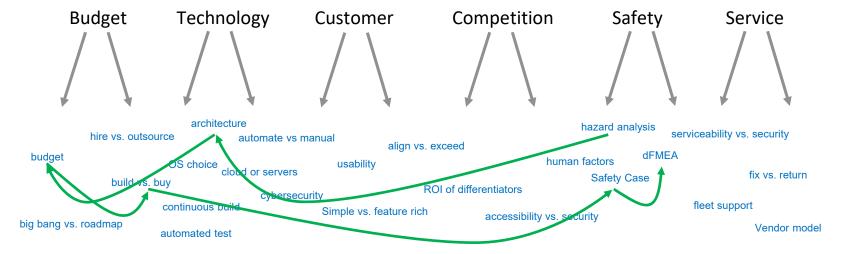
Roughly 40 person/years



Nature of the Game

Biggest project execution challenge is change





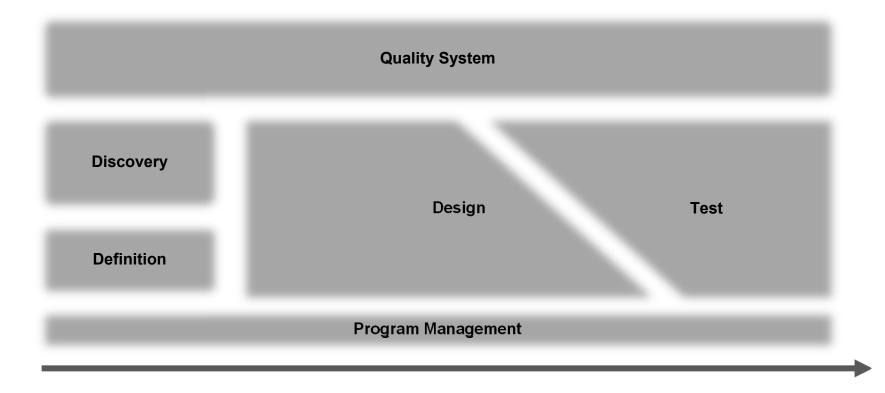
ICS

Strategy for Change

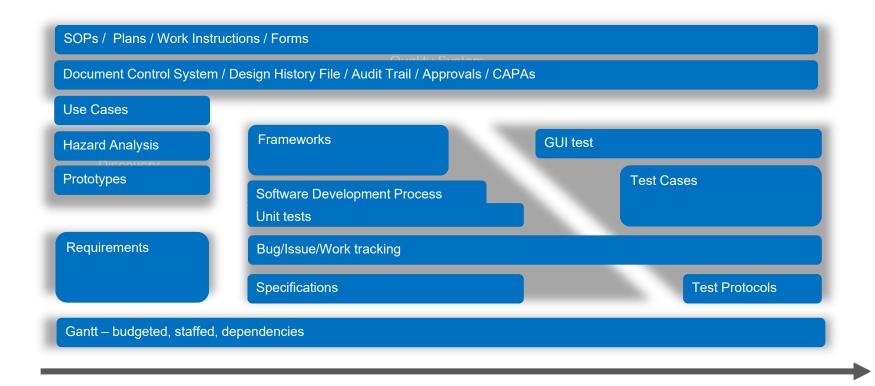
Kill Change - Accelerate changeUnknowns New Information Change

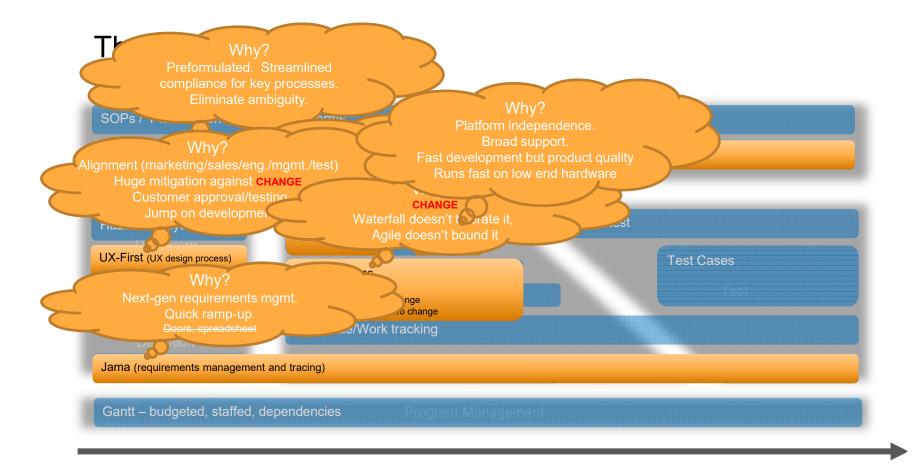
- ✓ High Fidelity Prototypes
- ✓ Formative review
- ✓ Early formal agreement

The Playing Field – MD Product Development

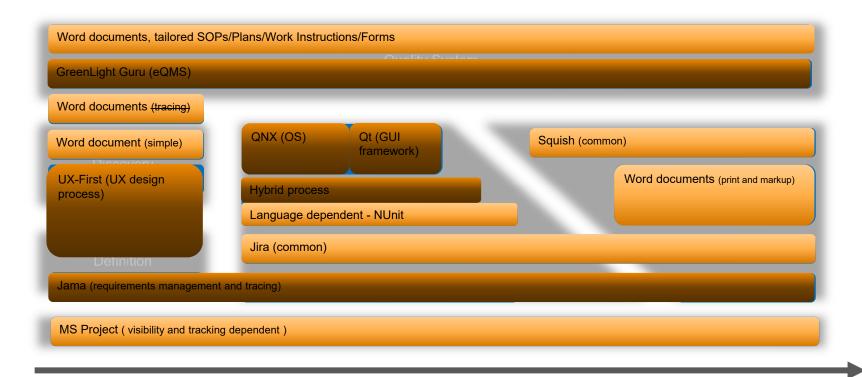


All the Positions



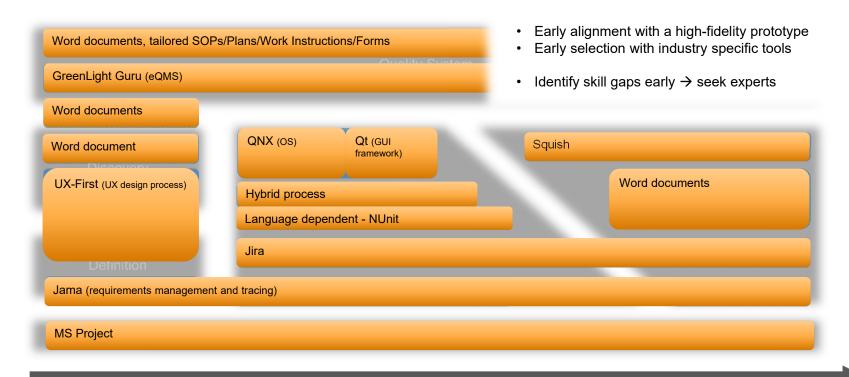


The Tried and True – Keep it Simple





Fantasy Team to Manage change



Thank You.



