Pretending to be agile
A difficult journey with a happy (?) ending
Let's start with a survey

https://www.menti.com/al895pud8mz3

Biggest Challenges in "agile" project execution?
One of the world’s leading medical technology companies

B. Braun aims to protect and improve the health of people around the world. For more than 180 years, we have shaped health care with our pioneering spirit and groundbreaking contributions.

Tradition and innovation
We protect and improve the health of people around the world.
We continuously develop our portfolio of more than 5,000 products.
We have subsidiaries in 64 countries who serve the different health care markets.
We continuously invest in the modernization & automation of our production sites
What do we mean by „agile“?
We talk about „agile“ – but what is it? More than a buzzword?
We talk about „agile“ – but what is it? Let’s try a definition.

From the “Manifesto for Agile Software Development”:

We are uncovering better ways of developing software by doing it and helping others do it. Through this work we have come to value:

- Individuals and interactions over processes and tools
- Working software over comprehensive documentation
- Customer collaboration over contract negotiation
- Responding to change over following a plan

That is, while there is value in the items on the right, we value the items on the left more.

See Manifesto for Agile Software Development (agilemanifesto.org)

Agile working is a practice which encourages adaptability while aligning with customer needs and requirements on a continuous basis. It promotes teamwork, self-organization, and accountability.
Our „MES History“
Imagine you're in need of treatment.

You want to be sure that

- all medical devices do what they are supposed to do,
- all pharmaceuticals contain exactly what they are supposed to contain,
- everything you get in contact with is clean, not contaminated, and will not cause an infection

This is the purpose of qualification and validation (Q&V) – to ensure and provide evidence that all our products do what they should and don’t pose a risk to patients and healthcare professionals.
What do authorities expect?

21 CFR 820 / 70

(i) Automated processes. When computers or automated data processing systems are used as part of production or the quality system, the manufacturer shall validate computer software for its intended use according to an established protocol. All software changes shall be validated before approval and issuance. These validation activities and results shall be documented.

EU-GMP Annex 15 – Qualification and Validation

Computerised systems used for the manufacture of medicinal products should also be validated according to the requirements of Annex 11. The relevant concepts and guidance presented in ICH Q8, Q9, Q10 and Q11 should also be taken into account.

To validate bad processes or bad software is almost impossible!
L.I.F.E. – Europe’s most advanced production site for infusion solutions

Leading Infusion Factory Europe (L.I.F.E.) has been one of the world’s first completely vertically integrated Pharmaceutical production site (SAP→Shop Floor)

Production performance:
- 1 Million Ecoflac-Plus containers / day (30 lorries)
- > 220 Millionen Ecoflac-Plus containers / year
Traditional MES Implementation Strategy – „Grand Design“ / V-Model

Development Phase

Release

User Requirements Specification

Requirements / Process Testing

Functional Specification

Functional Testing

Design / Configuration Specification

Integration Testing

Module Design Specification

Module Testing

Implementation

Development Testing

• White Box, Black Box Tests
• Integration Tests
• Regression Tests
• Load Tests
• Boundary Condition Tests
• Pre-FAT Tests

PQ
IQ2 / OQ2

• Equivalent to SIT/SAT
• Functional testing of SW Configuration Items installed on the target HW

IQ1 / OQ1

• Equivalent to FAT
• Can re-use test cases from Development Testing

DQ

• Reviews of Requirements & Design / Development deliverables

Recursion

• Development Testing

15  B. Braun Melsungen AG
What were our (the customer’s) needs?

- Get a fully validated system
  - works as specified
  - in time
  - in budget
  - Users are trained
  - Administration processes are documented

- Preconditions:
  - High-quality tender documentation available
  - Supplier is not preselected, time-consuming tender process
  - Supplier is able to map tender documentation to solution design during quotation phase
  - Supplier is committed to long-term support of custom developed solution
  - “Out of the box” / standard not a priority
From individual projects to template-based rollouts
### Standard Platforms, standard interfaces, aligned scope

**What should be produced?** When should it be produced?
- Which resources should be used? Which materials should be used?
- Which inspection need to be performed, and when?
- What is the initial status of resources (e.g. calibration, qualification)?

**How do we produce?**
- Start production, prepare resources, receive goods, verify qualification, handle material flow, execute inspections, report progress / status / results.
- Request to ERP/PLM for information / decision only, no control by ERP/PLM.

**Physical Execution & Control (implementation of unit operations)**
- (PLC, DCS, Manual operations, process equipment, machinery, … and SOPs)

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<table>
<thead>
<tr>
<th>Platform A</th>
<th>Platform B</th>
<th>Platform C</th>
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<tbody>
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ISA Levels:
- **ISA Level 1+2**: OPC UA
- **ISA Level 3**: Soap/XML
- **ISA Level 4**:
Template Approach

- **Control Strategy**
  - Product documentation (specification, risk analysis, defect list, …)
  - Process requirements (risk analysis, (local) regulatory requirements, …)
  - Template process (Best practices taken from similar plants and/or products, …)
  - Economic considerations
  - Site-specific considerations
  - Standard functions

- **Automation Strategy**
  - Template process prepared in PLM & ERP
  - Template Architecture, Harmonized interfaces

- **Operate & Maintain**
  - Tools & Methods for Q&V on ALL levels
  - Standardized Infrastructure, Security, …
  - Project milestones

- **Production**
  - (MES) Template Selection & Configuration
MES Template – Instance creation and roll-outs

Incorporation of selected extensions by solution owner

Subset of core Functions for site and product A

Site/product specific extensions are implemented by project team under control of solution owner

Site operations team is trained.

Operation, Local process support by site operations team.
Level 1 (gate to external support) by shared service

Level 2 by solution owner

Level 3 by external partners
What are our (the customer‘s) needs now?

- Get a fully validated system
  - works as specified
  - in time
  - in budget
  - Users are trained
  - Administration processes are documented

- Strategic decisions:
  - MES Platform is preselected
  - Supplier is preselected
  - MES Template is a „B. Braun product“
  - B. Braun technical know-how development is important
  - Out of the box (platform and template) is important

Agile working is a practice which encourages adaptability while aligning with customer needs and requirements on a continuous basis. It promotes teamwork, self-organization, and accountability.
A difficult journey ...
New production site in Melsungen (start of production May 2024)

Targets:
- Seamless Processes
- Touchless Operations
- Vertical Integration
- Technology Advancements
- Sustainable Operation
Changing (not only) the working mode

**TRADITIONAL**

- Complete set of tender documents created up front
- Intensive up-front discussions with potential suppliers to ensure maximum understanding of requirements and constraints
- **Supplier** is responsible for solution design and implementation
- Supplier is responsible to deliver documents / evidence as agreed in the contract
- Supplier is completely responsible to deliver in time and budget
- Supplier-caused delays may be penalized.
- Changes initiated by **B. Braun** must be evaluated by supplier and may effect time and budget.
- Deliverables are provided at the agreed milestones
- **B. Braun** focuses on review and acceptance tests, involvement during development phase is limited
- Need for **B. Braun** to understand architecture / detailed design of solution is limited.

- **B. Braun**-supplier interaction is milestone-driven and document-based

**NEW AGILE WORKING MODE**

- **B. Braun** team needs to understand the capabilities of the platform (in CMF speak – final „modelling“ is **B. Braun** task)
- **B. Braun** provides process description and high-level functional requirements known at the start of project.
- Incremental detailing of requirements with focus on staying close to „out of the box“ features (Supplier & **B. Braun**)
- Supplier provides implementation of features (functional modules), including documentation, test specifications and test results
- **B. Braun** reviews documentation
- **B. Braun** performs tests of feature
- **B. Braun** combines features to realize process
- **Responsibility to deliver in time and budget?**

- **B. Braun**-supplier interaction is regular and tool-based (Azure Devops)
MES Engineering with Azure DevOps/Modern Requirements

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<thead>
<tr>
<th>ADO System</th>
<th>Responsible</th>
<th>Work Item Hierarchy</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>L1 Requirements</strong></td>
<td>B. Braun</td>
<td><strong>Area</strong></td>
</tr>
<tr>
<td><strong>L2 Functional / Design Specifications</strong></td>
<td>CMF</td>
<td><strong>Epic</strong></td>
</tr>
<tr>
<td><strong>L3 Engineering Management</strong></td>
<td>Vendor</td>
<td><strong>Feature</strong></td>
</tr>
</tbody>
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**Boundary between B.Braun & Vendor depends on project execution model**

- **PQ Test Case**
- **IQ2/OQ2 Test Case**
- **IQ1/OQ1 Test Case**
- **DQ Design Review**
- **Issue (Bug, Enhancement)**
- **Test Plan**
- **Test Case**
- **Task**
“Working mode” in sprints (Version 4)

General Process and Design

1. Create Backlog, assign Backlog items (epics) to sprints
2. Provide Infrastructure, install Dev.-System

Start Project “Kick Off”

- General Process and Design
  - "Backlog-Alignment"

Start Sprint X-1 "Specification"

- Create Backlog
- Clarify process and requirements (Epics) in detail
- Create/update features, RA, user Stories and test-specifications (create 80%, modify 100% status)
- Define acceptance criteria
- Review, comment and pre-approve specifications for implementation

Select assigned Epics

Start Sprint X "Implementation"

- Implement (config, customize, program) functionality
- Internal test of functionality and config, docu of test results
- Sprint Progress Meeting
- Deliver Sprint Rollout package incl. test-results and documentation
- Install Sprint Rollout package
- Test Sprint functionality

Adjustments needed?

Test passed?

End of Project

Provide Infrastructure, install Staging System

Prepare Start of Quali, finalize and approve Specs.in BDoCS

Qualification (IQ, OQ)

Deviations, Bugfixes

All Backlog items implemented?

yes

no
How well can we manage various aspects of our project today?

- Establishing accountability for time and budget is a challenge, since there is no contract in place which enforces it.

- Estimating as we go along with refinement sprint by sprint is insufficient – we need the “big picture” and a regular check of where we are.

- The “big picture” requires a clear understanding of the overarching requirements and the intended solution architecture.

- How do we address these issues?
  - Management reviews
  - Automation Concept & Functional Architecture
  - Data, data, data ....
So, what are our biggest challenges?

**DILBERT**

I PUT TOGETHER A
PLAN FOR OUR DATA
CENTER PROJECT.

WE DON'T NEED A
PLAN. WE'RE AN AGILE
COMPANY.

IT'S BETTER TO MOVE
FAST AND FIX OUR
MISTAKES AS WE GO.

THAT DATA CENTER
WILL BE FULL OF
SOFTWARE. WILL IT NOT?

YES, BUT...

DON'T BE AFRAID OF
CHANGE.

WHAT IF I RAPIDLY MAKE A
PLAN AND TELL YOU
I DIDN'T?

**BY SCOTT ADAMS**

YOU'RE THINKING
OF SOFTWARE. WHERE
THE COST OF MISTAKES
IS LOW. THIS IS A
CONSTRUCTION
PROJECT.

IS THAT AGILE
ENOUGH FOR YOU?

I'LL NEED TO
GOOGLE
THAT.

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Let’s see if anything changed …

https://www.menti.com/al2xnhauh3m9

Biggest Challenges in "agile" project execution?

![QR Code]
Our biggest challenges

- Handle disturbances
- Ensure customer know-how
- Ensure supplier know-how
- Ensure quality (of code & documentation)
- Deliver a consistent solution
- Meet milestones
- Stay in budget
Final verdict
Are we an „agile“ team, or do we just pretend?

Agile working is a practice which encourages adaptability while aligning with customer needs and requirements on a continuous basis. It promotes teamwork, self-organization, and accountability.
Are we an „agile“ team, or do we just pretend?

We learn and improve as we go along. We openly discuss issues and work jointly on solutions. We’re far from where I would like us to be. But we’re moving into the right direction, and we’re moving as a team. So, for me this is „agile“.
What drives us

We protect and improve the health of people around the world.

Corporate movie