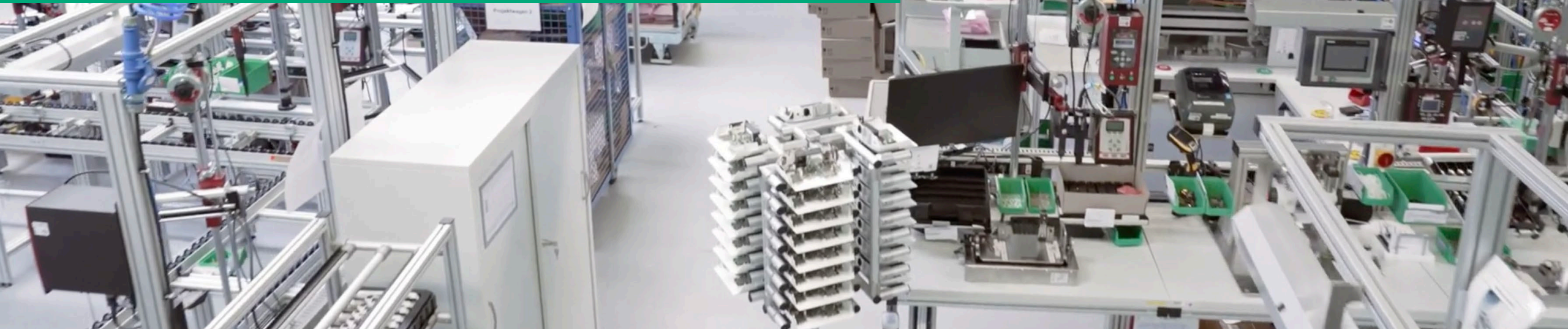
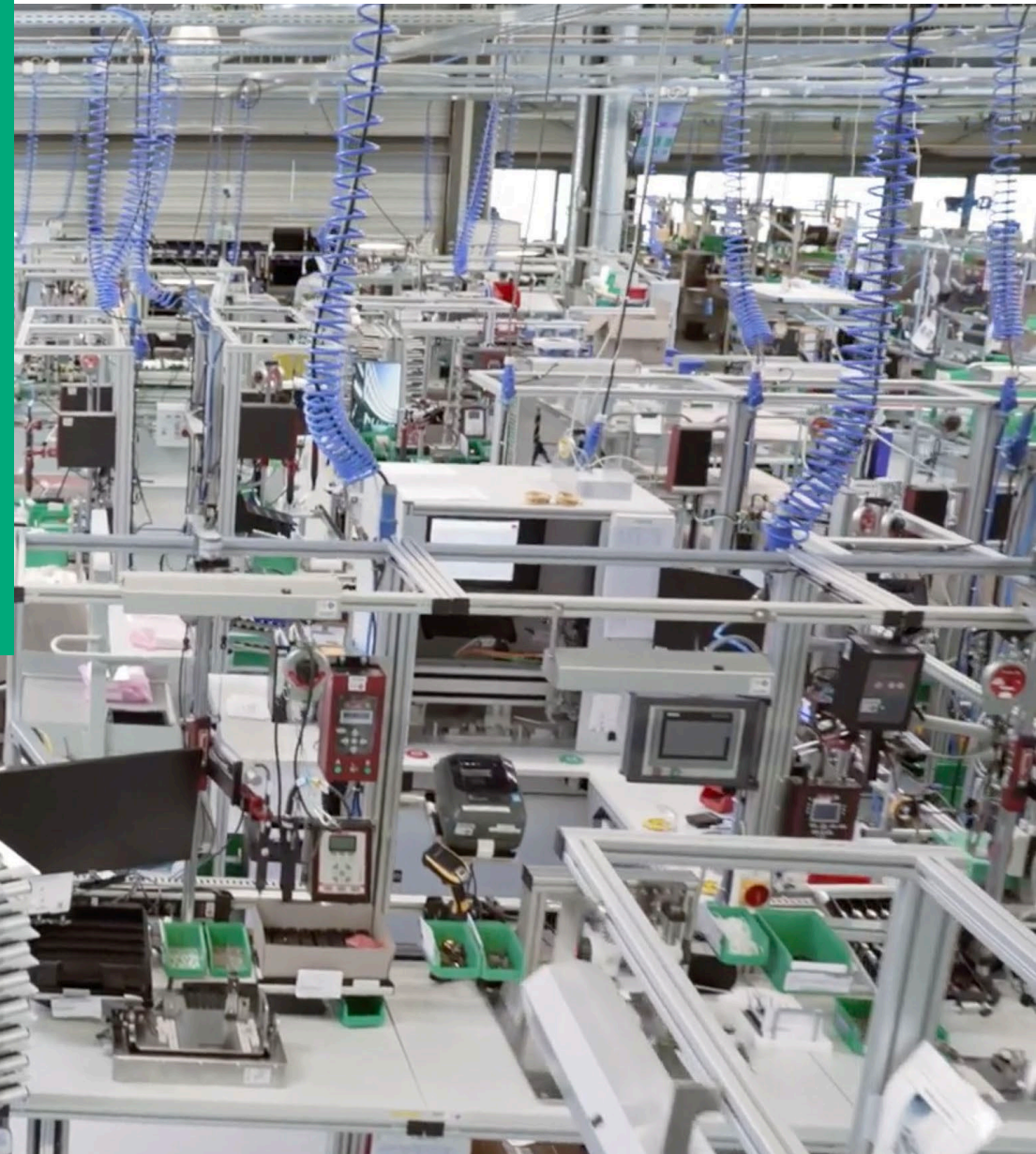


# Pretending to be agile

A difficult journey with a happy (?) ending

MES 4.0 – Porto, 2023-09-07/08

Dr. Michael Kaiser, Lead Smart Manufacturing, B. Braun Melsungen AG



# Let's start with a survey

<https://www.menti.com/al895pud8mz3>

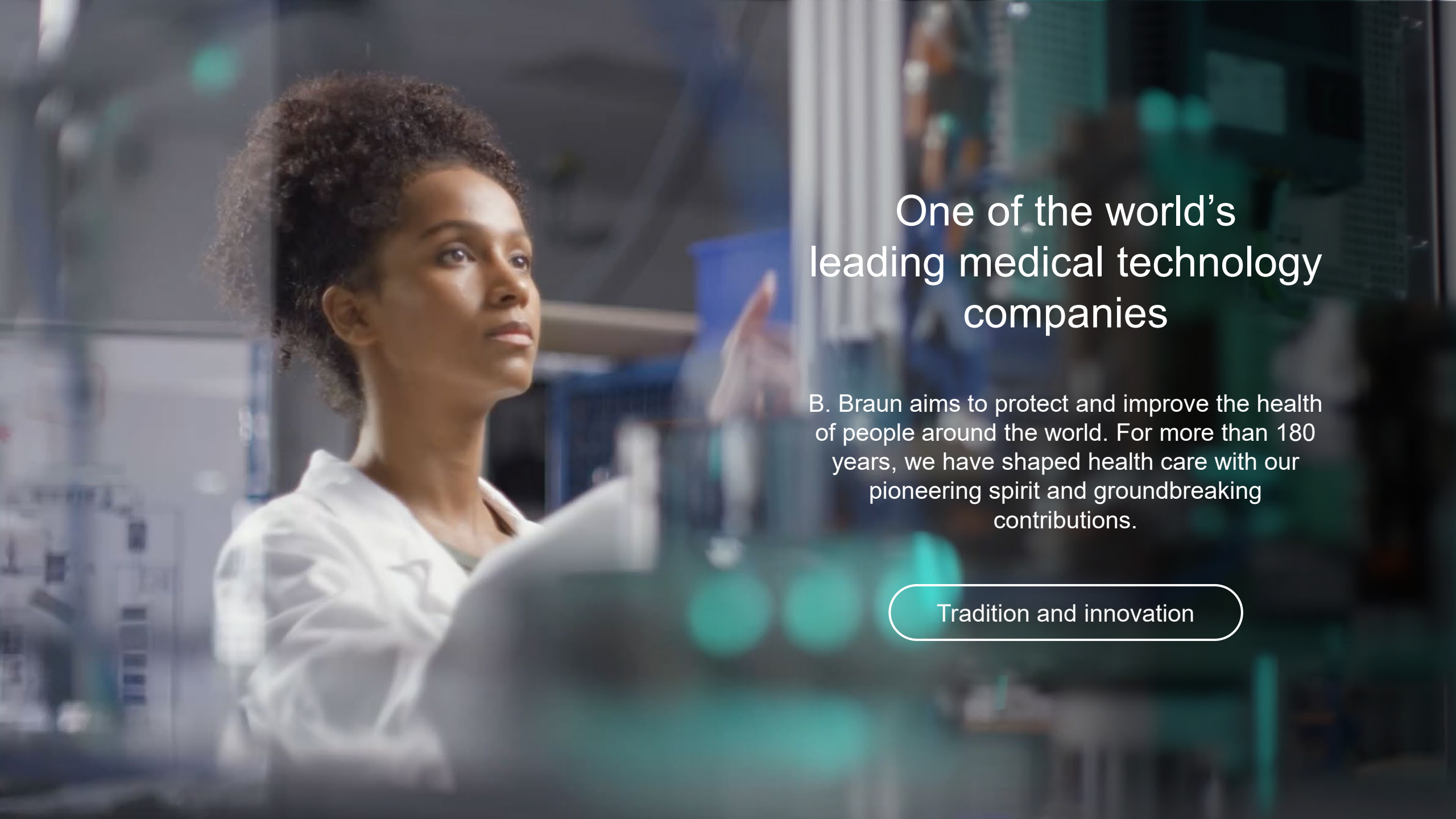
Join at [menti.com](https://www.menti.com) use code 1299 9367

Biggest Challenges in "agile" project execution?

0	0	0	0	0	0	0
Deliver a consistent solution	Meet milestones	Stay in budget	Ensure customer know-how	Ensure supplier know-how	Handle disturbances	Ensure Quality





A woman with dark curly hair, wearing a white lab coat, is shown in profile, looking upwards and to the right. She is pointing her right index finger towards a large, out-of-focus screen or display in the background. The setting appears to be a modern laboratory or medical facility, with various pieces of equipment and blue lighting visible in the blurred background.

## 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

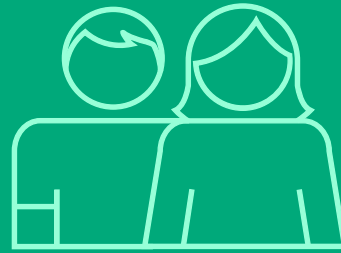
## Sales

in € million



8,500

## Employees



65,000

## Investments

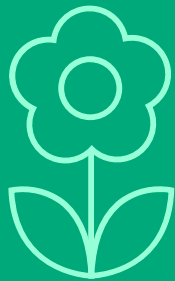
in € million



647

## CO<sub>2</sub> Emissions

Reduction of Scope 1&2 CO<sub>2</sub>-eq  
2022 vs. 2021



-12.7%

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

Facts & Figures

## Research & Development

in € million; adjusted

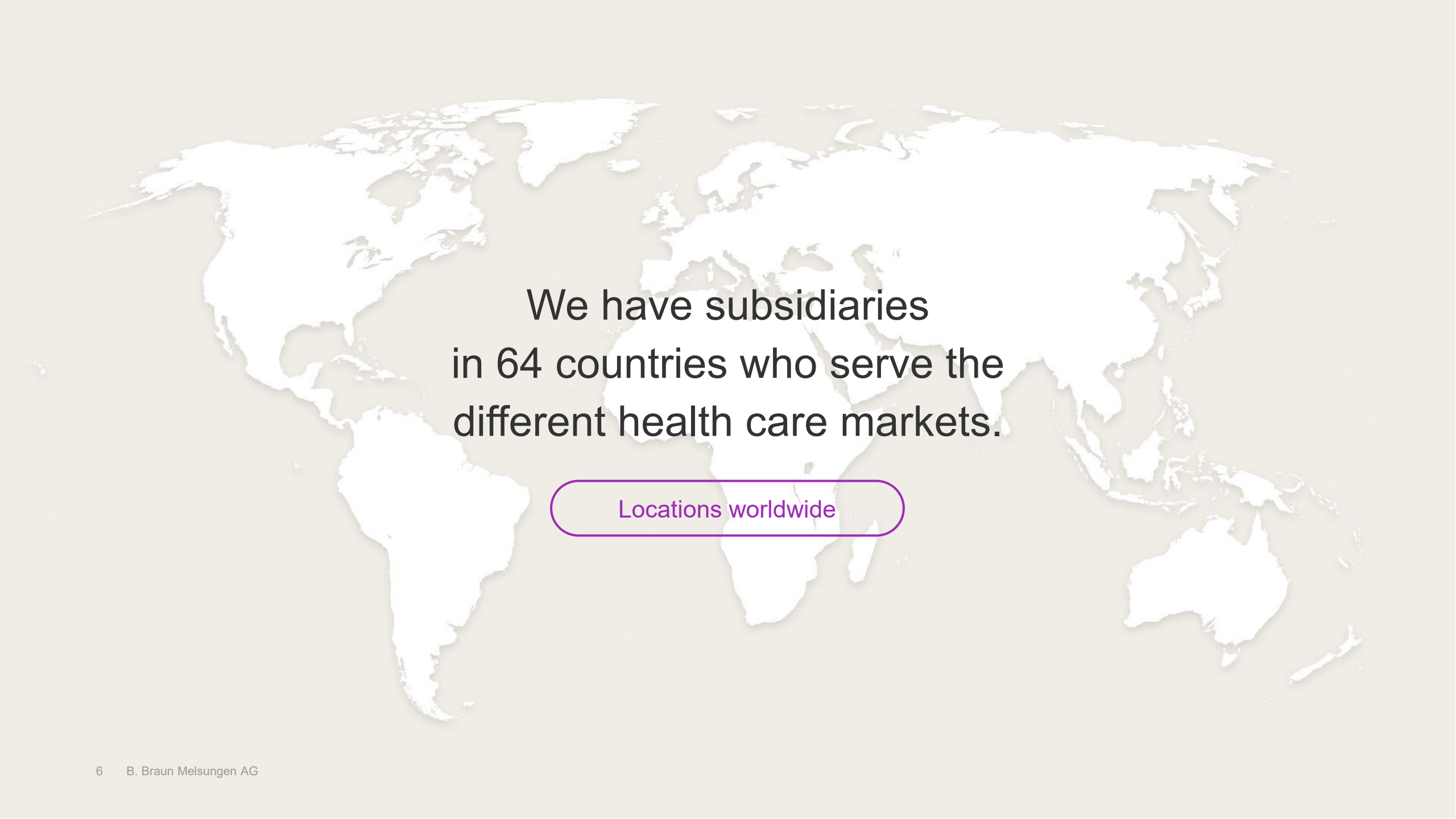


466



We continuously  
develop our portfolio  
of more than  
5,000 products.

[Product catalog](#)



We have subsidiaries  
in 64 countries who serve the  
different health care markets.

Locations worldwide



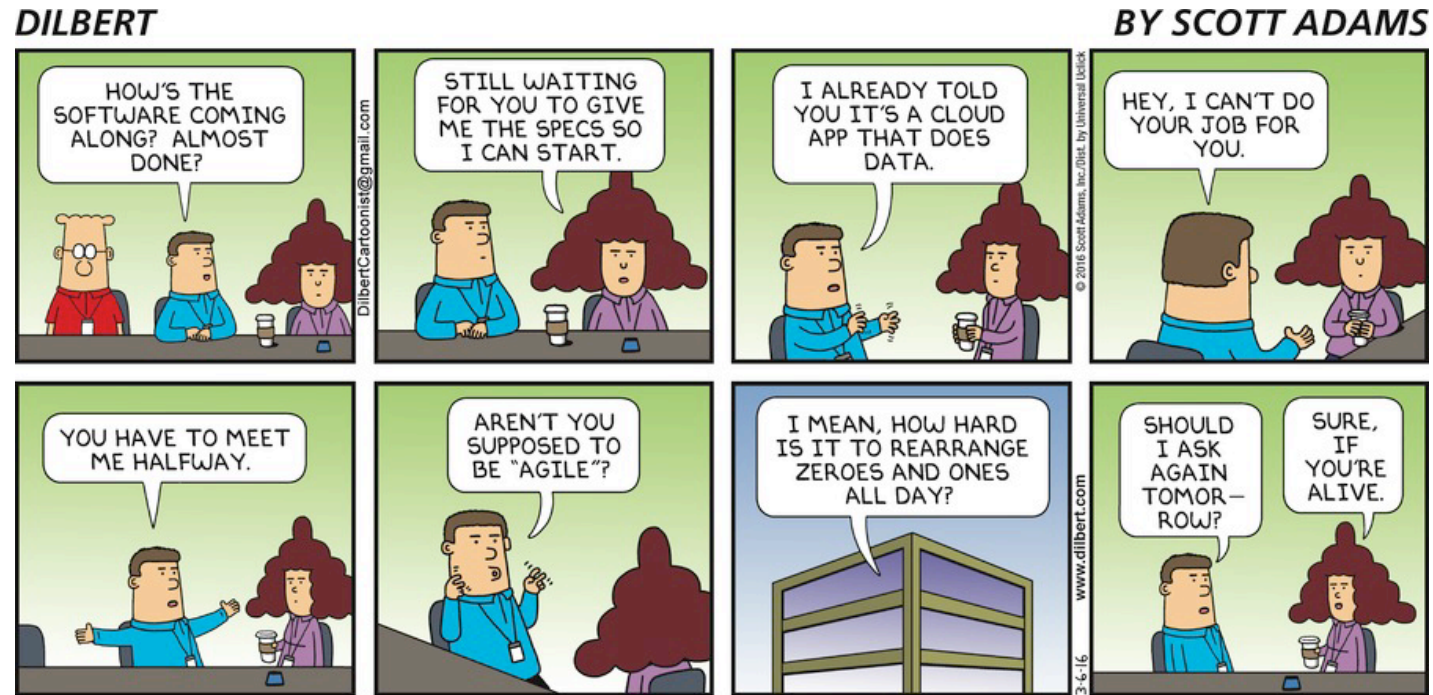
We continuously invest in the modernization & automation of our production sites



What do we mean by „agile“?



# We talk about „agile“ – but what is it? More than a buzzword?



*Cartoon by Scott Adams. Images copyrighted by Andrews McMeel Syndication and/or its creators. Used with permission for educational purposes.*

# 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](https://agilemanifesto.org)  
([agilemanifesto.org](https://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“



# Qualification and Validation



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



Deutschland  
Land der Ideen



Ausgewählter Ort 2007

### 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)

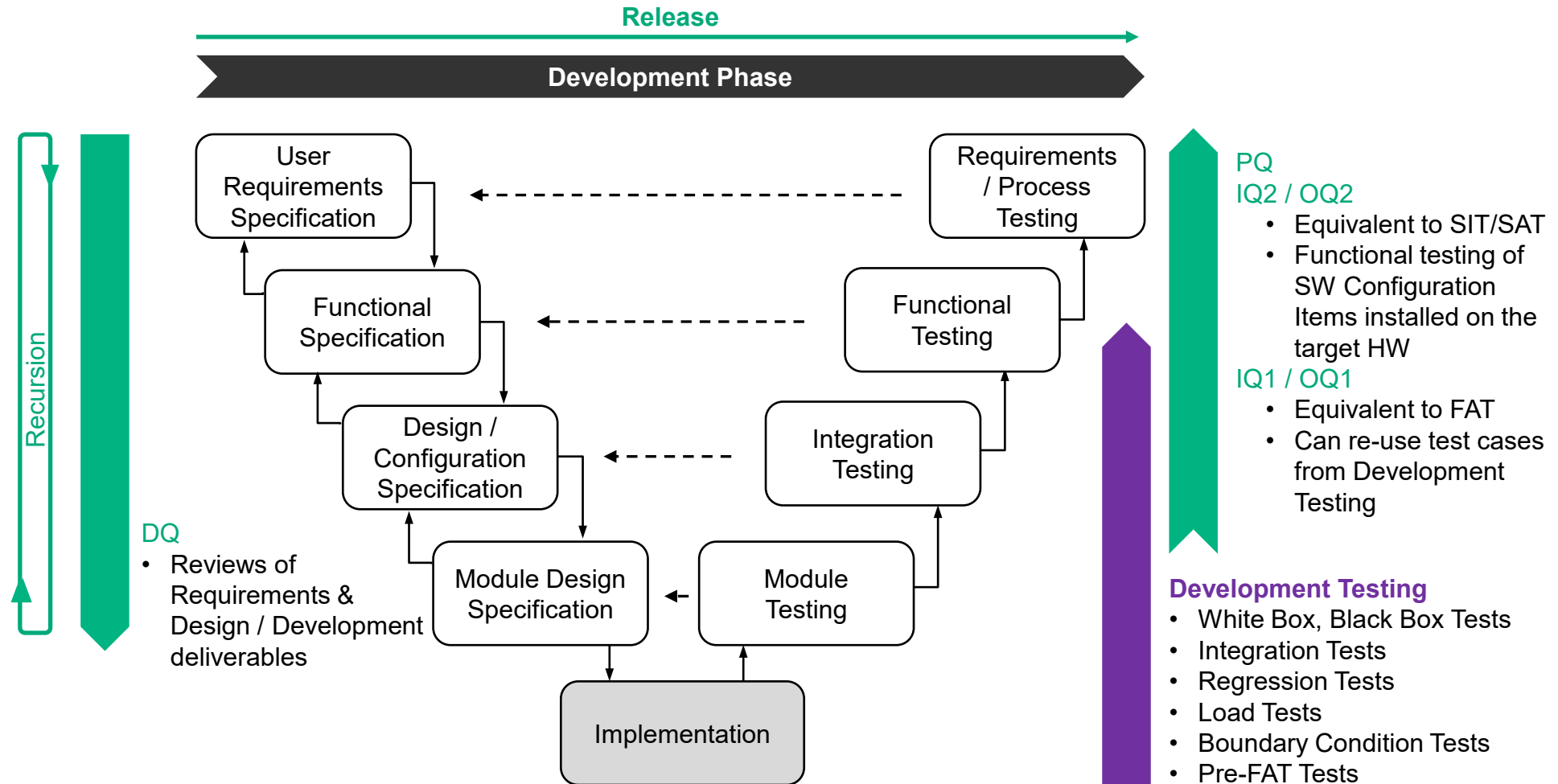
### Production performance:

- 1 Million Ecoflac-Plus containers / day (30 lorries)
- > 220 Millionen Ecoflac-Plus containers / year



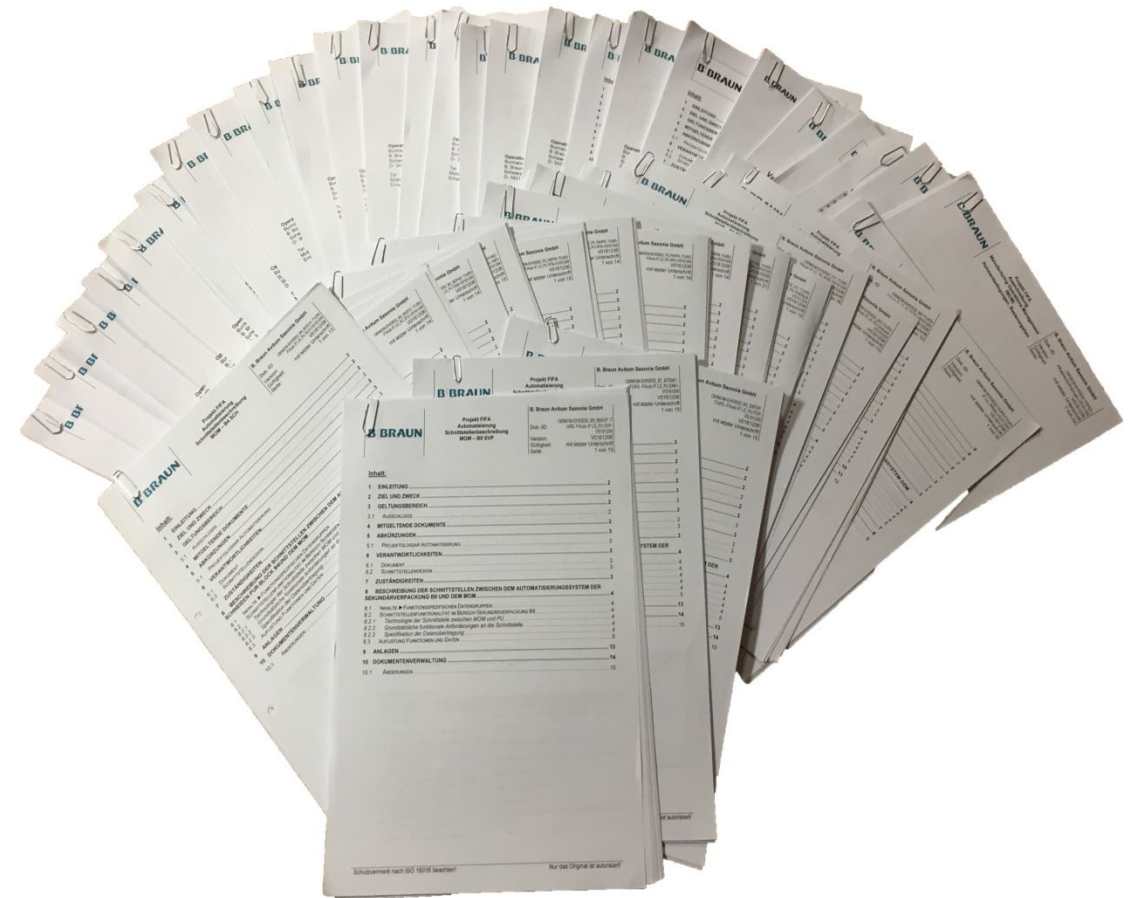


# Traditional MES Implementation Strategy – „Grand Design“ / V-Model



# What were our (the customer's) needs?

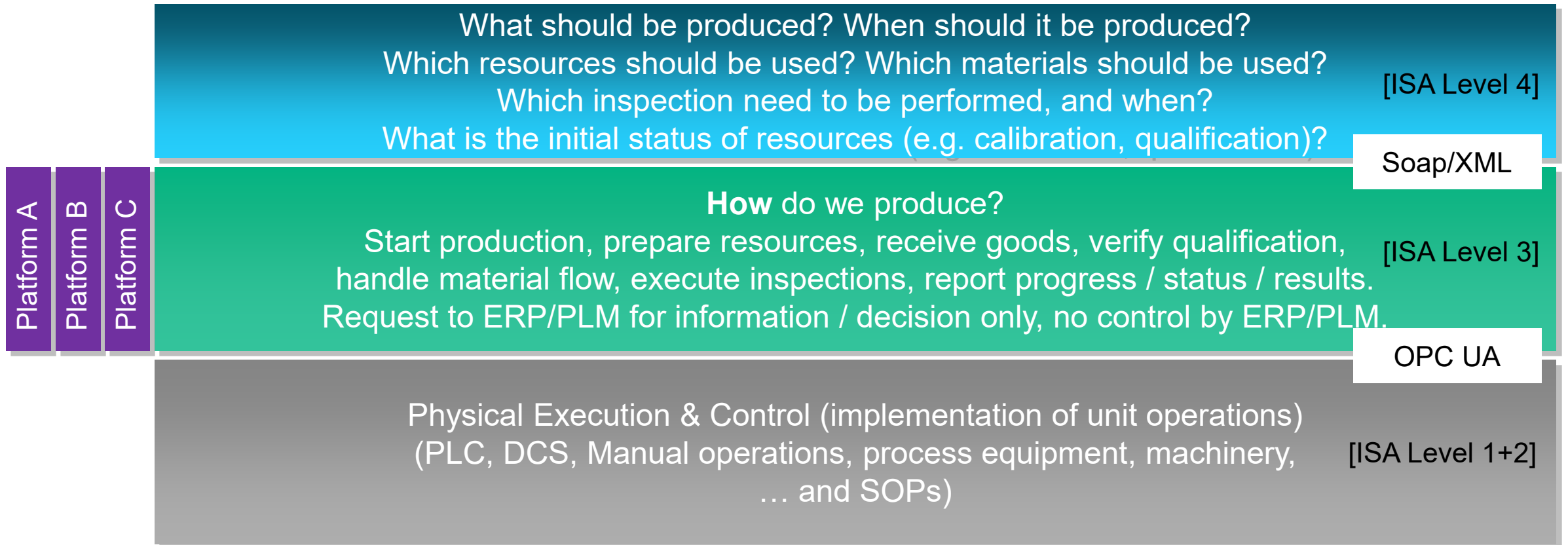
- **Get a fully validated system**
  - works as specified
  - in time
  - in budget
  - Users are trained
  - Administration processes are documented
- **Preconditions:**
  - High-quality tender documentation available
  - Supplier is not preselected, time-consuming tender process
  - Supplier is able 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



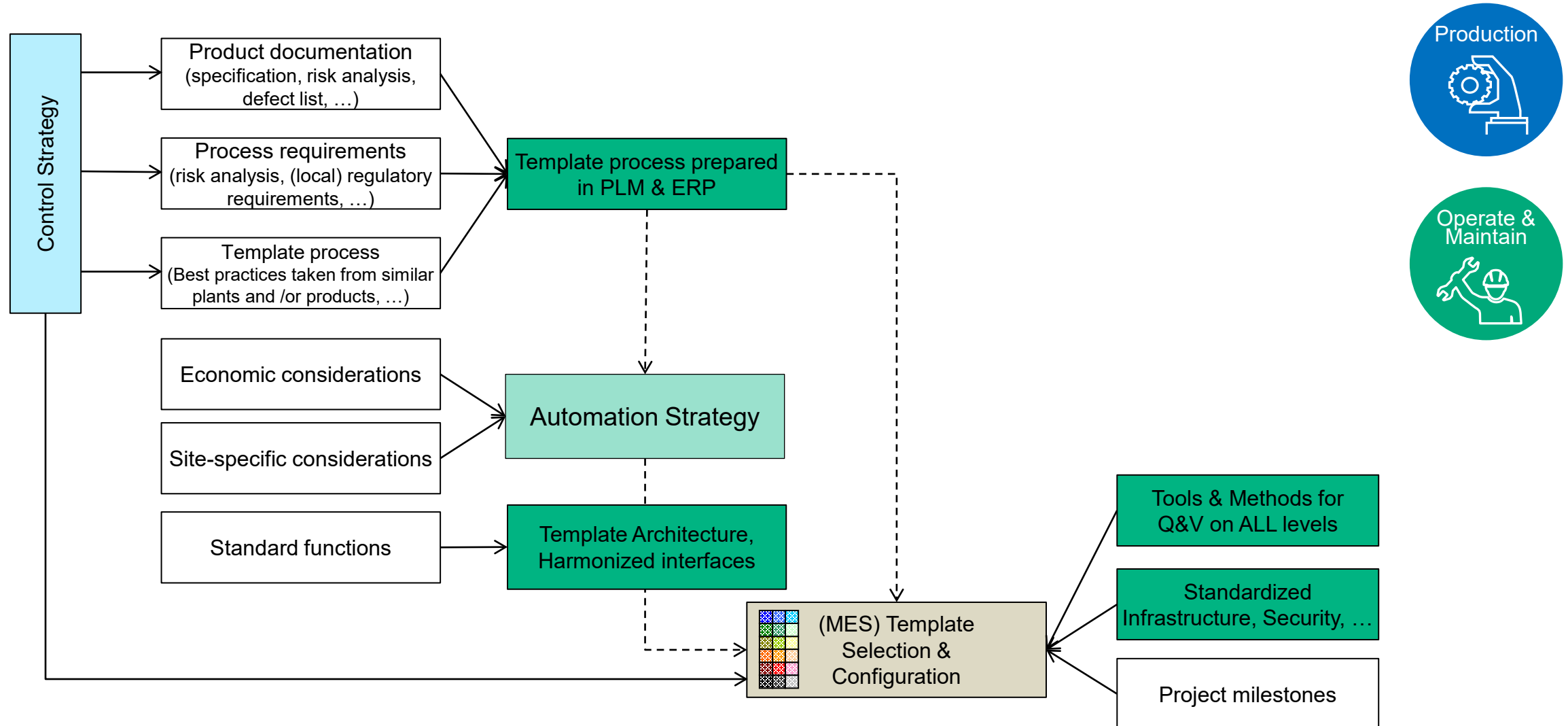
From individual projects  
to template-based rollouts



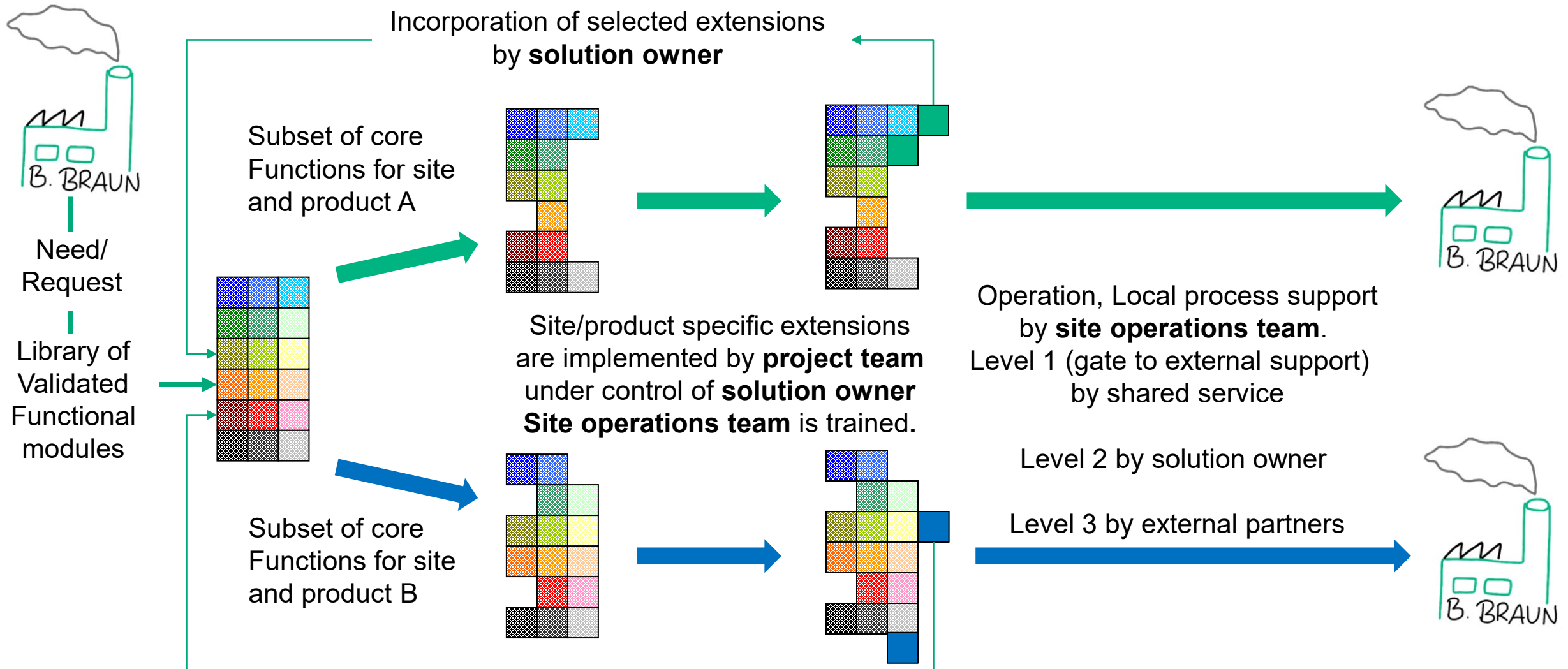
# Standard Platforms, standard interfaces, aligned scope



# Template Approach



# MES Template – Instance creation and roll-outs





# 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

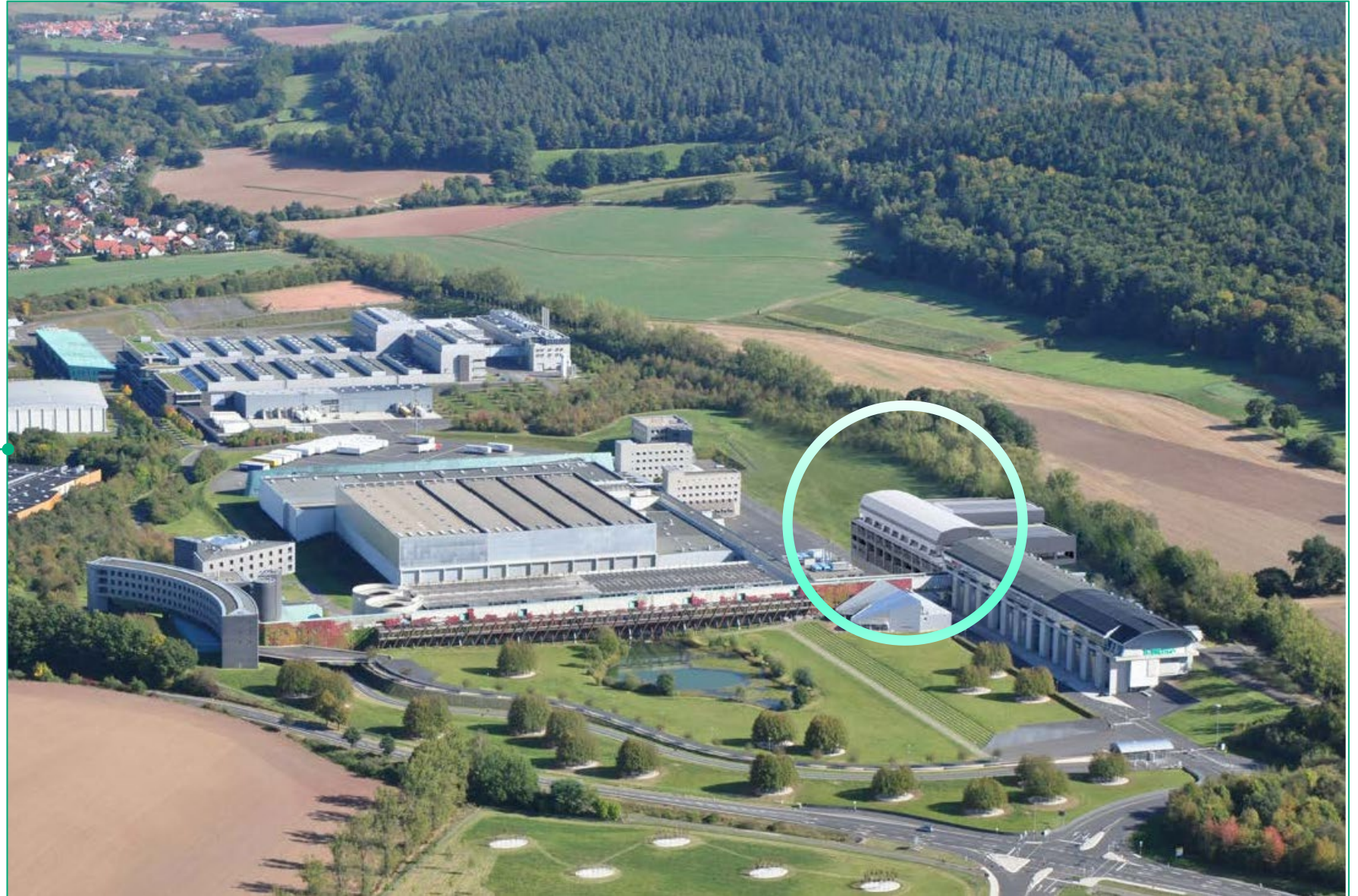
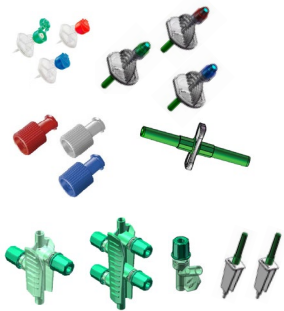
Agile working is a practice which encourages adaptability while aligning with customer needs and requirements on a continuous basis. It promotes teamwork, self-organization, and accountability.

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

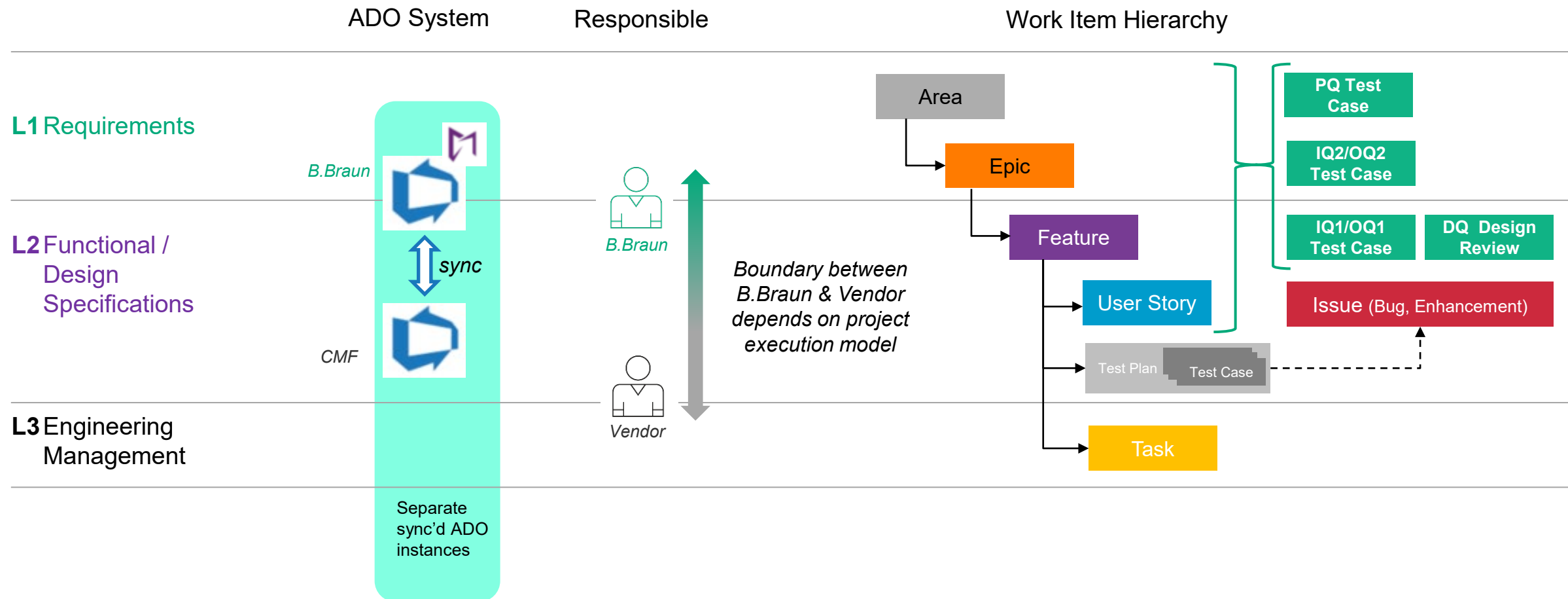
- Complete set of tender documents created up front
- Intensive up-front discussions with potential suppliers to ensure maximum understanding of requirements and constraints
- Supplier is responsible for solution design and implementation
- Supplier is responsible to deliver documents / evidence as agreed 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

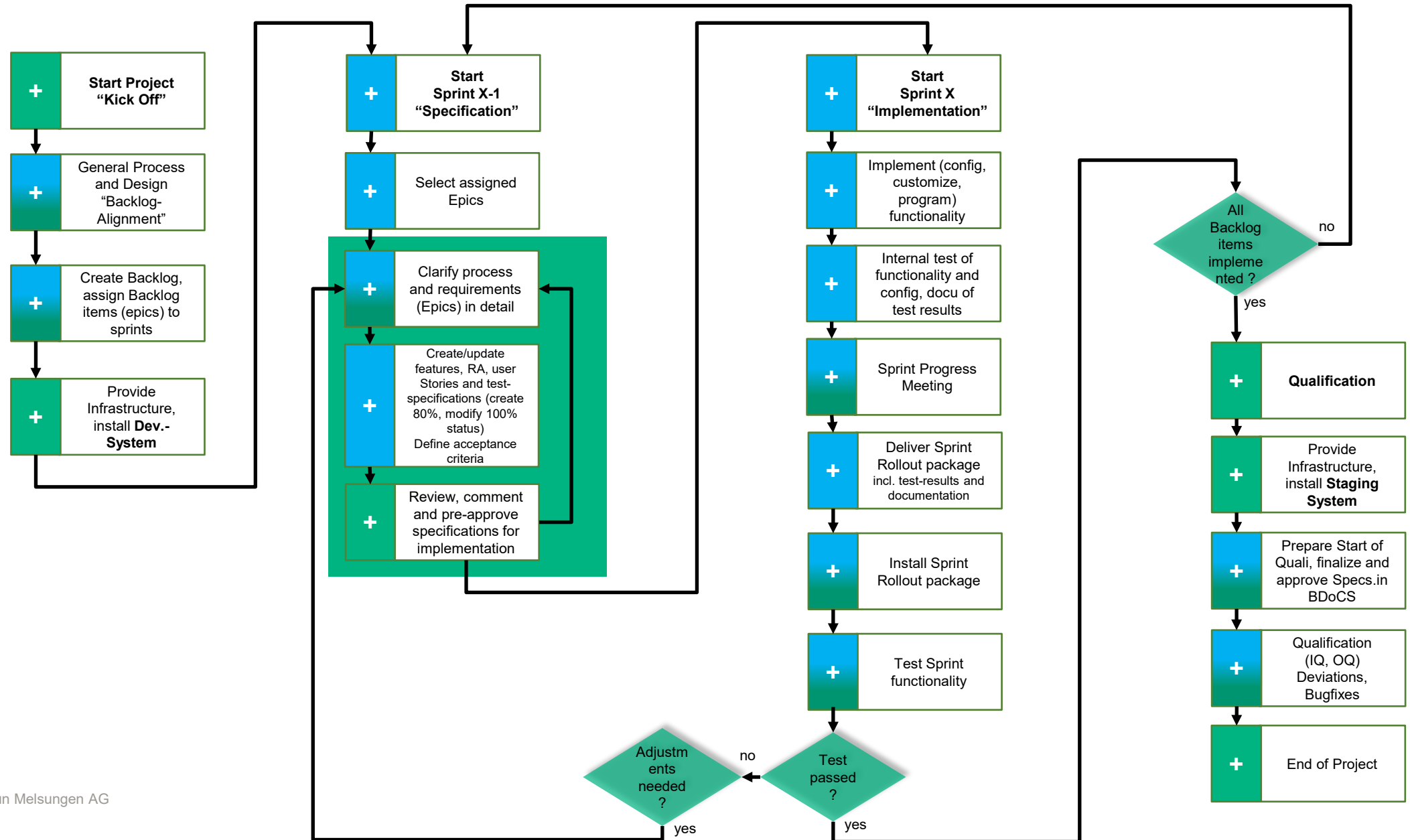
- B. Braun team needs to understand the capabilities of the platform (in CMF speak – final „modelling“ is B. Braun task)
- B. Braun provides process description and high-level functional requirements known at the start of project.
- Incremental detailing of requirements with focus on staying close to „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



# “Working mode” in sprints (Version 4)



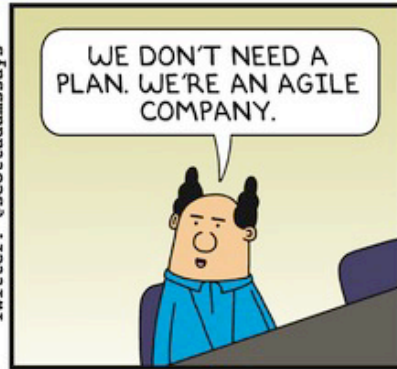
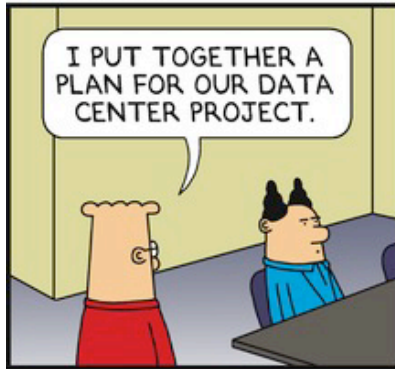
# How well can we manage various aspects of our project today?



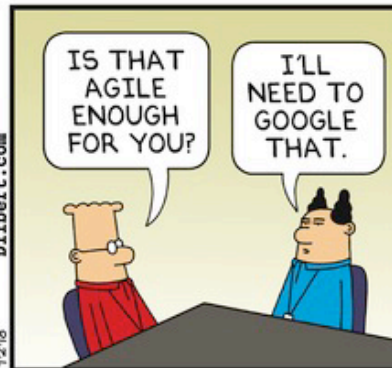
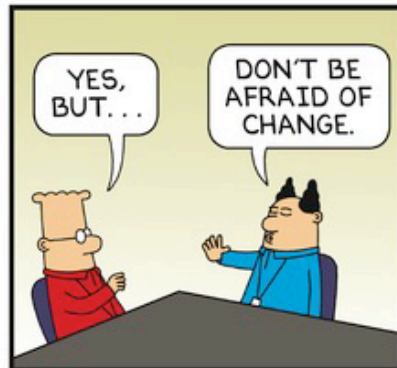
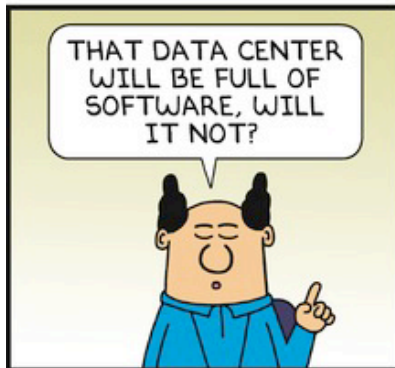
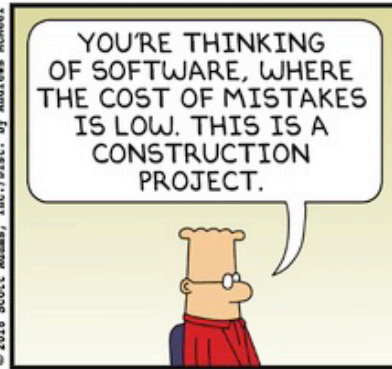
- Establishing accountability for time and budget is a challenge, since there is no contract in place which enforces it.
- Estimating as we go along with refinement sprint by sprint is insufficient – we need the “big picture” and a regular check of where we are.
- The “big picture” requires a clear understanding 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**



**BY SCOTT ADAMS**



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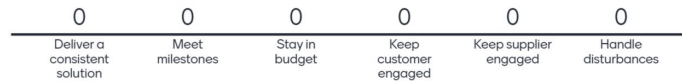


# Let's see if anything changed ...

<https://www.menti.com/al2xnauh3m9>

Join at [menti.com](https://www.menti.com) use code 2858 2023

## Biggest Challenges in "agile" project execution?



# 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?





# Are we an „agile“ team, or do we just pretend?

Encourage  
adaptability

Work  
continuously

Promote  
teamwork

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“.

Promote  
accountability

Align with  
customer  
needs

Promote self-  
organization



What drives us

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

Corporate movie

