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Sabrina Leuenberger

BDD – A Practicable Approach for Computerised System Validation?

Bachelor Thesis SF2020 FHNW

30th of July 2020

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Agenda

1	GAMP5 with BDD for OQ
2	Feature Files: Specification and Testscript in One
3	OQ Automation with BDD
4	The Audit: We Are on the Right Way!
5	Questions & Answers

2

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GAMP5 with BDD for OQ

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Computerised System Validation in the Pharmaceutical Industry

GAMP5

- A Guide
- Covers Validation of Computerised Systems during the whole life cycle of a product in a risk based approach.

➢ Fitness for Intended Use
➢ Compliance to Regulation

} Patient Safety

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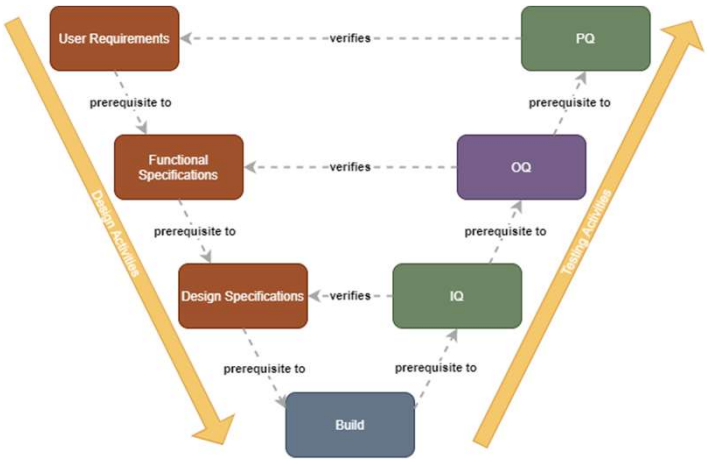
CSV needs Testing...



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... a lot of Testing

https://commons.wikimedia.org/wiki/File:Panicking_Cartoon_Guy_Working_Overtime_With_A_Lot_Of_Paperwork.svg

- OQs
  → often done manually: checking activities based on test script
  → time consuming, error prone and expensive.

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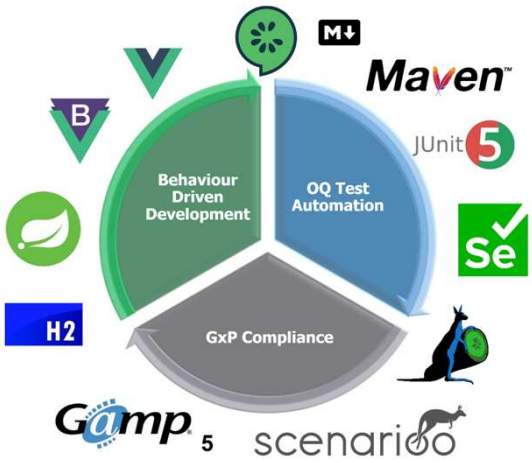
Let's Automate!



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Our Questions

- Do the artefacts from the BDD-OQ process satisfy the GAMP5 OQ requirements?
- How can the executable requirement suite be adapted to the evolving nature of the application?
- Can automation tools like Cucumber/Gherkin, Selenium and Scenarioo be used together in validated environments?
- And how could be dealt with new versions of the automation tools in terms of validation?

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In Four Steps to Our Results

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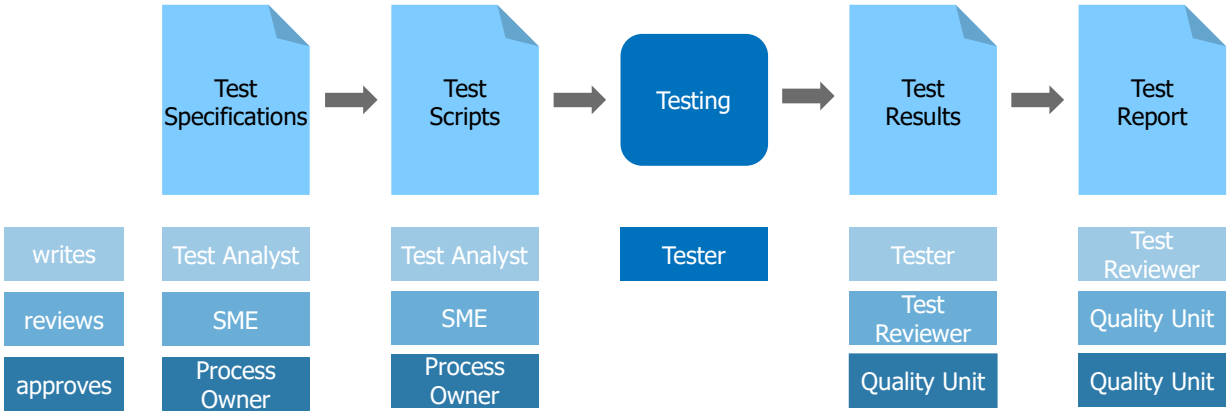
OQ = Formal Proof for Functional Specs (FS)



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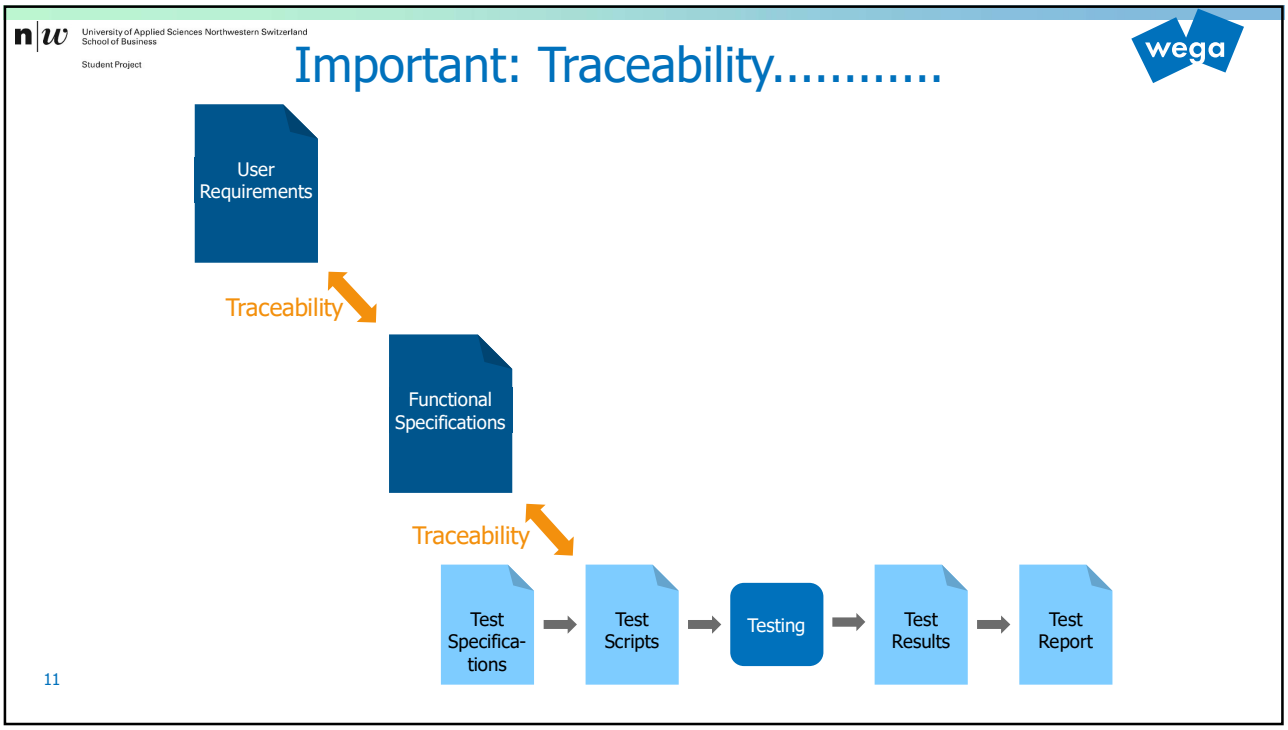
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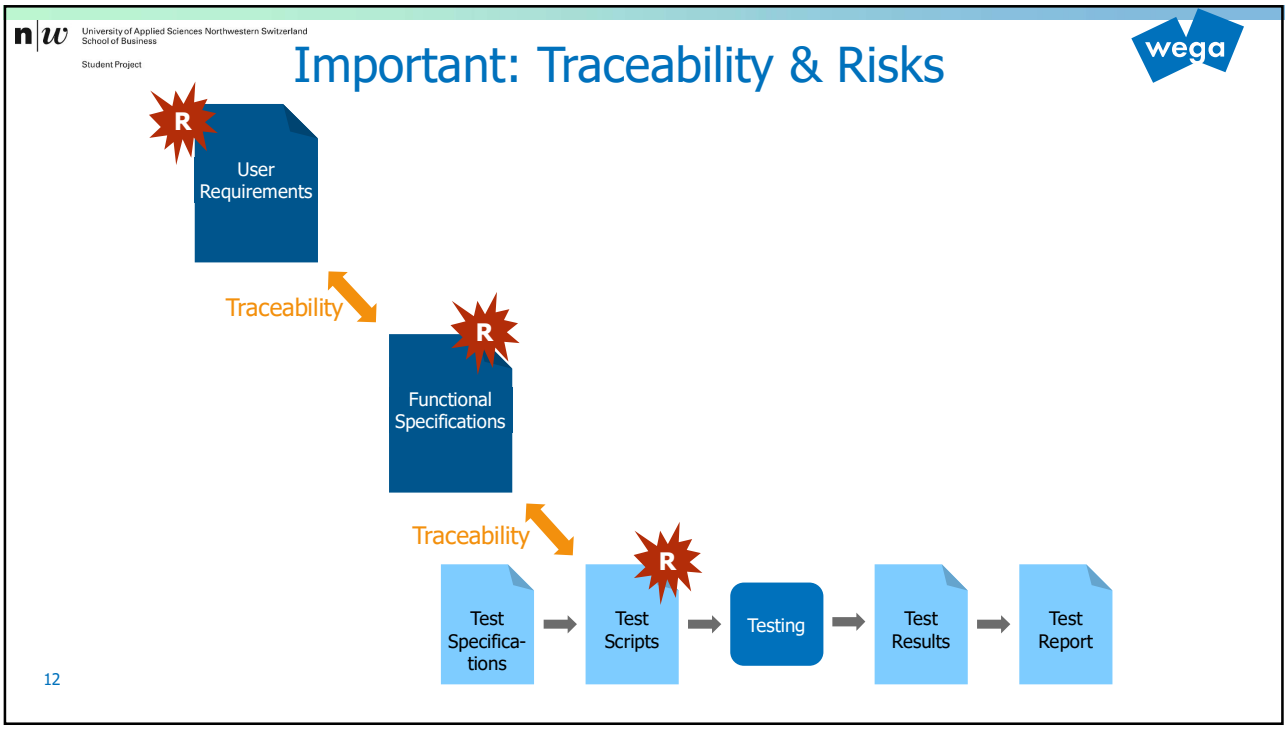
Important: Traceability.....
wega
User Requirements
Traceability
Functional Specifications
Traceability
Test Specifica-tions
Test Scripts
Testing
Test Results
Test Report
11

11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Important: Traceability & Risks
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R
User Requirements
Traceability
R
Functional Specifications
Traceability
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Test Specifica-tions
Test Scripts
Testing
Test Results
Test Report
12

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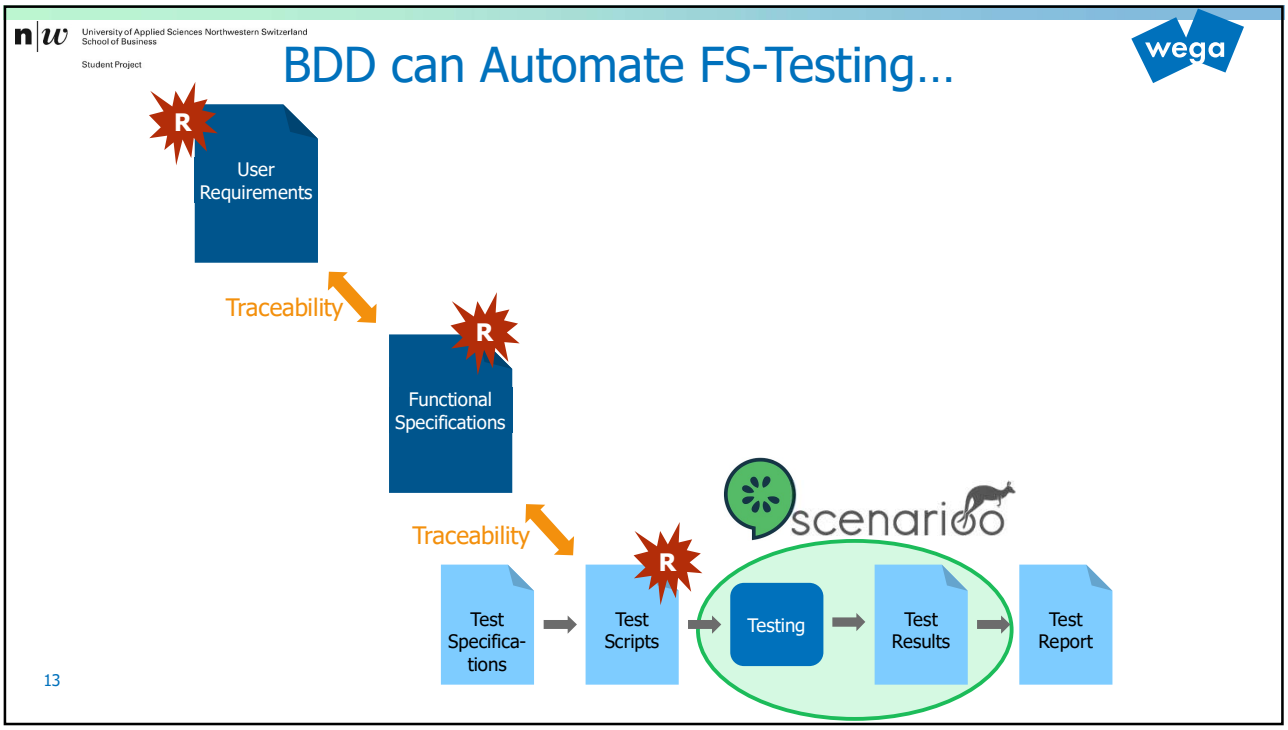
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BDD can Automate FS-Testing…
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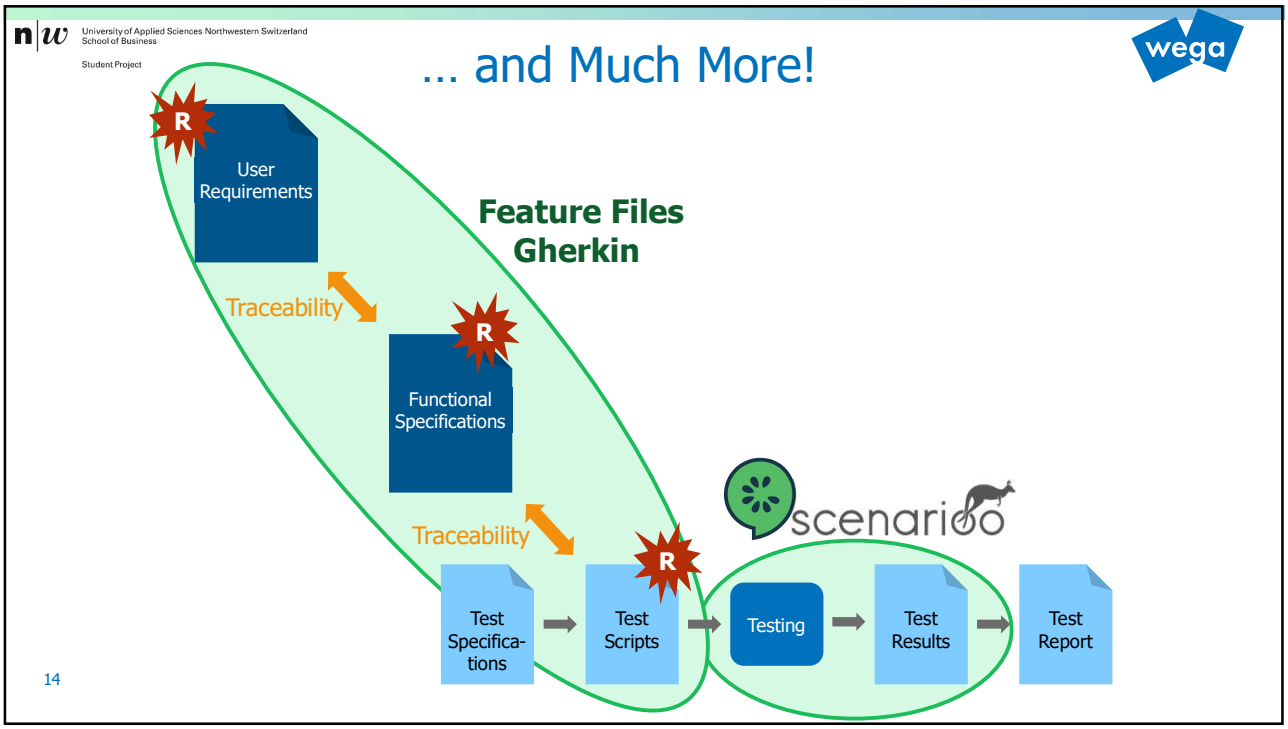
R
User Requirements
Traceability
R
Functional Specifications
Traceability
scenario
R
Test Specifica-tions
Test Scripts
Testing
Test Results
Test Report
13

13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… and Much More!
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R
User Requirements
Feature Files
Gherkin
Traceability
R
Functional Specifications
Traceability
scenario
R
Test Specifica-tions
Test Scripts
Testing
Test Results
Test Report
14

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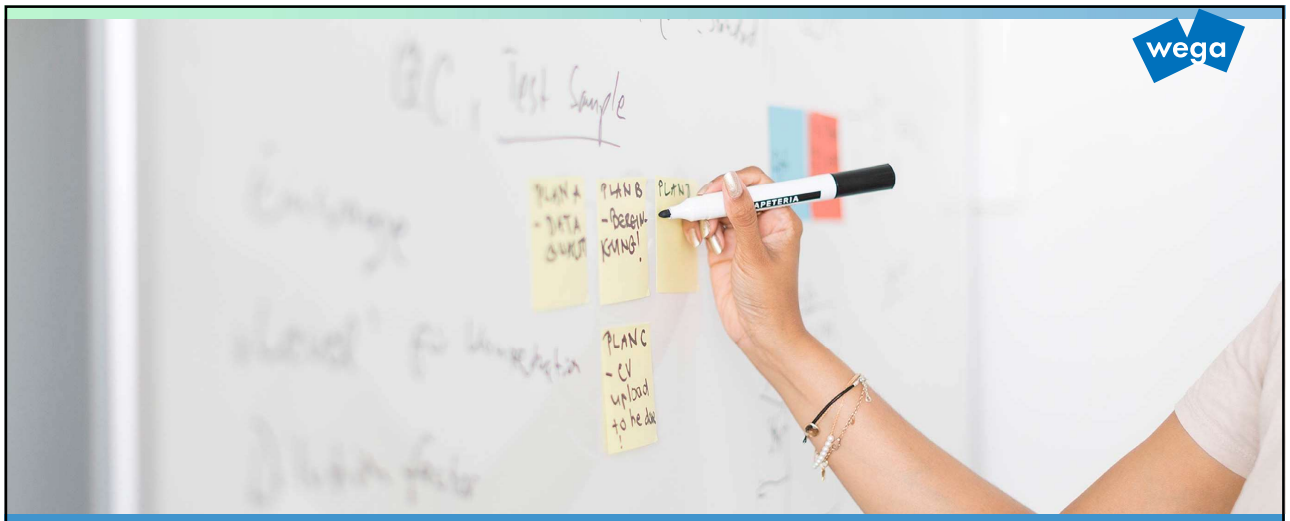

Feature Files: Specification and Testscript in One

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From Specification to Test Results with BDD

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Discovery
- Rules
- Examples

Formulation
- **Feature Files**

Automation
- Cucumber Test Report

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The Feature File as Key Element

Specification brief

Scenario

```
Feature: Participant's overview
  An overview of all registered participants is displayed, so that starting from this overview,
  the baseline weight measurement can be set for the participants where it was not done so far

  Covered Requirements:
  bddoq-50: Overview (List) of all Registered Participants

  History (the last 8 versions are displayed on this list):
  ```
Sig. V.	Description	Name	Date	dig.Sig.
0.0.0.1	FS initial version --> bddoq-50	Sabrina Leuenberger	23-May-2020	le
0.0.0.2	FS initial version reviewed	Patricia Walker	24-May-2020	wp
0.0.1.0	FS initial version approved	Hank McKoy	25-May-2020	mh
0.0.1.1	FS adapted as Test script (TS)	Andreas Hosbach	03-Jun-2020	ha
0.0.1.2	TS reviewed	Patricia Walker	04-Jun-2020	wp
1.0.0.0	TS approved --> ready for OQ	Hank McKoy	04-Jun-2020	mh
  ```

  Size:
  1 active scenario
  3 active step


  Background:
    Given Patricia has the application open

  Scenario: Overview of all registered participants

    Given participants with first name, last name, birthday, gender are registered
      | "Natasha" | "Romanoff" | "1st of January 1984" | "female" |
      | "Scott"   | "Lang"     | "1st of March 1997"   | "male"   |
      | "Bruce"   | "Banner"   | "1st of May 1962"     | "male"   |
      | "Betty"   | "Ross"     | "1st of May 1962"     | "female" |
    Then the participants should be found in the overview
```

Title / ID

Document History & Signatures

Step

Test Data

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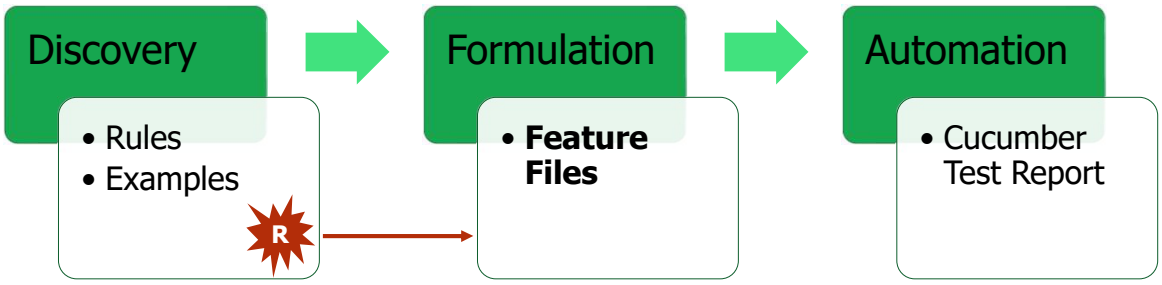
BDD With Risk Management



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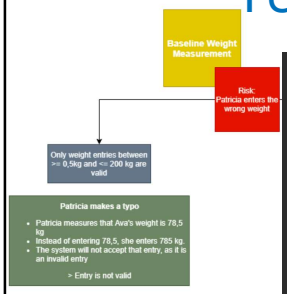
Feature File With Risk Management




```
Scenario Outline: Allowed weight entry values: <weight>
To minimise the risk of wrong entries, only entries between >=0.5 and <=200 are valid

  Given a participant with first name <first_name>, last name <last_name>, birthday "21.09.2014", gender "male" is registered
  And <first_name> has no baseline weight measurement entry yet
  And Patricia wants to set <first_name>'s baseline weight measurement
  When Patricia enters <weight> kg and any valid date time
  Then she can set the baseline weight measurement
  Examples:
    | first_name | last_name | weight |
    | "Alec"     | "Turner"  | 0.5    |
    | "Elec"     | "Turner"  | 200.0  |
    | "Ilex"     | "Turner"  | 12.8   |

Scenario Outline: Forbidden weight entry values: <weight>
To minimise the risk of wrong entries, values are invalid when they are not in the range between >=0.5 and <=200

  Given a participant with first name "Eric", last name "Turner", birthday "21.09.2014", gender "male" is registered
  And "Eric" has no baseline weight measurement entry yet
  And Patricia wants to set "Eric"'s baseline weight measurement
  When Patricia enters <weight> kg and any valid date time
  Then she cannot set the baseline weight measurement
  Examples:
    | weight |
    | 785    |
    | 0.45   |
    | 0.3    |
    | -20.0  |
    | 200.05 |
```

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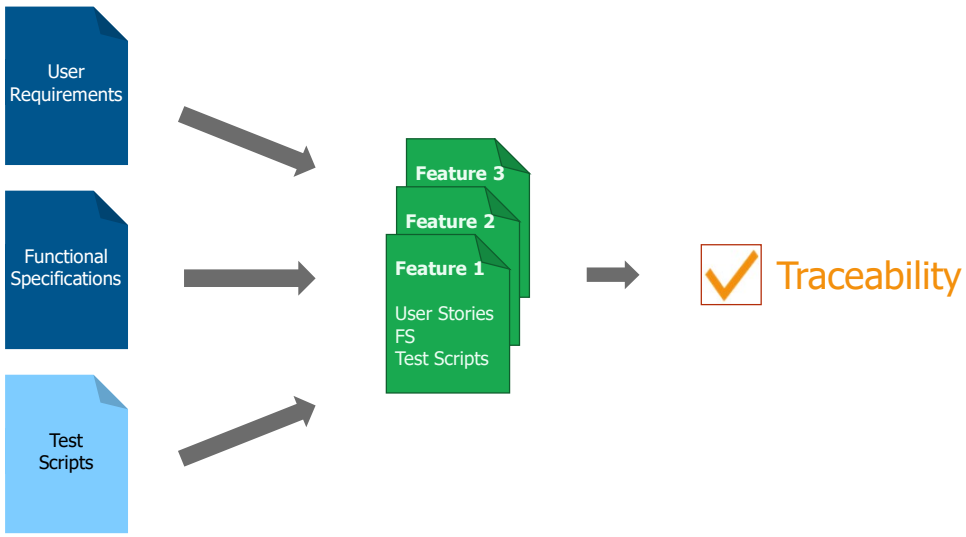
Feature File as Single Source of Truth



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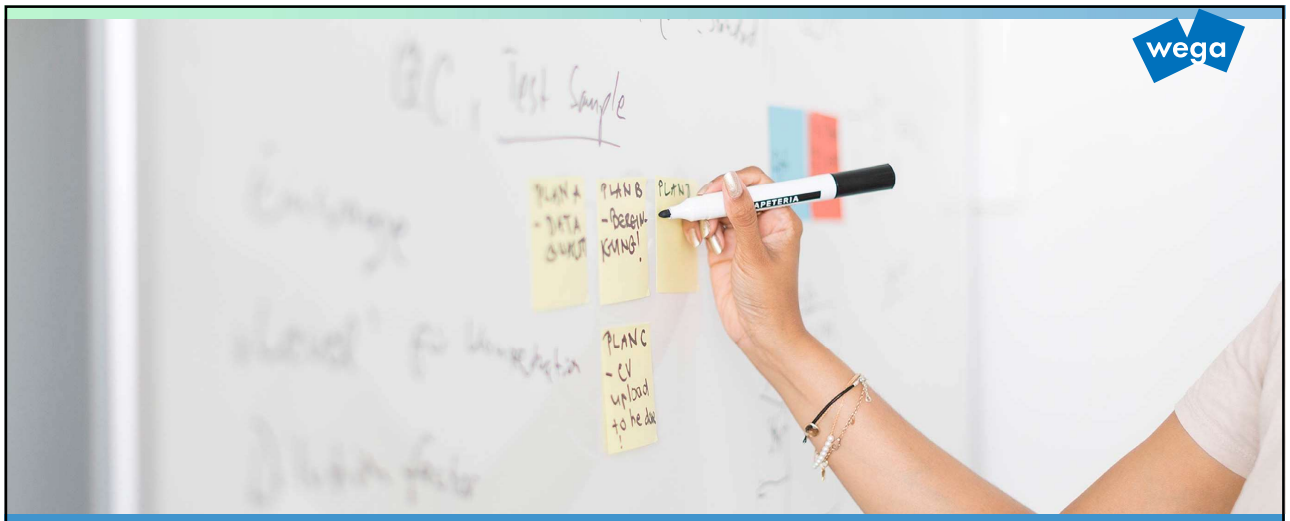
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OQ Automation with BDD

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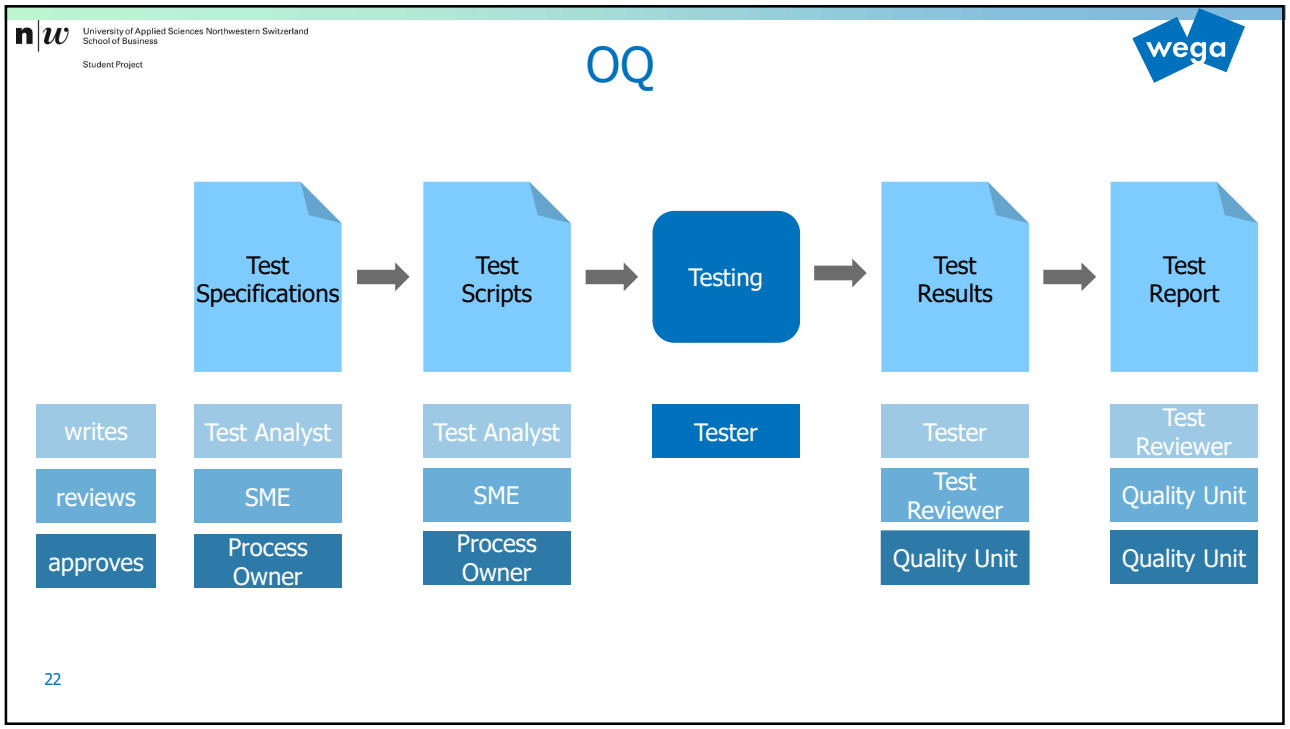
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OQ
wega
Test Specifications
Test Scripts
Testing
Test Results
Test Report
writes
reviews
approves
Test Analyst
SME
Process Owner
Test Analyst
SME
Process Owner
Tester
Tester
Test Reviewer
Quality Unit
Test Reviewer
Quality Unit
Quality Unit
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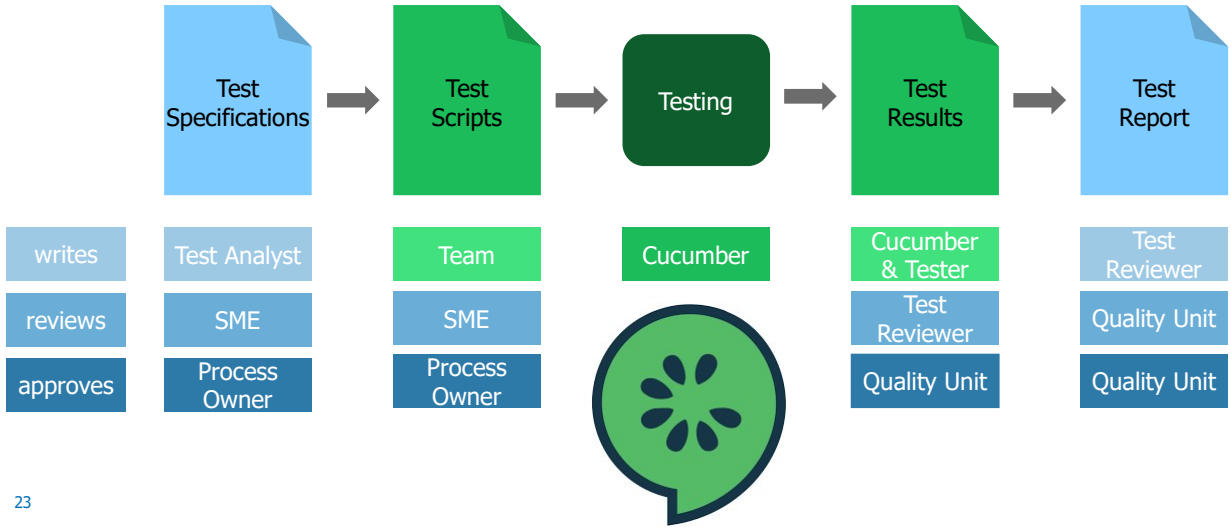
Automated OQ



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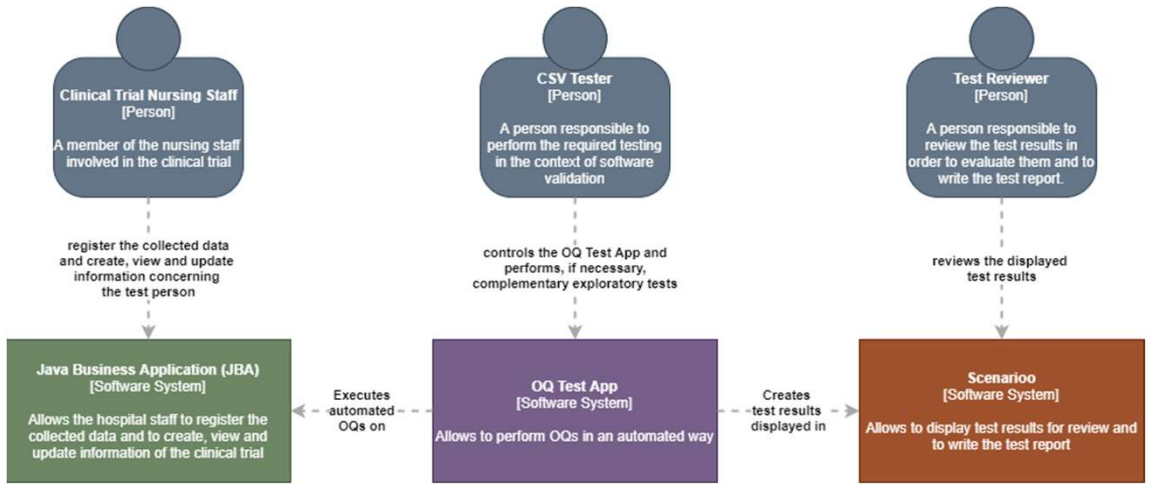
Architectural Needs



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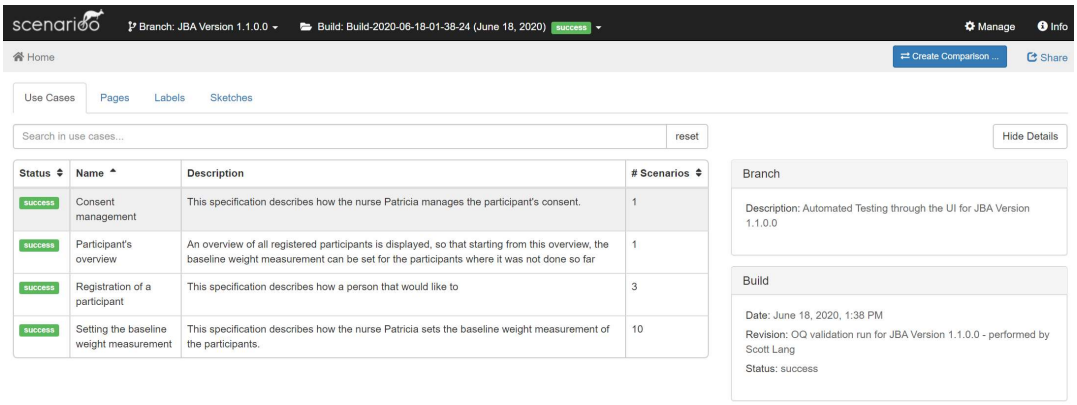
OQ Test Results: In an Overview...



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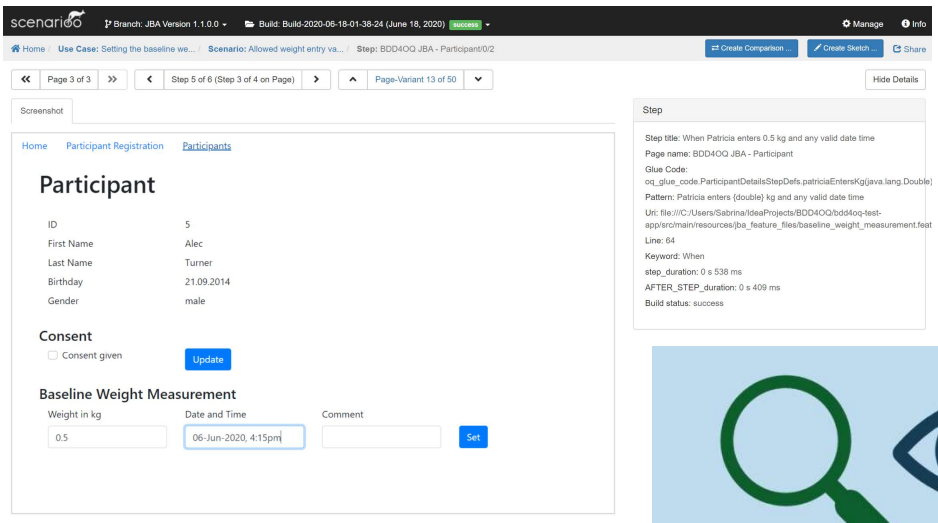
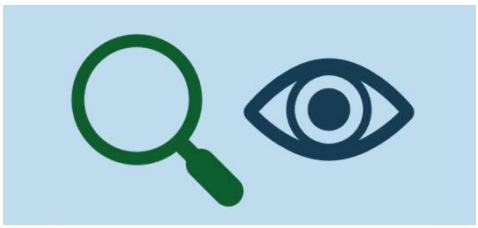
... But also in Detail





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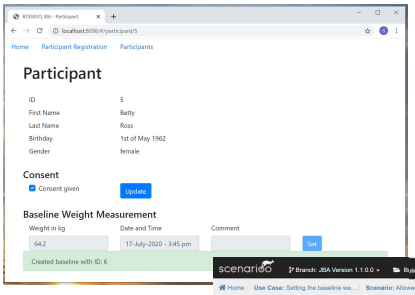
And Your Application is Documented!



Cucumber-Scenarioo-plugin

```
Scenario Outline: Allowed weight entry values: <weight>
To minimise the risk of wrong entries, only entries between >=0.5 and <=200 are valid

  Given a participant with first name <first_name>, last name <last_name>, birthday "21.0
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  When Patricia enters <weight> kg and any valid date time
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  Examples:
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```

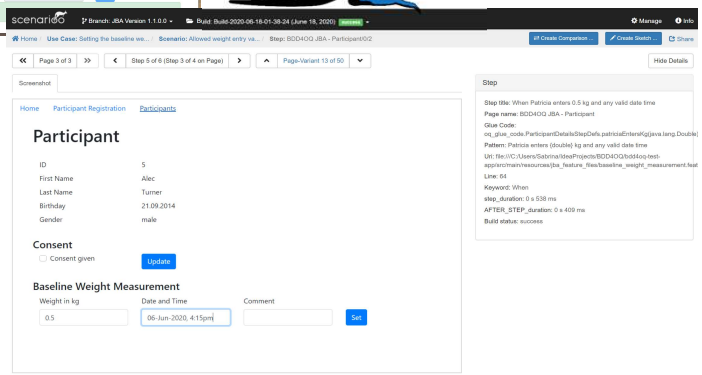

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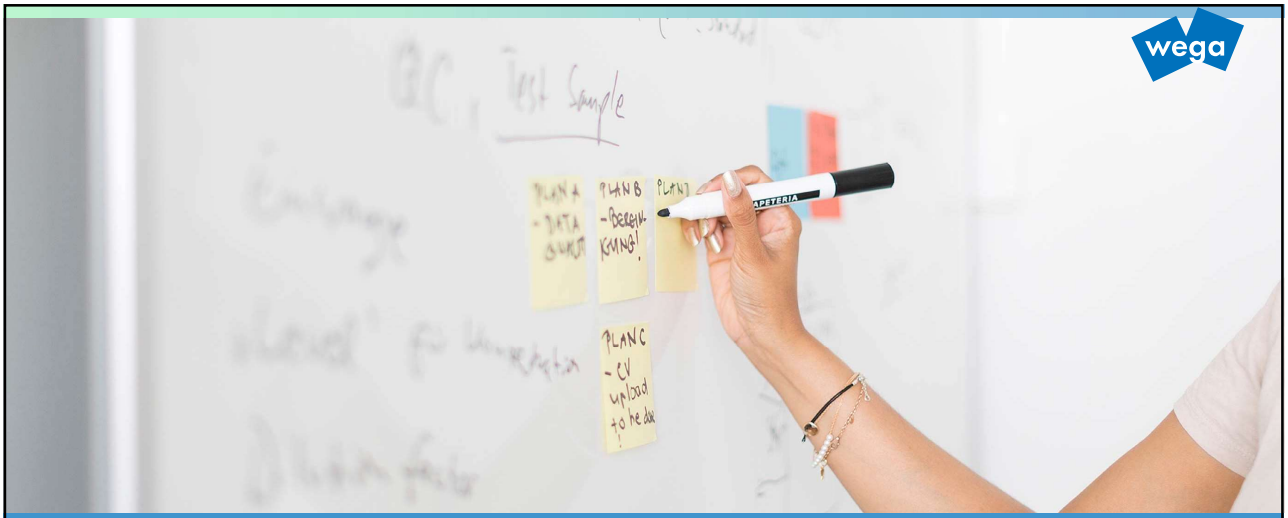

The Audit: We Are on the Right Way!

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The Prototype Is Compliant to GxP...

1.4 Conclusion

Repeatable processes have been demonstrated for the OQ testing of GMP computer systems. Processes related to the definition, development, and validation, release, maintenance and retirement were not in scope of the audit. However especially aspects around definition (specification), release and maintenance were also considered where required for the OQ testing process.

Some minor deficiencies and recommendations have been identified, those are mainly needed to improve the robustness of the OQ process. These findings should not be regarded as being a comprehensive inventory of all existing GMP deficiencies; they represent only those deficiencies identified by the auditor However, the recommendation made have no major impact on system or process quality.

Overall the audited area meets GxP quality standards and demonstrates compliance to GxPs quality systems.

Overall the audited area meets GxP quality standards and demonstrates compliance to GxPs quality systems.

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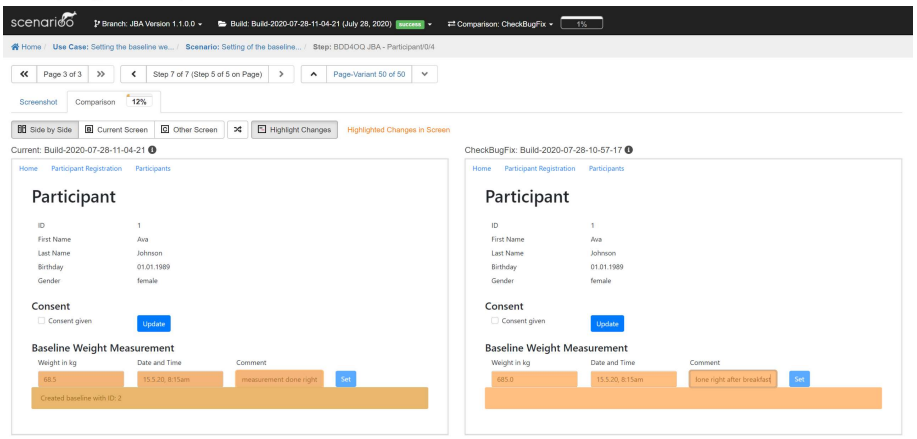
... But Can Be Improved

- The OQ Test App should contain a log of the activities that were conducted with the application (minor).
- The test results should be stored in the same location where Scenarioo can access them, so that the test results do not have to be moved manually (minor).
- Scenarioo provides an out-of-the-box functionality that allows automated comparison of different test runs. This functionality was not considered for the prototype but has the potential to improve the review process (recommendation).



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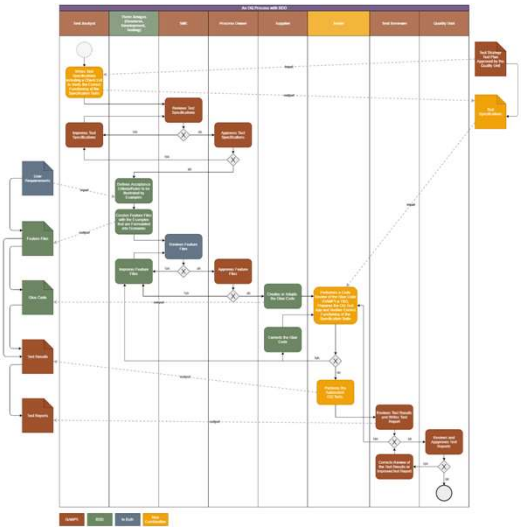
The Answers to Our Initial Questions

- Do the artefacts from the BDD-OQ process satisfy the GAMP5 OQ requirements?
  YES
- How can the executable requirement suite be adapted to the evolving nature of the application?
  Feature File, Regression Tests, Scenarioo
- Can automation tools like Cucumber/Gherkin, Selenium and Scenarioo be used together in validated environments?
  YES with high Probability
- And how could be dealt with new versions of the automation tools in terms of validation?
  On Premise & Maven



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To Make a Long Story Short...

- Feature File: A Valuable Artefact
  - Single source of Truth: Requirements/Specifications/Tests
  - English or any other Language
  - Machine Readable AND Business Specific
- Automated Testing (Regressentesting!)
- = Automated Documentation
- Transparent and Traceable

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But Most Importantly: Let's Continue!

Real Added Value

Test Automation for Device Integration

Full Automation:
IQ – OQ – PQ

Artificial Intelligence

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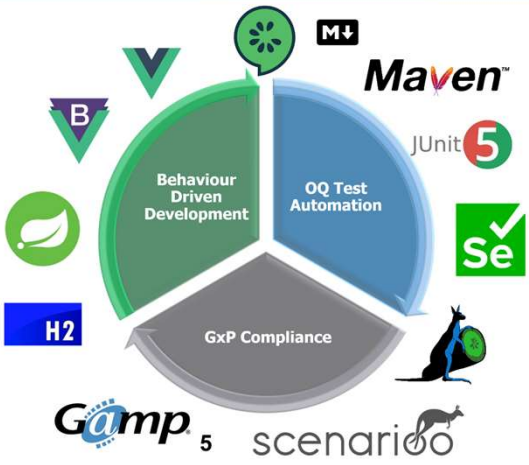

Many Thanks!!!

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Many Thanks for Your Support!

- Wega: Daniel Juchli
- FHNW: Stephan Jüngling
- Mathias Fuchs
- Evelyne Daniel
- Andreas Hosbach

➢ It would not have been possible without you!

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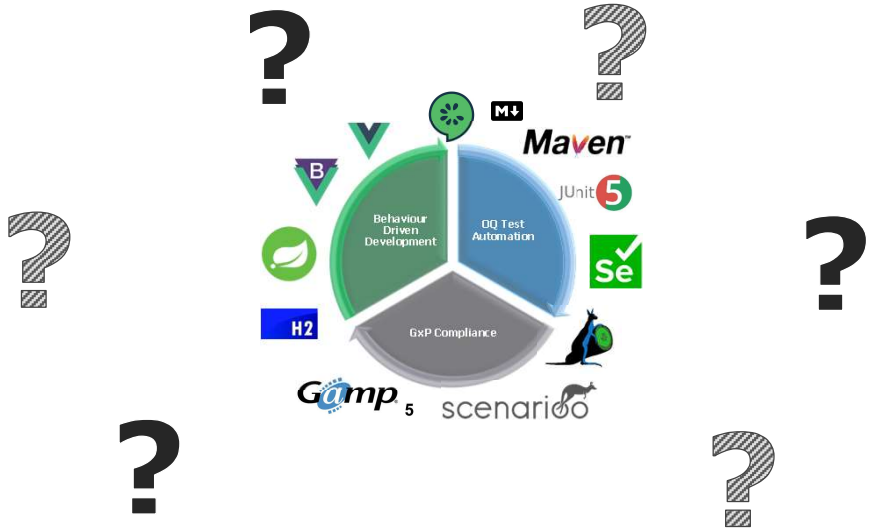
Many Thanks for Your Attention!



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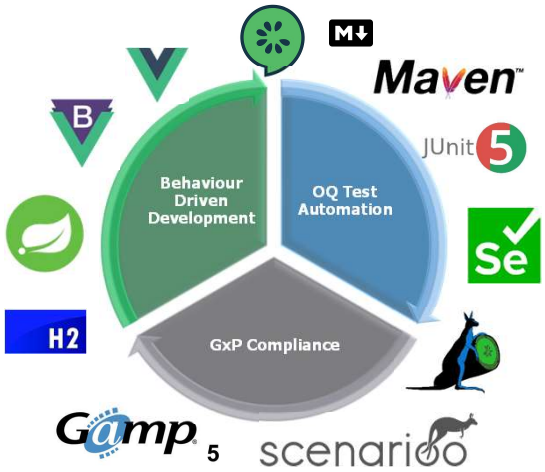
Behaviour Driven Development
OQ Test Automation
GxP Compliance
Maven
JUnit 5
H2
Gamp 5
scenario

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