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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

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GAMP5 with BDD for OQ

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**Computerised System Validation
in the Pharmaceutical Industry**

GAMP5

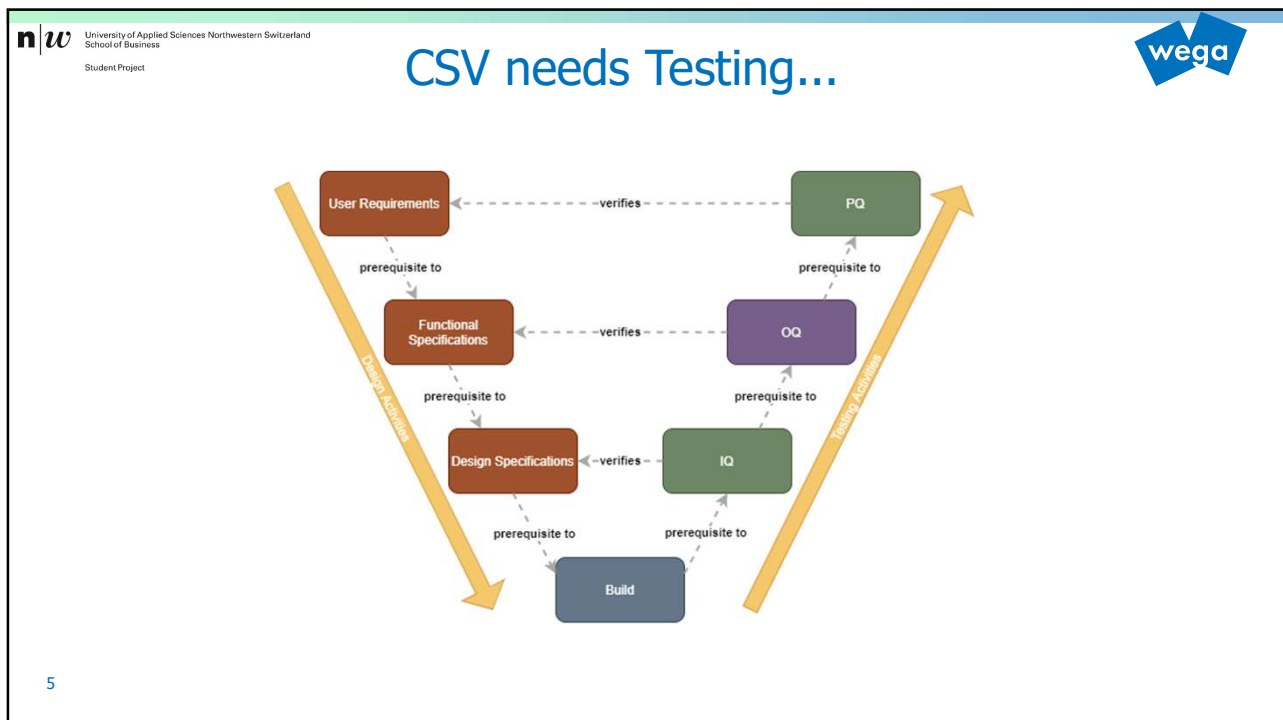
- A Guide
- Covers Validation of Computerised Systems during the whole life cycle of a product in a risk based approach.

➤ Fitness for Intended Use
➤ Compliance to Regulation

} Patient Safety

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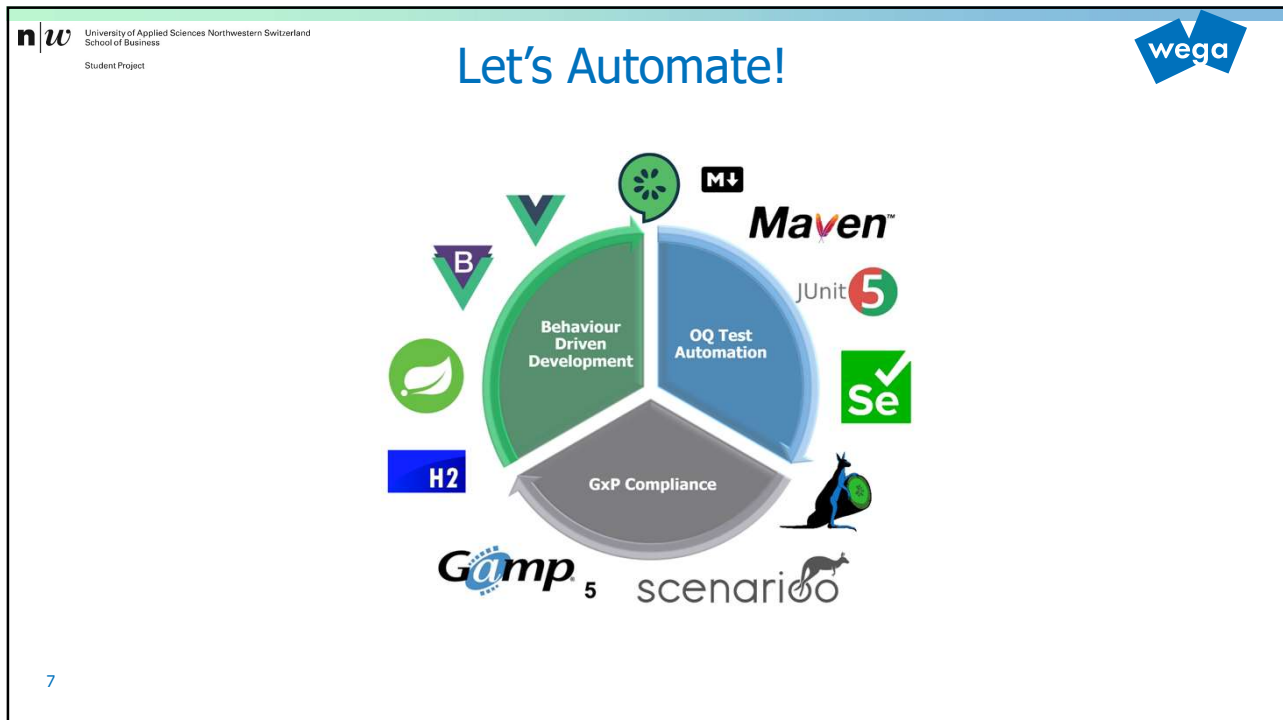
... a lot of Testing

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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Our Questions

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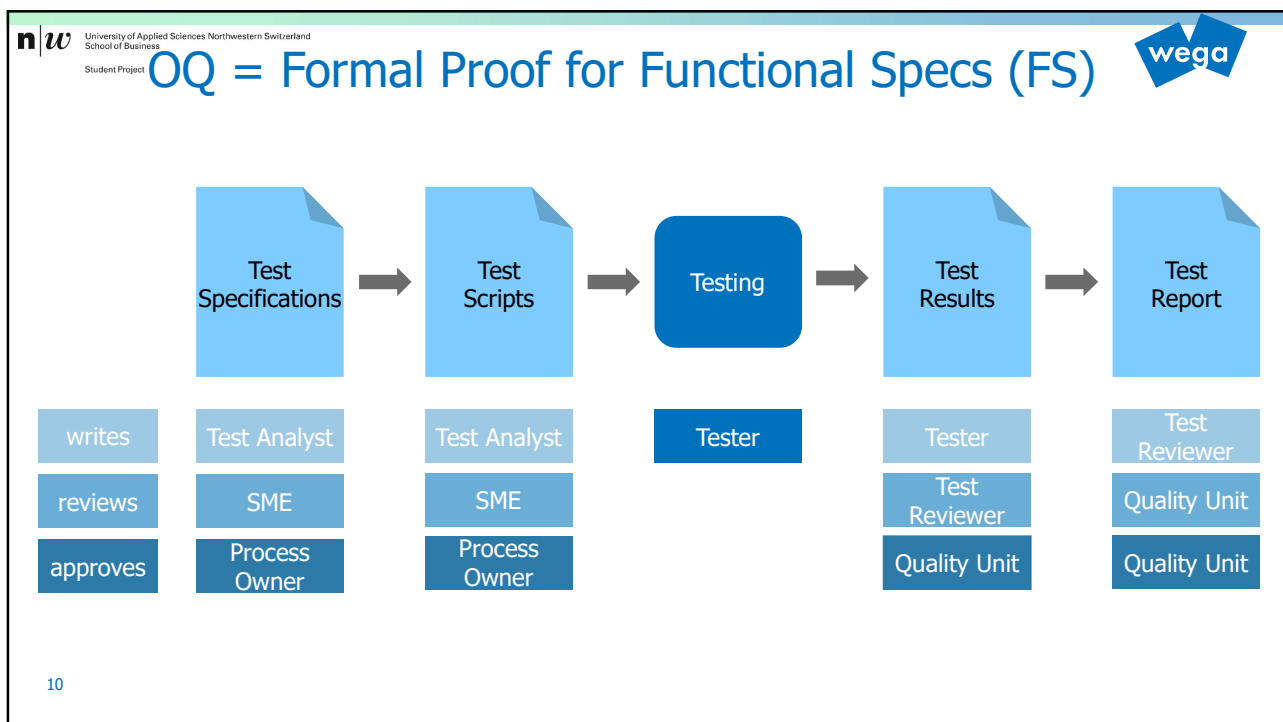
- Do the artefacts from the BDD-OQ process satisfy the GAMP5 OQ requirements?
- How can the executable requirement suite be adapted to the evolving nature of the application?
- Can automation tools like Cucumber/Gherkin, Selenium and Scenarioo be used together in validated environments?
- And how could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

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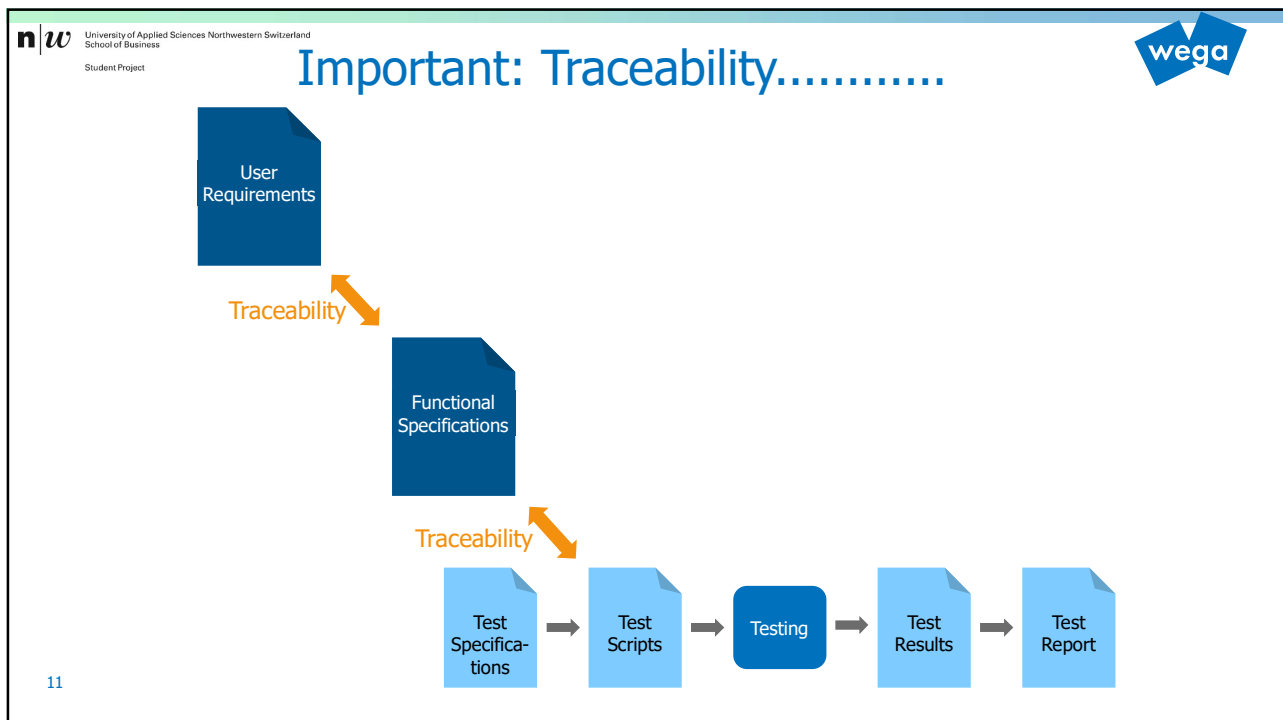
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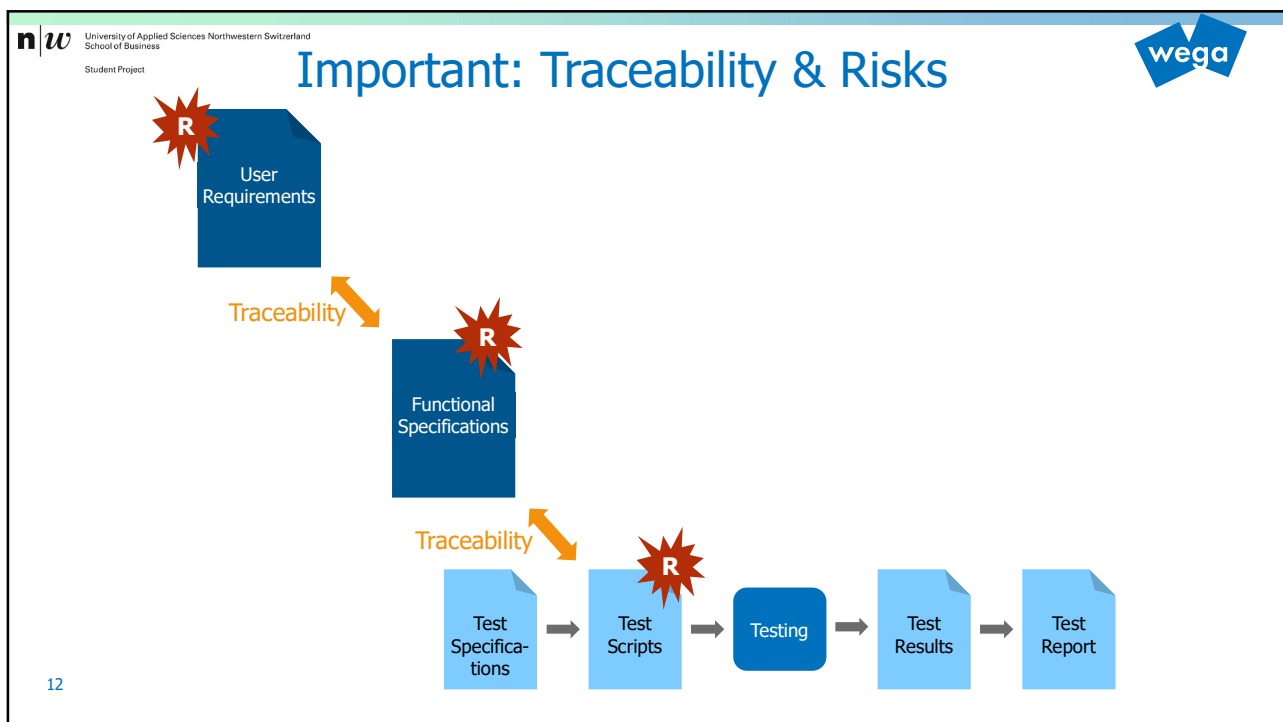
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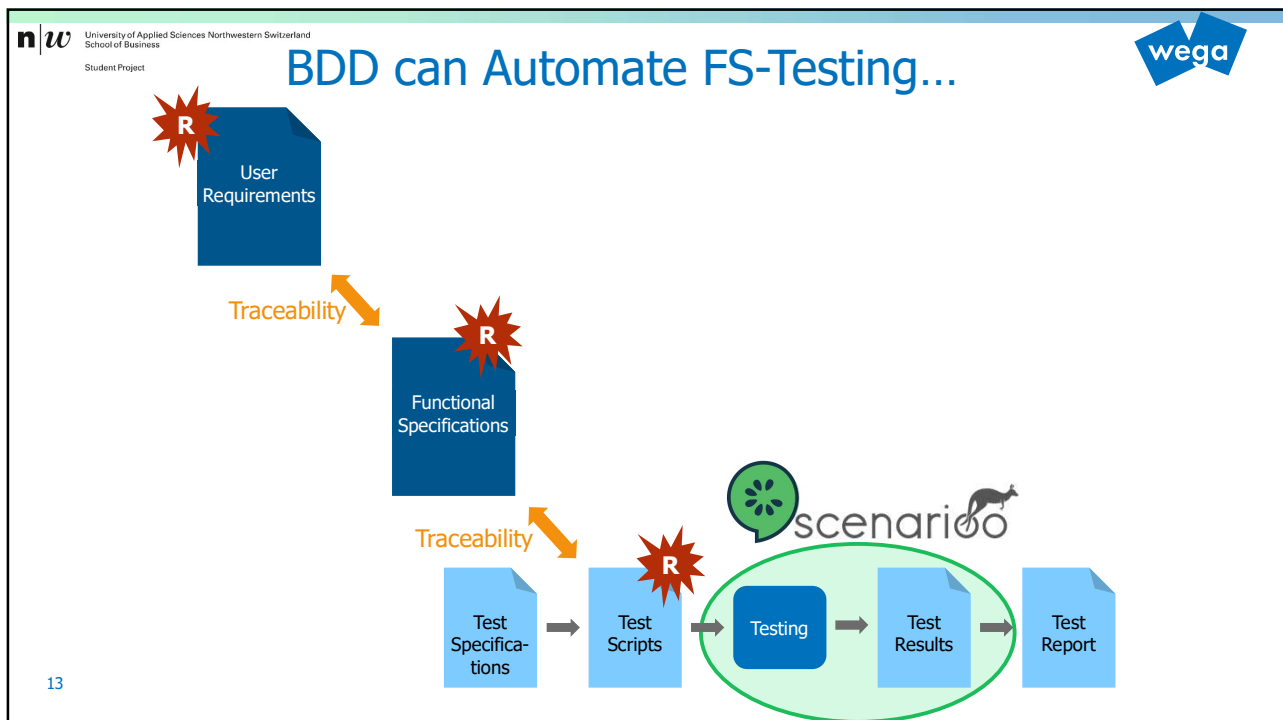
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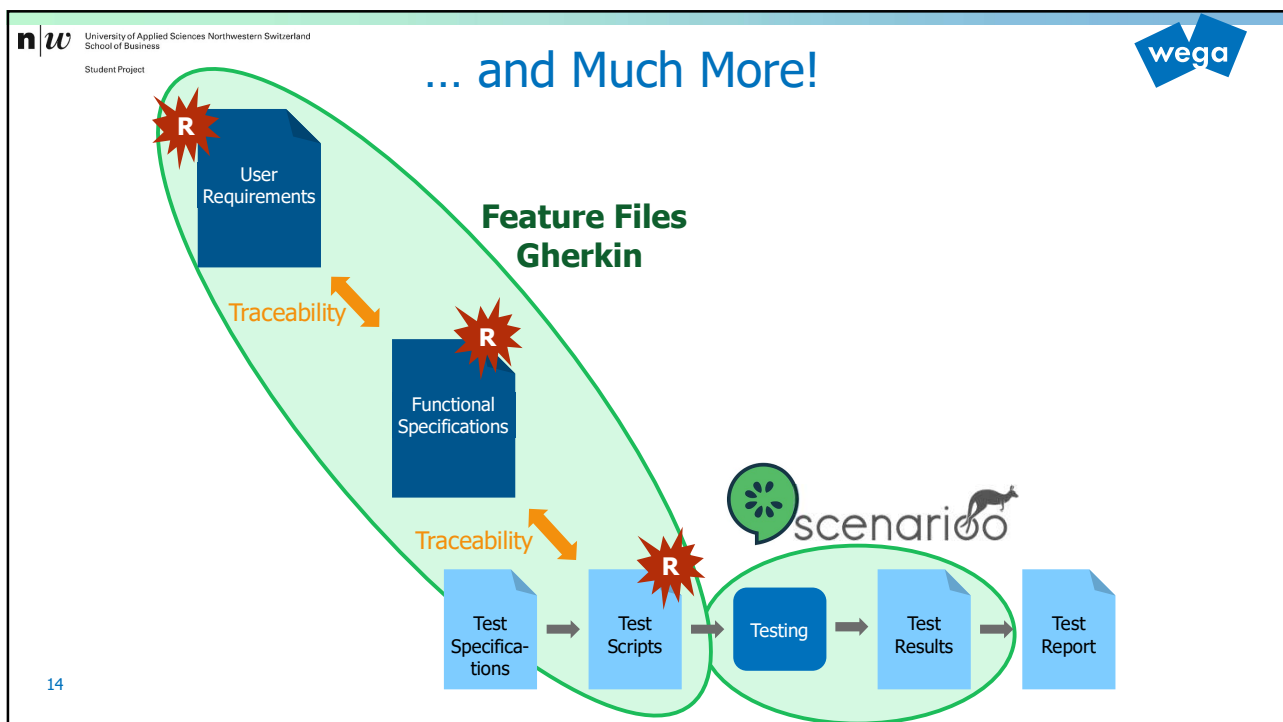
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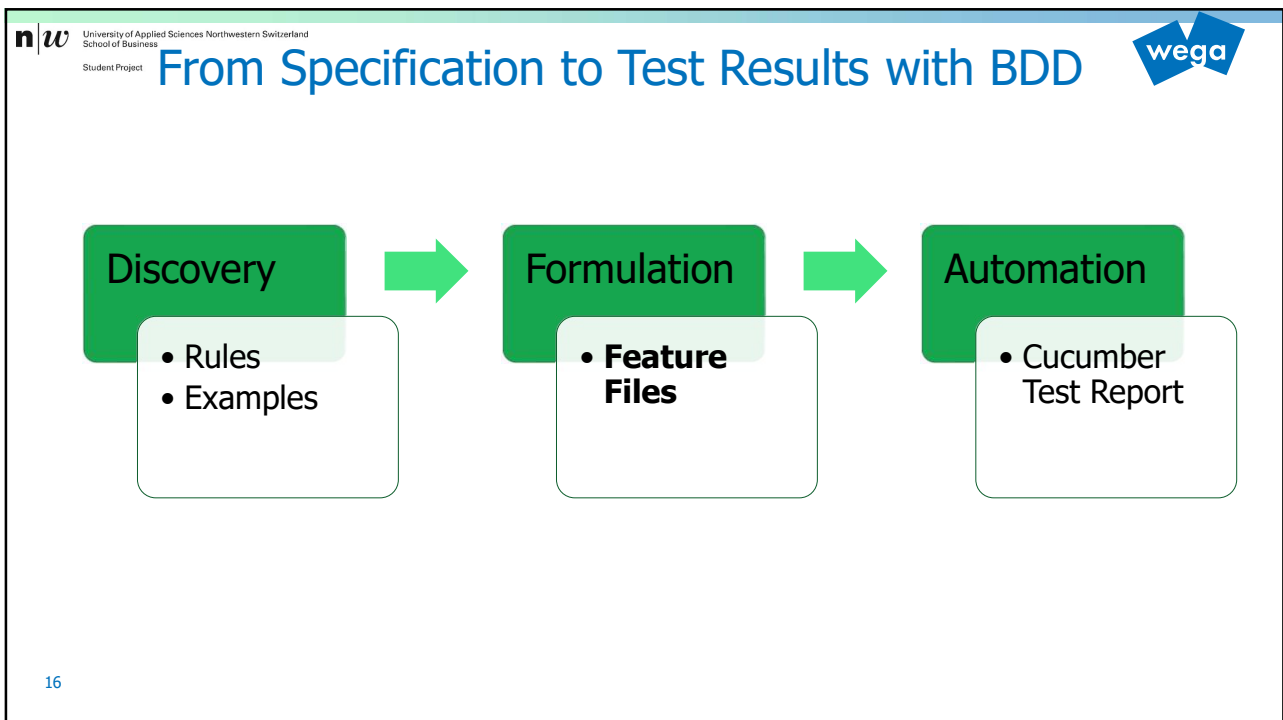
14



A person is writing on a whiteboard. There are three yellow sticky notes on the board. The first note says 'PLAN A - DATA START'. The second note says 'PLAN B - BEGRIFF KUNGS!'. The third note says 'PLAN C - CV upload to he do'. The person is holding a black marker. In the top right corner, there is a blue logo with the word 'wega'.

Feature Files: Specification and Testscript in One

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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:
  bddog-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 --> bddog-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

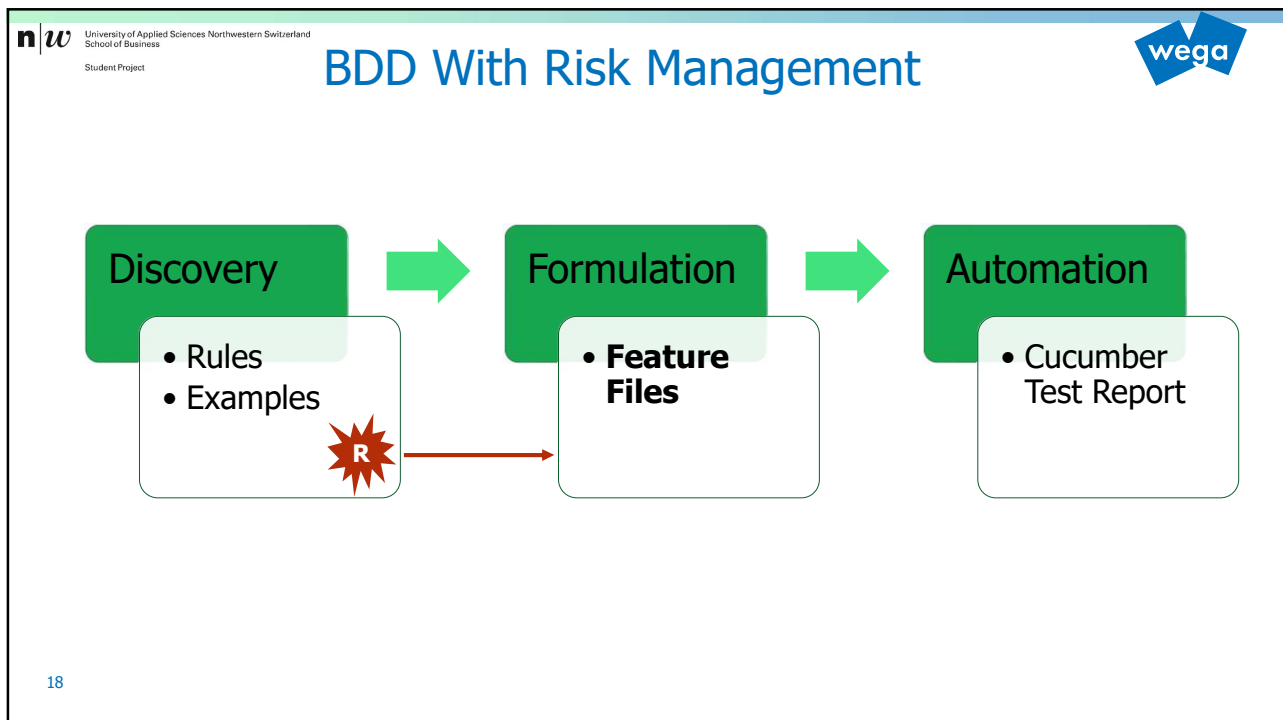
Document History & Signatures

Step

Test Data

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Feature File With Risk Management

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Baseline Weight Measurement

Risk: Patricia enters the wrong weight

Only weight entries between ≥ 0.5 kg and ≤ 200 kg are valid

Patricia makes a typo

- Patricia measures that Alec's weight is 78.5 kg
- Instead of entering 78.5, she enters 716 kg
- The system will not accept that entry, as it is an invalid entry
- Entry is not valid

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
"Eric"	"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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User Requirements

Functional Specifications

Test Scripts

Feature 3

Feature 2

Feature 1

User Stories
FS
Test Scripts

Traceability

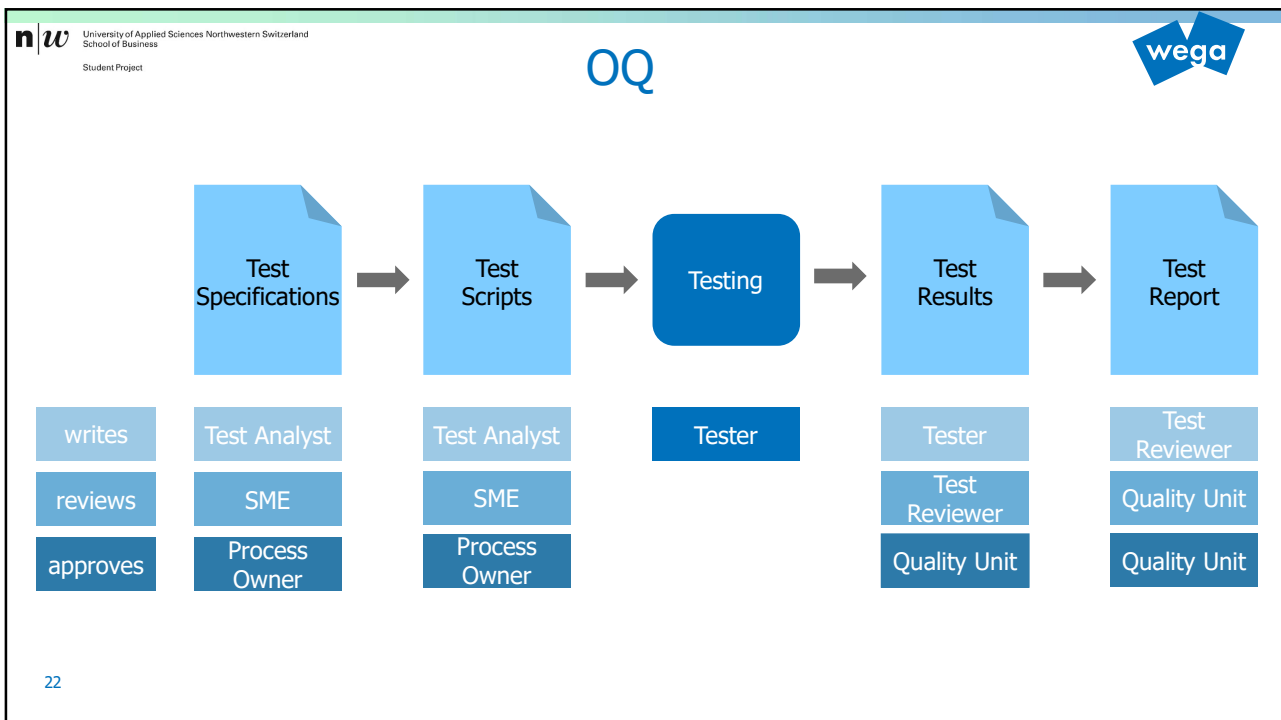
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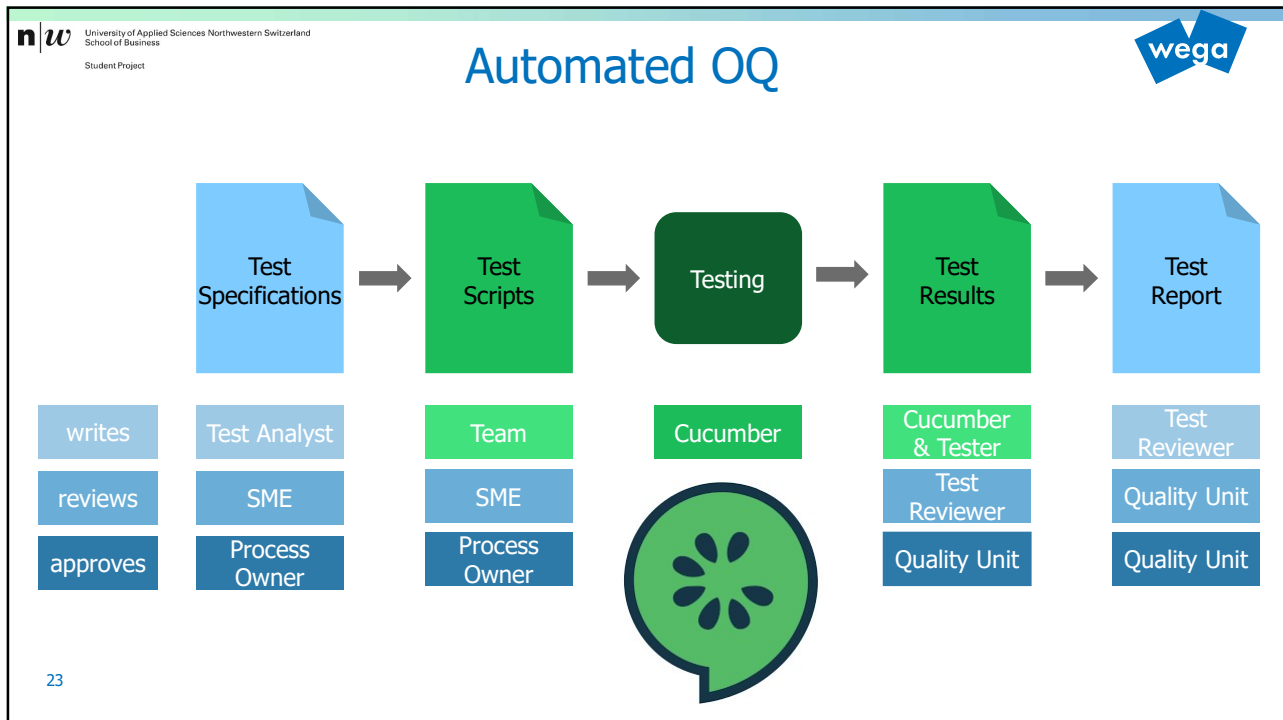


OQ Automation with BDD

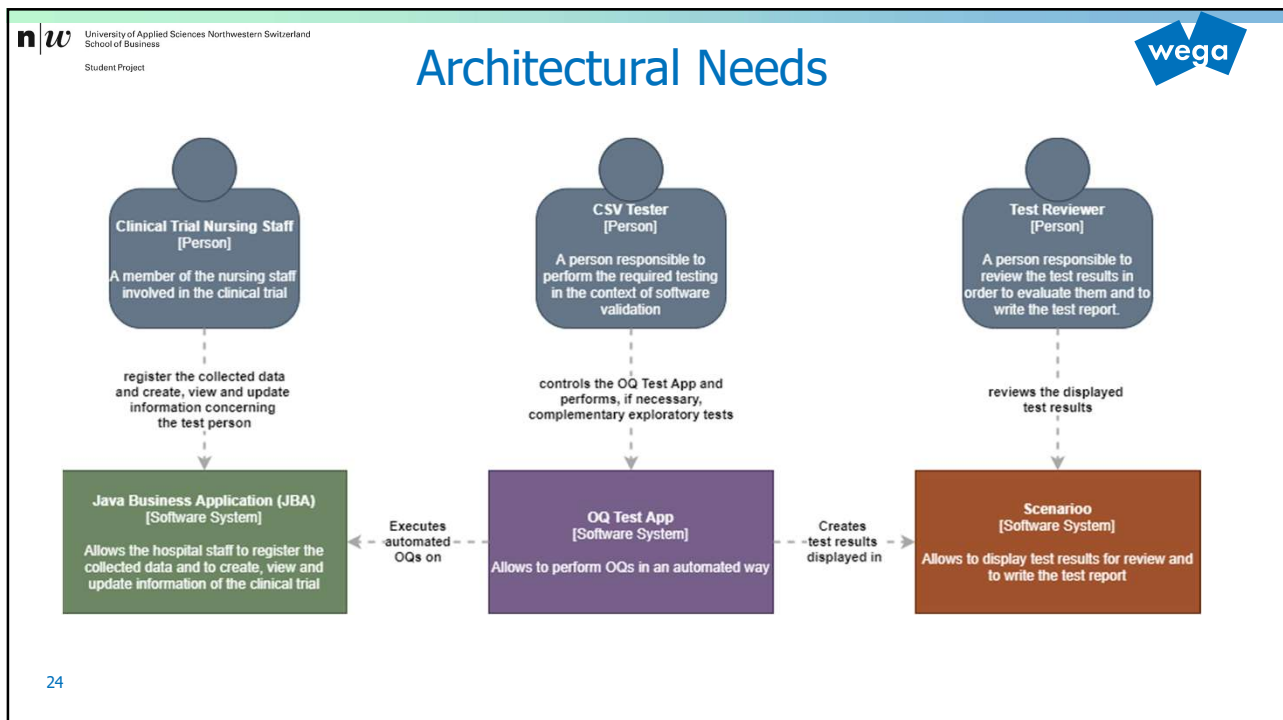
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OOQ Test Results: In an Overview...

scenario
Branch: JBA Version 1.1.0.0
Build: Build-2020-06-18-01-38-24 (June 18, 2020) success
Manage
Info

Home
Create Comparison...
Share

Use Cases
Pages
Labels
Sketches

Search in use cases...
reset
Hide Details

Status	Name	Description	# Scenarios
success	Consent management	This specification describes how the nurse Patricia manages the participant's consent.	1
success	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	1
success	Registration of a participant	This specification describes how a person that would like to	3
success	Setting the baseline weight measurement	This specification describes how the nurse Patricia sets the baseline weight measurement of the participants.	10

Branch


Description: Automated Testing through the UI for JBA Version 1.1.0.0

Build


Date: June 18, 2020, 1:38 PM
Revision: OOQ validation run for JBA Version 1.1.0.0 - performed by Scott Lang
Status: success

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... But also in Detail

scenario
Branch: JBA Version 1.1.0.0
Build: Build-2020-06-18-01-38-24 (June 18, 2020) success
Manage
Info

Home
Use Case: Setting the baseline we...
Scenario: Allowed weight entry va...
Step: BDD4OOQ JBA - Participant0/2
Create Comparison...
Create Sketch...
Share

Page 3 of 3
Step 5 of 6 (Step 3 of 4 on Page)
Page-Variant 13 of 50
Hide Details

Screenshot

Home
Participant Registration
Participants

Participant

ID: 5
First Name: Alec
Last Name: Turner
Birthday: 21.09.2014
Gender: male


Consent
☐ Consent given
Update

Baseline Weight Measurement

Weight in kg: 0.5
Date and Time: 06-Jun-2020, 4:15pm
Comment:
Set

Step

Step title: When Patricia enters 0.5 kg and any valid date time
Page name: BDD4OOQ JBA - Participant
Glue Code:
oo_glue_code: ParticipantDetailsStepDefs.patriciaEntersKg(java.lang.Double)
Pattern: Patricia enters (double) kg and any valid date time
Url: file:///C:/Users/Sabrina/IdeaProjects/BDD4OOQ/bdd4ooq-test-app/src/main/resources/jba_feature_files/baseline_weight_measurement.test
Line: 64
Keyword: When
step_duration: 0 s 538 ms
AFTER_STEP_duration: 0 s 409 ms
Build status: success



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And Your Application is Documented!

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Cucumber-Scenarioo-plugin

Participant

ID: 5
First Name: Betty
Last Name: Ross
Birthday: 1st of May 1962
Gender: female

Consent
☒ Consent given

Baseline Weight Measurement
Weight in kg: 64.2
Date and Time: 17-July-2020 - 3:45 pm
Comment: [empty]
Created baseline with ID: 6

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

Given I have a participant with first name <first_name> last name <last_name> birthday "21.06.1962"
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
Ilex	Turner	200.0
Ilex	Turner	12.8

Participant

ID: 5
First Name: Alec
Last Name: Turner
Birthday: 21.09.2014
Gender: male

Consent
☐ Consent given

Baseline Weight Measurement
Weight in kg: 0.5
Date and Time: 06-Jun-2020, 4:15pm
Comment: [empty]

Step 1: When Patricia enters 0.5 kg and any valid date time
Page name: BDDHQOQ_JSA - Participant
Gherkin Code:
@ui_base_node ParticipantDetailsDialogData.patriciaEnterWeightDialog.DoubleClick
Pattern: Patricia enters (double) kg and any valid date time
Url: file:///C:/Users/Satrina/OneDrive/Projects/BDDHQOQ/bddhq-test/app/requirements/app_base_test/ui_base_node_weight_measurement.html
Line: 54
Keyword: When
step_duration: 0 s 538 ms
AFTER_STEP_duration: 0 s 409 ms
Build status: success

A person's hand is shown writing on a whiteboard with a black marker. The whiteboard has several yellow sticky notes attached to it. The notes contain handwritten text: 'PLAN A - DATA SUKSES', 'PLAN B - Berhasil Kuning!', 'PLAN C', and 'PLAN C - CV unluod to he do'. The background is a whiteboard with some faint, illegible handwriting. In the top right corner, there is a blue logo with the word 'wega' in white.

wega

QC, Test Sample


PLAN A
- DATA
SUKSES

PLAN B
- Berhasil
Kuning!

PLAN C


PLAN C
- CV
unluod
to he do

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.

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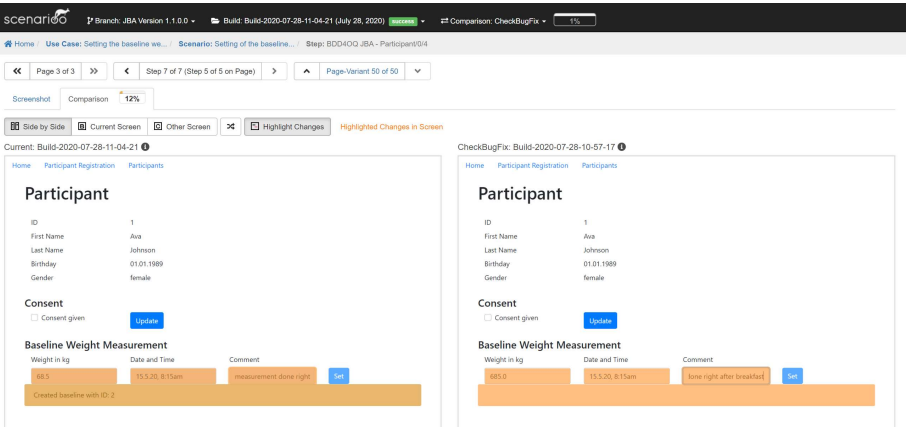


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... But Can Be Improved




- 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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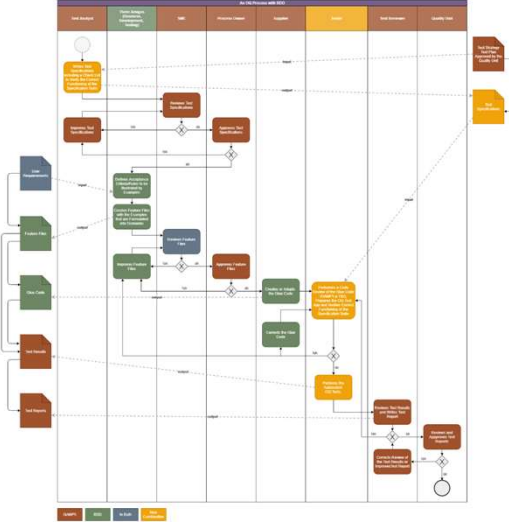


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The Answers to Our Initial Questions




- 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, Scenario
- Can automation tools like Cucumber/Gherkin, Selenium and Scenario 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!

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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!

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

➤ It would not have been possible without you!

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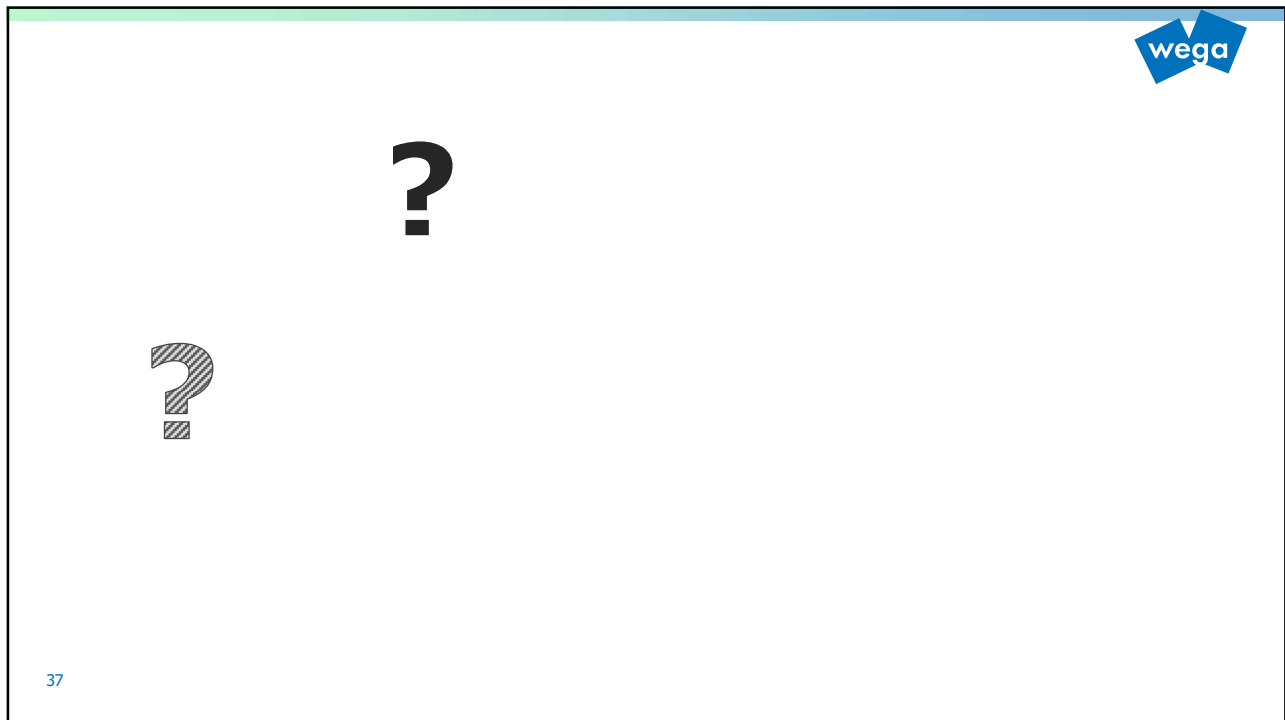
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Many Thanks for Your Attention!

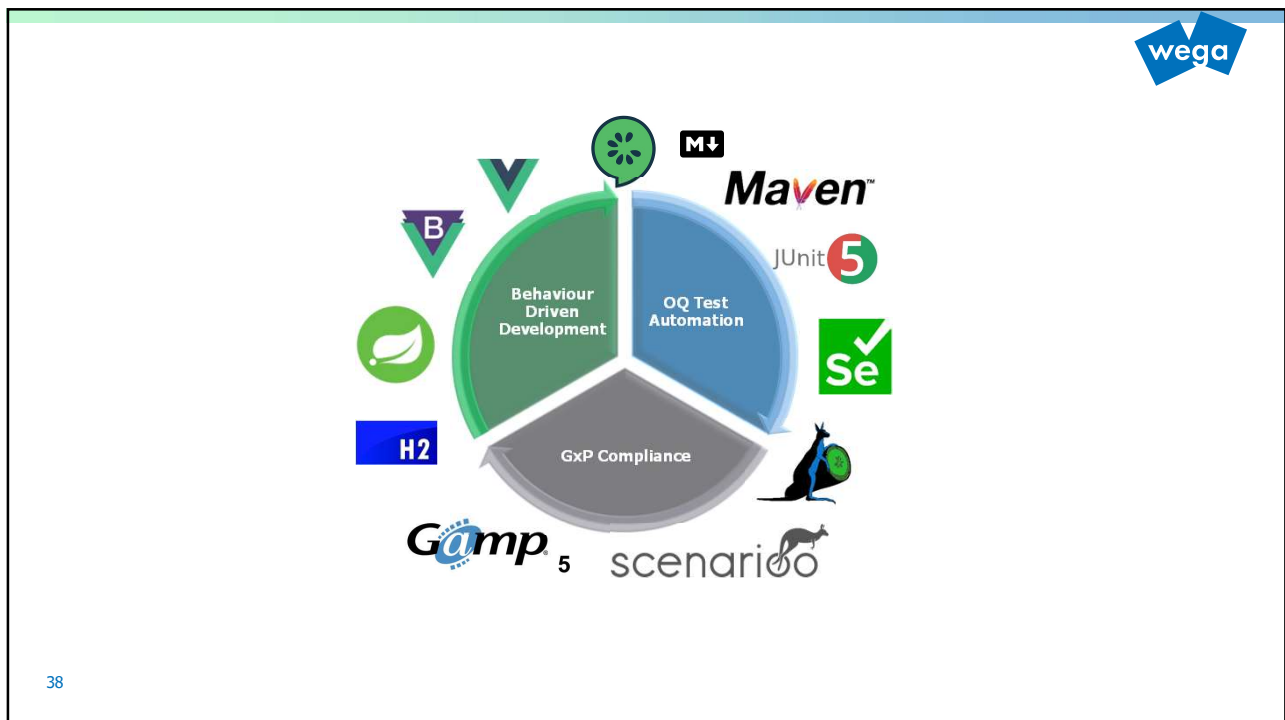
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