

# Introducing: Design Controls as a Service

*– Plugin to a ready-made machine to manage development, risks, and create your technical file!*



# Who is Taipuva?

- Private company founded in 2011, based in Finland and Sweden
- Having ~15 experts specializing in how to make processes work smoothly in regulated industries – such as medical devices and in-vitro diagnostics
- Partner of Siemens Digital Industries Software for Polarion® digital platform
- Having solid expertise how to use modern digital tools – making working easier and more enjoyable

Mission:

***Help companies  
improve the efficiency  
of R&D and projects***

We have been successful in helping our customers!



PLANMECA

SARTORIUS

phoTono

ThermoFisher  
SCIENTIFIC

KAVO KERR

XO

Innokas  
Medical

MEHILÄINEN

Dvysr

bk  
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tobii

WSAudiology

Boule

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UNEEG<sup>™</sup>medical

muRata  
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stuk

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VTT

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DYNAMICS

Consilium

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Region  
Stockholm

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VETENSKAP  
OCH KONST

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Valmet  
FORWARD

NIBE

Danfoss

VALMET AUTOMOTIVE

taipuvo

[See cases and what our customers say!](#)



## It's a winding road:

- to get your *processes* up & running
- to *digitalize* it all to full extent

Know what to  
do and how?

Choose your  
expertise partners

Design your  
processes and  
ways of working

Choose your IT  
environment and  
tools

Implement  
your processes  
on IT tools

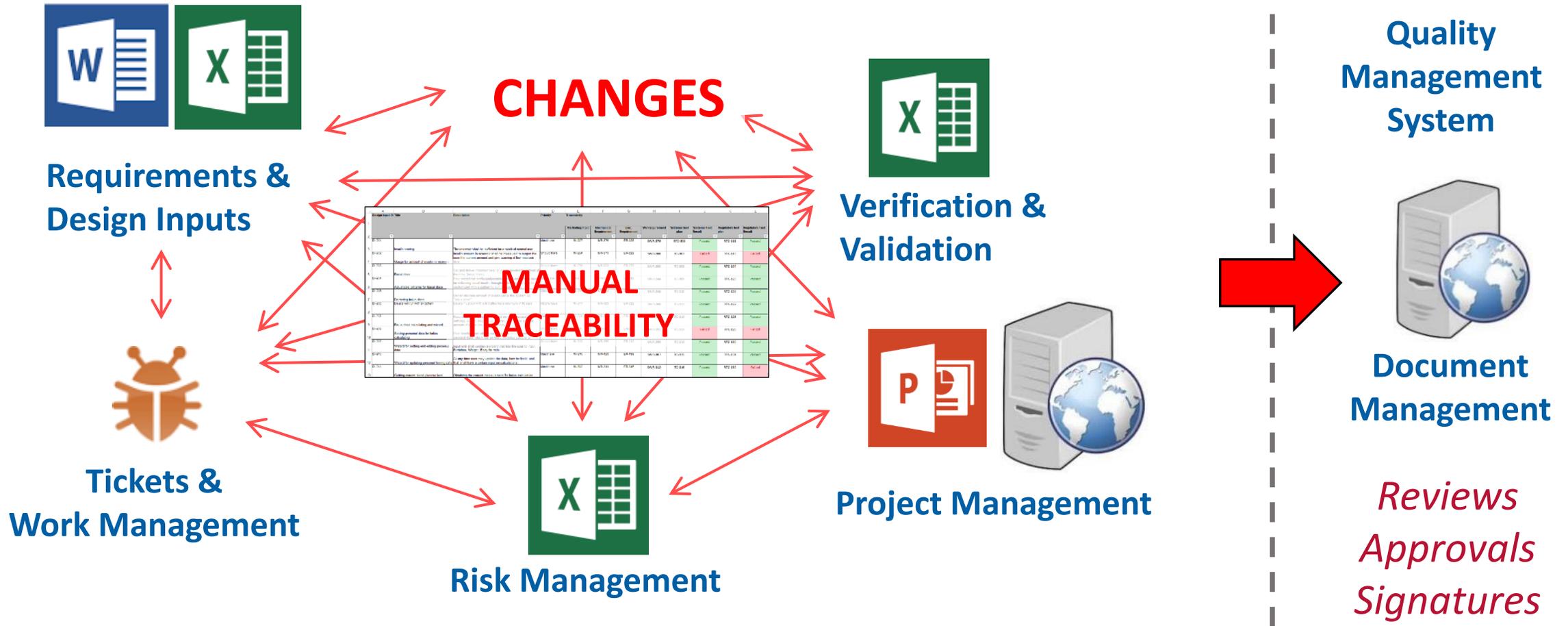
Know how to  
work efficiently

*How long will it take?*

*How much does it cost, in salary & external service fees?*

*How do you know it's compliant & efficient?*

# Often the resulting solution looks something like this...



## Usual problems and inefficiencies:

*Processes and information are disconnected. Traceability is a burden instead of helping you to carry out changes. Exports and snapshots need to be taken to documents. Reviews & approvals are done file-based in big chunks. Agile ticketing systems do not support all areas and features are lacking for: proper traceability (especially for risk mgt), content freezing, automated workflows, reviews, approvals, consistent full history, audit trail, document management and e-signing.*

You might accept it as “good enough” for now...

...but what if it *slows you down* and eats up your money & makes your experts frustrated?



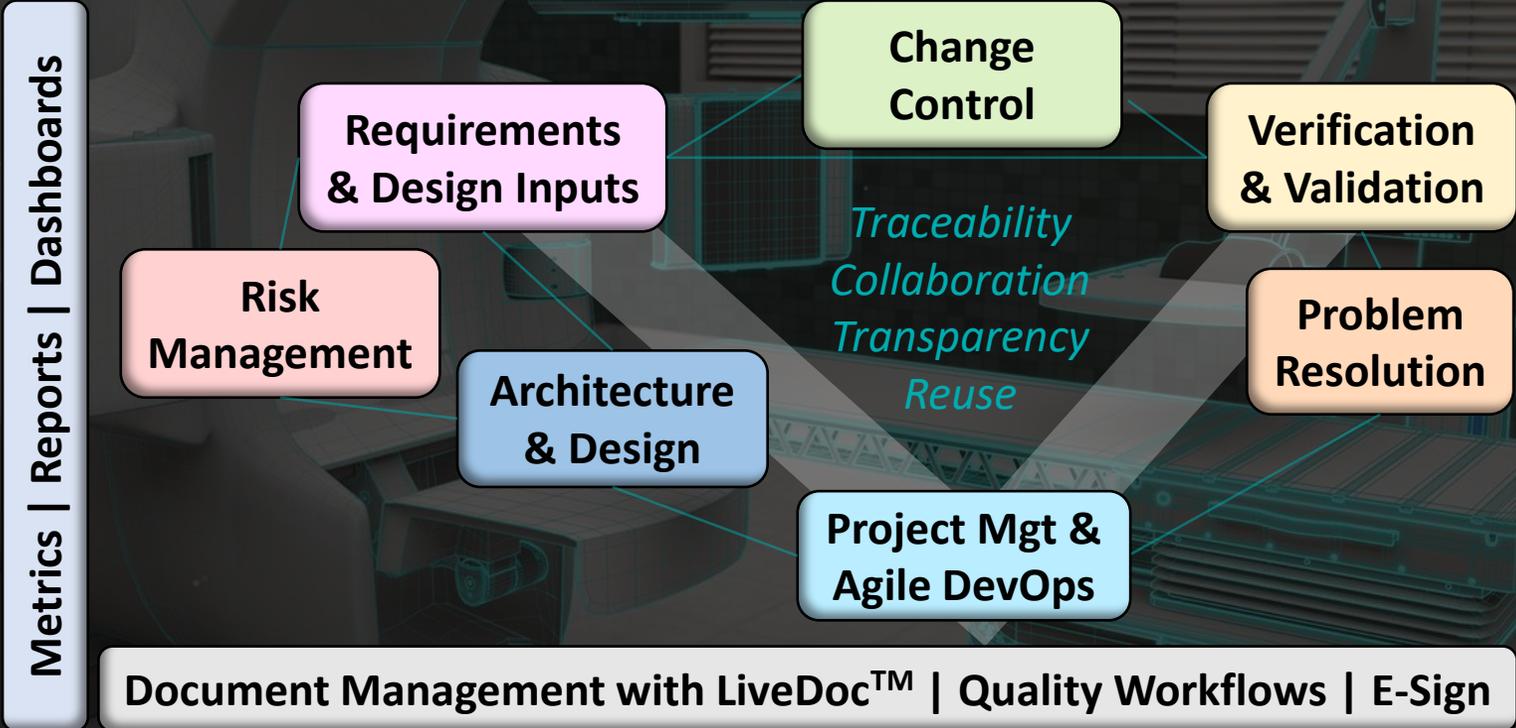
# Would there be a better way?

*...so that it makes you much faster and more efficient*

- ✓ **Speeding up** development by several months or even years!
- ✓ **Reducing the risk** of rework or failing audits
- ✓ **Guiding** people how to do things right and find gaps – making work much more enjoyable
- ✓ **Enabling the full reuse** of information for following products or variants – Cutting effort to a small fraction

# Launching: DESIGN CONTROLS AS A SERVICE

All needed process areas in one –  
seamlessly connected – online for smooth collaboration



Powered by **SIEMENS Polarion®**  
– Enabling the all-connected digitalization

# How Does It Work?

- Subscribe to Taipuva's service with a certain amount of users
- Your organization obtains a dedicated online service, for example **mycompany.taipuva.com**
- You access a ready-made Polarion® instance there, with the amount of projects you need
- It runs Taipuva-created, simple but powerful processes – proven effective and compliant with 10 years of expertise in medical devices
- We backup and secure your valuable information
- Bring your existing data to the service from Word, Excel or other sources (Taipuva's migration service is available to help)
- Export to PDF, Excel or Word formats – whenever you need to submit your technical file or get information out for other purposes
- Otherwise the service itself is your reliable digital archive, with full history

# DESIGN CONTROLS AS A SERVICE – Key Features

- Packaged, ready-made & easy – just start taking the advantage
- All connected, end-to-end traceability
- Create & maintain technical file, within electronic archive
- Supports software lifecycle process according to IEC 62304
- Validated for ISO 13485
- Use to write *any* documents

## Comes with

- Training
- Support

to get you going and productive!

Following pages showcase some features in more detail...

# Requirements Management & Design Inputs

- Write requirements and design inputs into easy Polarion® LiveDoc™ documents, which are online and always at the latest version.
- You have the power of Word, Excel and database combined into one – as requirements are individual “work item” objects embedded.
- Work items are **not** extracted from documents, but they *live* and exist in documents and database at the same time.

↑ METE-908 - Gauge for amount of insulin in reservoir

↑ METE-644 METE-1385 METE-1518 METE-1656 +

Type: **User Requirement** Assignee(s): **Pasi Ahola**

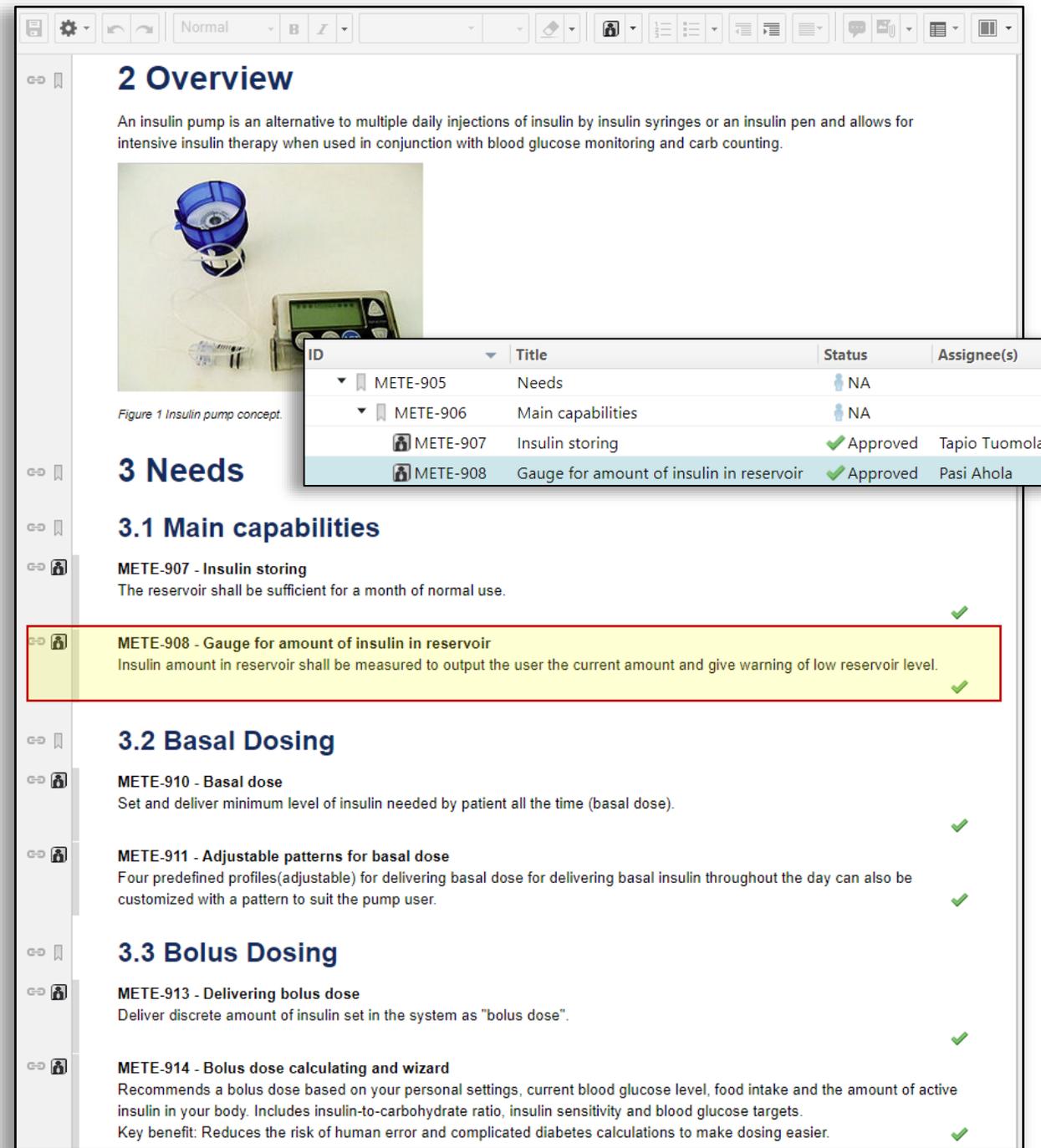
Original Source: **Marketing claims for key user features** Status: **Approved**

Source Category: **User Need** Resolution:

**Description**

Insulin amount in reservoir shall be measured to output the user the current amount and give warning of low reservoir level.

- Work items are unique, identified and traceable.
- Work items can have any needed metadata, in a variety of fields.
- Documents can be edited by multiple people simultaneously.
- Documents can be exported to a Word round-trip format for commenting or even editing by external parties.
- LiveDocs are not *only* for requirement specifications but **architecture and design documents, quality manuals, SOPs, work instructions, design reviews memos**, meeting memos, anything you need ...



## 2 Overview

An insulin pump is an alternative to multiple daily injections of insulin by insulin syringes or an insulin pen and allows for intensive insulin therapy when used in conjunction with blood glucose monitoring and carb counting.



Figure 1 Insulin pump concept.

ID	Title	Status	Assignee(s)
METE-905	Needs	NA	NA
METE-906	Main capabilities	NA	NA
METE-907	Insulin storing	Approved	Tapio Tuomola
METE-908	Gauge for amount of insulin in reservoir	Approved	Pasi Ahola

## 3 Needs

### 3.1 Main capabilities

**METE-907 - Insulin storing**  
The reservoir shall be sufficient for a month of normal use. ✓

**METE-908 - Gauge for amount of insulin in reservoir**  
Insulin amount in reservoir shall be measured to output the user the current amount and give warning of low reservoir level. ✓

### 3.2 Basal Dosing

**METE-910 - Basal dose**  
Set and deliver minimum level of insulin needed by patient all the time (basal dose). ✓

**METE-911 - Adjustable patterns for basal dose**  
Four predefined profiles (adjustable) for delivering basal dose for delivering basal insulin throughout the day can also be customized with a pattern to suit the pump user. ✓

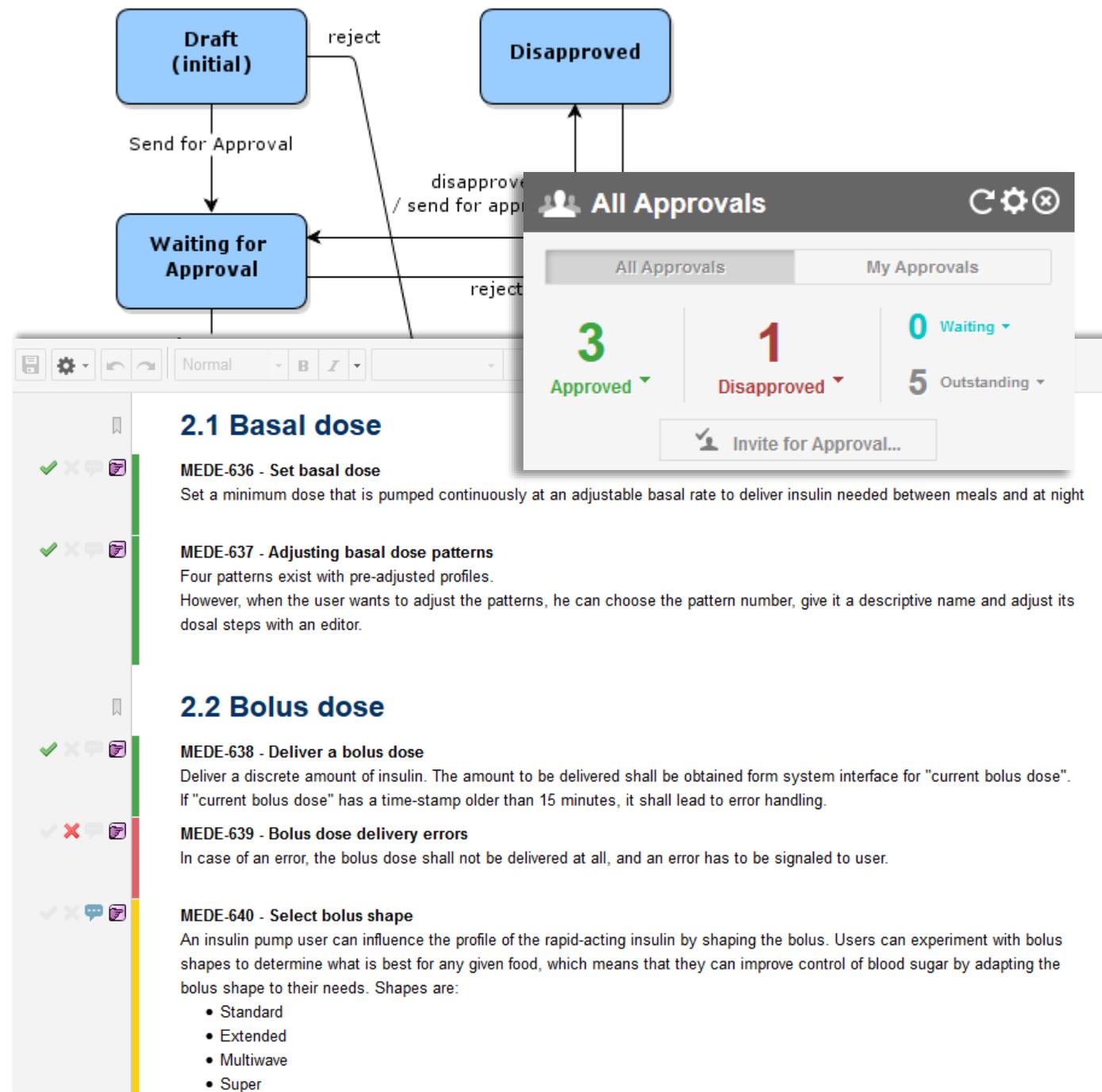
### 3.3 Bolus Dosing

**METE-913 - Delivering bolus dose**  
Deliver discrete amount of insulin set in the system as "bolus dose". ✓

**METE-914 - Bolus dose calculating and wizard**  
Recommends a bolus dose based on your personal settings, current blood glucose level, food intake and the amount of active insulin in your body. Includes insulin-to-carbohydrate ratio, insulin sensitivity and blood glucose targets. Key benefit: Reduces the risk of human error and complicated diabetes calculations to make dosing easier. ✓

# Workflow – Reviews, Approvals, E-Sign

- You do not need a separate document management system. You can rely on Polarion® as your electronic archive that provides FDA 21 CFR Part 11 compliant e-signatures, full history and audit trail.
- Having everything in one place with the needed process and signatures greatly shortens the time required for handling changes.
- Ready-made workflows are optimized to what is needed in the medical device industry – for both, documents and work items.
- Reviews are facilitated easily online, in collaboration – again leaving the required audit trail.
- Multiple people may comment and enter review verdicts at the same time.
- Review meetings can focus on the content itself, as the process is under control.
- Design Review memos may be recorded as separate LiveDocs, containing needed actions as work items (Tasks for example).
- Capture the full history of what was changed and why, so that decisions behind changes and the design can be understood.
- LiveDoc is all you need – no need to export to external systems. Attachment files are supported, too, if you want to control external file-based documents.



# Traceability – End-to-End

- By linking work items it is very easy to set up traceability between Requirements, Verification Cases and Risks.
- It is not just links, but different *types* of links, so it is possible to limit your view to the relations you want to focus on at each time.
- End-to-end reporting shows verification/validation results against all levels of requirements and risk mitigations being realized.
- Save enormous amount of time and effort, when there is no manual checking needed at all.
- Avoid quality issues, which might be due to manual errors or not seeing all change impacts.
- Avoid the risk of being non-compliant regarding this highly important regulatory requirement.

ID	Title	Status
METE-910	Basal dose	Approved
METE-636	Set basal dose	Approved
METE-686	Set basal dose	Approved
METE-911	Adjustable patterns for basal dose	Approved
METE-637	Adjusting basal dose patterns	Approved

Starting Level	Dependent Items	Test Case	Latest Test Result
<ul style="list-style-type: none"> <li>METE-911 - Adjustable patterns for basal dose</li> </ul>	<ul style="list-style-type: none"> <li>METE-637 - Adjusting basal dose patterns</li> </ul>		
<ul style="list-style-type: none"> <li>METE-910 - Basal dose</li> </ul>	<ul style="list-style-type: none"> <li>METE-636 - Set basal dose</li> </ul>	<ul style="list-style-type: none"> <li>METE-686 - Set basal dose</li> </ul>	<ul style="list-style-type: none"> <li>Passed (2019-02-11 22:53)</li> <li>Sys03 - System Verification</li> </ul>
<ul style="list-style-type: none"> <li>METE-913 - Delivering bolus dose</li> </ul>	<ul style="list-style-type: none"> <li>METE-639 - Bolus dose delivery errors</li> </ul>		
	<ul style="list-style-type: none"> <li>METE-638 - Deliver a bolus dose</li> </ul>	<ul style="list-style-type: none"> <li>METE-688 - Set bolus dose</li> </ul>	<ul style="list-style-type: none"> <li>Passed (2019-02-11 22:53)</li> <li>Sys03 - System Verification</li> </ul>

Polson Software  
Drive Pilot (AP) System Requirements (rev. 13399)

## User Requirements

### 3 Requirements

#### 3.1 General Operations

WR-413 - DrivePilot shall easily engage operations while the vehicle is at rest. [✓ Approved, Version 1.0 ]

WR-414 - DrivePilot may not be engaged while the vehicle is under manual control.

- provide voice authentication
- provide handicap access
- provide manual backup
- can only be activated by driver

[✓ Approved, Version 1.0 ]

WR-416 - DrivePilot shall be easy to operate without extensive training. [✓ Draft, Version 1.0 ]

WR-419 - Before any user may engage DrivePilot on public roads, that user must successfully complete a tutorial and test DrivePilot operation. [✓ Draft, Version 1.0 ]

WR-417 - DrivePilot will disengage with audible, visual notifications if the following occurs:

- steer change requests to manually activated
- brake is manually engaged
- user shouts "Stop"
- Accelerator pedal is manually engaged
- Turn signal is activated

[✓ Draft, Version 1.0 ]

WR-422 - DrivePilot is NOT compatible with any vehicle that has "auto parking" capability. Some models of vehicles come equipped with capability. Not all models are so equipped, only when correctly optioned out.

Manufacturer	Model
Toyota/Lexus	Prius, LX200
Volkswagen	Tiguan, PassatCC, Golf

[✓ Draft, Version 1.0 ]

WR-469 - DrivePilot shall operate with input power of 12 Volts, not to exceed 15 Amps with a +/- variance tolerance of 10%. [✓ Draft, Version 1.0 ]

#### 3.2 User Console

WR-423 - The DrivePilot user console shall have common views in the built-in displays, and alternative console applications. [✓ Draft, Version 1.0 ]

WR-424 - The DrivePilot user console will operate in the following platforms: [✓ Draft, Version 1.0 ]

- WR-425 - Embedded, wired Native Console [✓ Draft, Version 1.0 ]
- WR-427 - Apple iPad Application (Bluetooth) [✓ Draft, Version 2.0 ]
- WR-428 - Android Application (Bluetooth) [✓ Draft, Version 2.0 ]

1 | Page Polson ALM 2012 2019-01-28 14:21

Polson Software  
Drive Pilot (AP) Software Design Specification (rev. 14819)

## System Requirements

### 1 Introduction

#### 1.1 Purpose

This document describes the design of a DrivePilot software application. Software components described in this document have been identified as needed to implement requirements from System Requirements Specification. Together, it provides the design specification needed to implement the system.

#### 1.2 References

System Requirements

### 2 Component Design

#### 2.1 User Console

WR-424 - The User Console will resemble a typical dashboard display and include options for system configuration.

#### 2.1.1 DrivePilot iPad Console Application

WR-446 - iPad User Interface application can be downloadable through AppStore, but requires authentication code from DrivePilot to download and operate.

WR-461 - DrivePilot iPad console shall connect via secure Bluetooth to DrivePilot Controller.

WR-448 - The connection is established through connect command of Bluetooth v2.0 protocol.

#### 2.1.2 DrivePilot Android Console Application

WR-447 - Android User Interface application can be downloadable through Google Play, but requires authentication code from DrivePilot to download and operate.

WR-463 - DrivePilot Android console shall connect via secure Bluetooth to DrivePilot Controller.

WR-448 - The connection is established through connect command of Bluetooth v2.0 protocol.

### 3 Requirements Traceability

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Polson Software  
Drive Pilot (AP) Software Test Specification (rev. 14821)

## System Verification

### 1 Introduction

#### 1.1 Purpose

The Software Test Case Specification document collects the test cases that verifies the Software Requirements. Each test case specifies inputs, predicted results, and a set of execution conditions for a test item.

### 2 Approach Refinement

The approach described in the following test plan should be used to perform the testing:

- Software Verification Test Plan

### 3 Test Cases

#### 3.1 DrivePilot iPad Console Application

TWPLT-282 - Check Application requires authentication code

Step	Description	Expected Result
Start Drive Pilot	Connect the DrivePilot to the car	
Connect iPad Console App	Start the application and connect to the DrivePilot	The Application says "Enter Auth Code."
Generate Code	Generate code using DrivePilot native console	
Enter Code	Enter the generated code to the app	
Submit	Submit the code	The app says: "Connected"

1 | Page Polson ALM 2012 2019-01-28 14:28

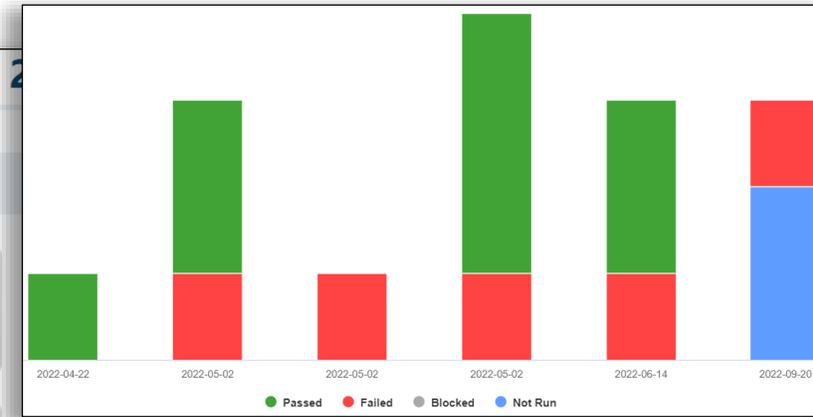
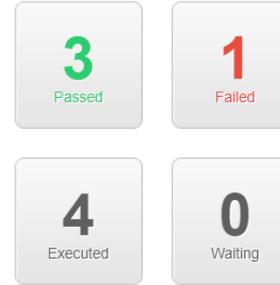
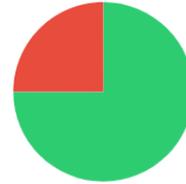
ape	<ul style="list-style-type: none"> <li>Failed (2019-02-11 22:54)</li> <li>Sys03 - System Verification</li> </ul>
ape	<ul style="list-style-type: none"> <li>Passed (2019-02-11 22:53)</li> <li>Sys03 - System Verification</li> </ul>
	<ul style="list-style-type: none"> <li>Passed (2019-02-11 22:53)</li> <li>Sys03 - System Verification</li> </ul>

# Verification & Validation (V&V)

- V&V protocols and checks can easily be written as work items in LiveDocs (example below). The content style is up to you. Step-by-step protocols are supported.
- Traceability to requirements and risks is straight-forward.
- Test Management capability can be used to execute the work items and report results of **design outputs** – with evidence if wanted (text, screen shots, attachment files).
- Separate reporting is not needed as results are stored in real-time, and they can be shown in desired formats.
- Excel round-trip is available to report results off-line.

## 20220502-1513 - Acceptance 2

### Test Run Status - Failed



### Test Run Signatures

✖ Failed (2022-05-02 15:29)

✔ Pasi Ahola

Signed

2022-05-02 15:29

### Test Run Information

Assignee(s)	Pasi Ahola
Test Type	✔ Acceptance
Version	DP2-581
Platform	Linux
Planned Within	Version 2.0 (2017-10-31)

### Test Results

📊 [Browse All Test Run Records](#)

Test Case	Test Result	Executed	Executed by	Duration	Defect
📄 DP2-543 - Simple check with no protocol	✔ Passed	2022-05-02 15:18	Pasi Ahola	20.000 s	

## 2.1 Basal dose

### METE-686 - Set basal dose

This test is to test the basic functionality of setting the basal dose on correct level and verify that the system gives the correct amount of insulin.

Step Name	Step Instruction	Expected Result
Power	Switch power on	Systems is on
Navigate	Go to settings in control panel and select Basal Dose adjustment	Basal dose adjustment is selected and current value of the dose is visible
Set dose	Change amount of the dose	New basal dose is set and visible in the control panel
Measure	Measure the amount of dosed insulin during next 60 min	Amount is according to the basal dose set in previous step
Record the measure to database	Input you measurement values into the test database	Values are gathered

# Risk Management

- Control both safety and cybersecurity risks.
- Connect them seamlessly to requirements, mitigating actions and verifying test cases.
- Control traceability easily in one place, and obtain reports end-to-end.
- **Control changes** and their impacts throughout the complex dependency chain, effectively and securely.

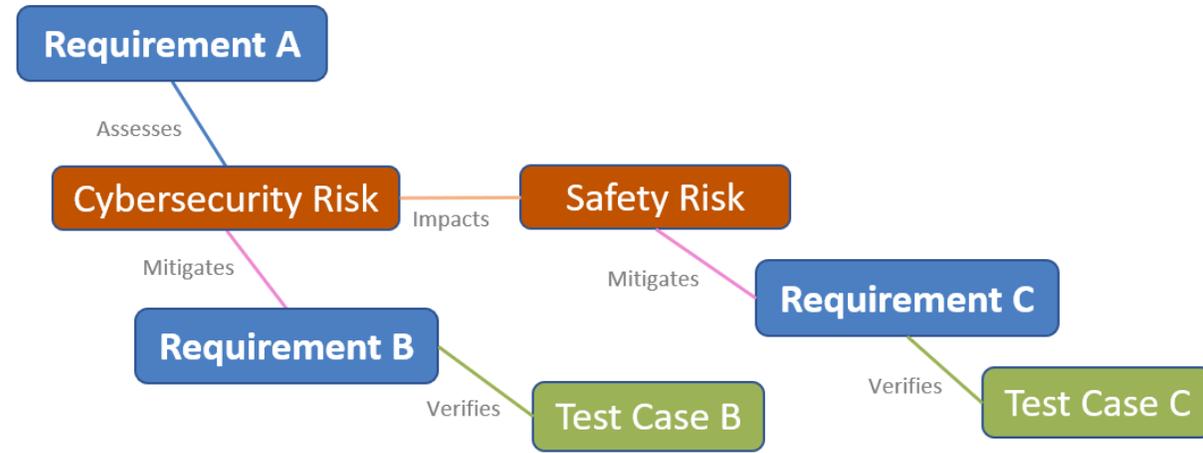


Figure showing an example of requirement assessment and a cybersecurity risk impacting a safety hazard. Further on risk controlling requirements may affect safety or cybersecurity (not depicted), so the relationships (links) between objects can become very complex.

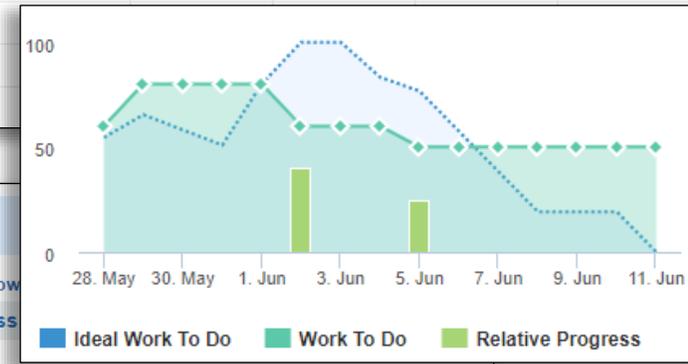
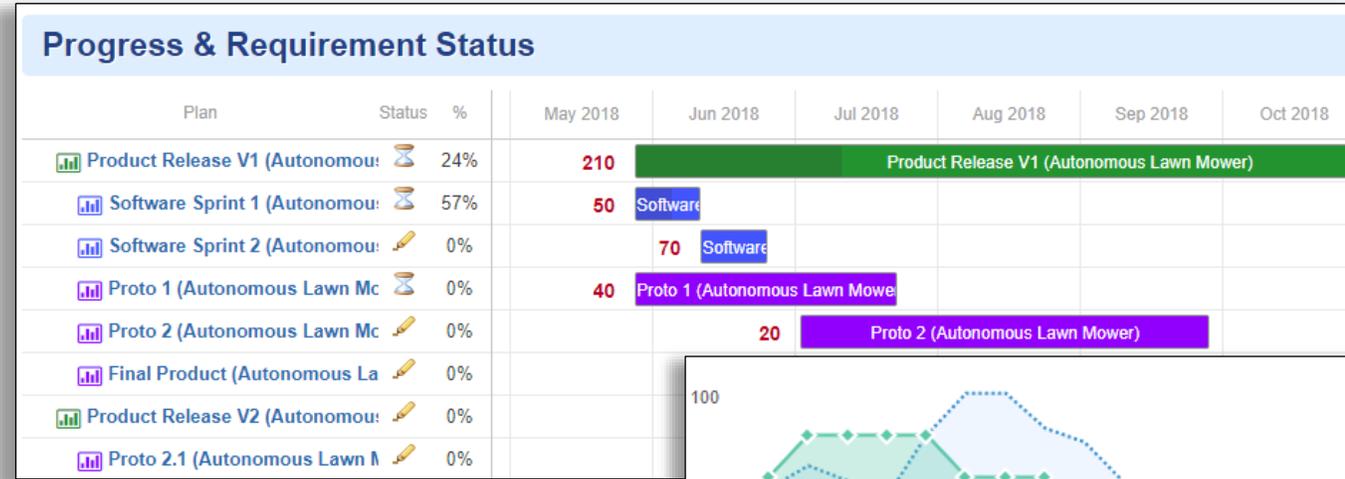
## Risk Traceability Report

Assessed Requirement(s)	Risk ID	Status	Risk Owner	Hazard	Possible Cause(s)	Harm
METE-644 - Gauge for amount of insulin in reservoir	METE-696 - Insulin reservoir gauge fails due to sensor fault	Analyzed	Tapio Tuomola	The gauge in reservoir does not correctly measure the amount of insulin left, because of faulty sensor.	Gauge is of bad quality.	Insulin pump delivers a wrong dosage and harms the patient.
METE-639 - Bolus dose delivery errors	METE-697 - Bolus dose delivery error not signaled	Mitigated	Tapio Tuomola	Bolus dose is not delivered and error is not signaled to user, because error handling or signaling fails. This causes a risk that the user does not notice the bolus dose not being delivered.	Fault in error handling or signaling.	Patient may face health issues.

Mitigating Actions	Risk Actionee	Verification	Verification Result
<input checked="" type="checkbox"/> METE-698 - Reservoir gauge sensor self-diagnostics or warning logic	Carl User	METE-1407 - Verifies: Reservoir gauge sensor self-diagnostics or warning logic	Passed 20210826-1651 - Retesting
<input checked="" type="checkbox"/> METE-726 - Mitigate: Bolus dose delivery error not signaled - color of the insulin	Pasi Ahola	METE-748 - Color of the insulin must be easily noticeable	Passed 20201118-1359 - Integration Test Run

# Project Management & Agile DevOps

- Project management, product roadmaps and agile development – Combine these all in the same tool.
- A seamless connection between work management and all other things simplifies the process and enables transparency on status.
- Having it all online establishes collaboration between teams and organizations – Have the big picture on progress at all levels.
- Polarion® Plans can be nested, with an unlimited number of levels.
- Establish solid version and release management by connecting product content to Plans.
- You can choose your own methodology.
- Traditional Gantt charts and agile Kanban boards are both available.
- Define your own rules which work items you want to plan to which plans.
- It is also possible to connect to other tools, if you favor them for work management.



### Plan Board

 Prioritize Planned Items   
 Add Work Items to the Plan   
 Browse

4 Open      3 In Progress

✓  ALMS-1384 - Stop blades on impact

Integration

 ALMS-1580

Implementation

 ALMS-1389

🔧  ALMS-1380 - Connect to other units 5.0

Implement connection polling

 ALMS-1381

Start Progress

Reject

Mark Done

✓  ALMS-1346 - The mower unit must be able to guide itself also to a bolted loading station 20.0

Implement docking complete check

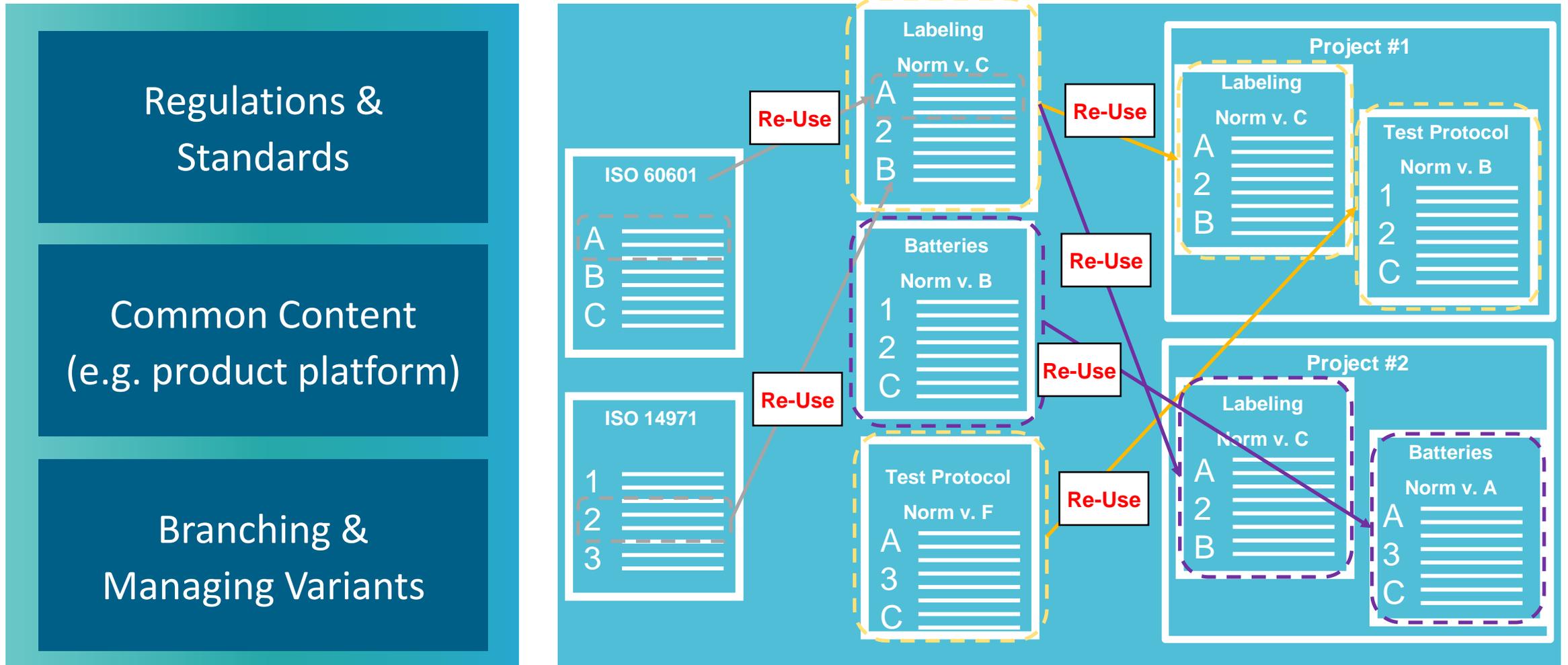
 ALMS-1367

Implement docking sequence

 ALMS-1366

# Information Reuse

- Kick off your next generation products by reusing selected parts of your existing technical file.
- Reuse entire structures of linked objects, just like that!
- Reuse requirements based on standards, regulations or guidelines.
- Control their version changes centrally and effectively.
- Branch different products models from each other, or maintain several product versions that were originated from the same base.



# Think ...

- ❑ *What would the productivity impact be (working as described previously)?*
- ❑ *How long would it take to construct a similar system (fully digital and all-connected & traced)?*

Now we are offering it all, processes ready-made in a simple package!

# You still get to influence the final service! – *What would you need?*

## Example Features:

- Quality system & manual
- Document templates
- CAPA process ...

## Example Service Offerings:

- Phone support
- Access to QA/RA expert(s)
- Guided process retrospectives ...

Respond to our survey – it only takes 2 minutes!  
(it is anonymous)

# Otherwise... your next step

Feel free to contact us for any questions or feedback!

[contact@taipuva.com](mailto:contact@taipuva.com)

Follow [Taipuva on LinkedIn](#) for updates!