













**WSAudiology** 









**UNEEG** medical







The Active Cold Chain

















Stockholm

**Dvysr**<sub>®</sub>



























We improve the ways of working

PROCESSES
INFORMATION MANAGEMENT
COLLABORATION

PRODUCT DEVELOPMENT

**PRODUCT MANAGEMENT** 

**PROJECTS** 

**QUALITY & COMPLIANCE** 

#### YES

How to combine the areas above. How to be effective and efficient.

- **⇒** Consultancy & Experience Advice
- ⇒ Bring things to <u>real life</u> with a digital platform, not just "on paper"

#### <u>NO</u>

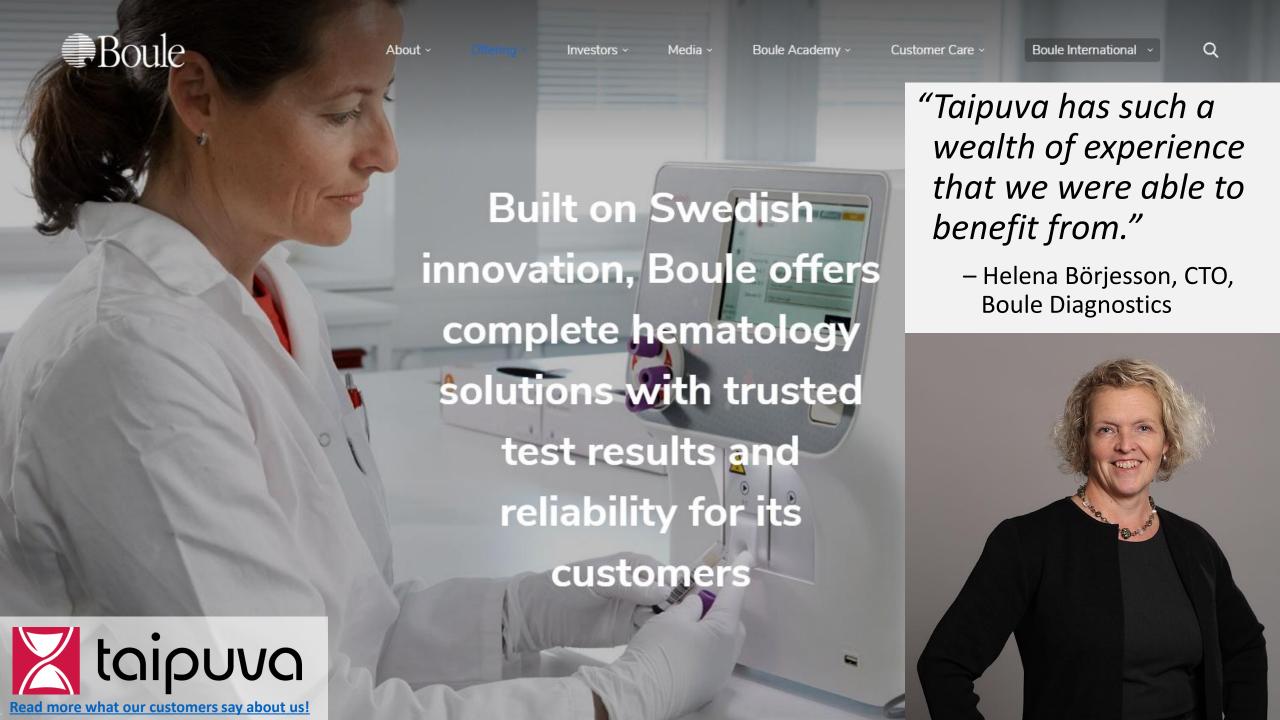
Consultancy on

- Regulatory affairs
- Standard content, etc.

#### <u>NO</u>

- Outsourced project resources
- Subject-matter experts





# SCOPE OF OUR PROCESS EXPERTISE: Design Controls and more

Product Management & Roadmaps

Risk Management Change Management

Requirements & Specifications

Product Architecture & Design

Verification & Validation

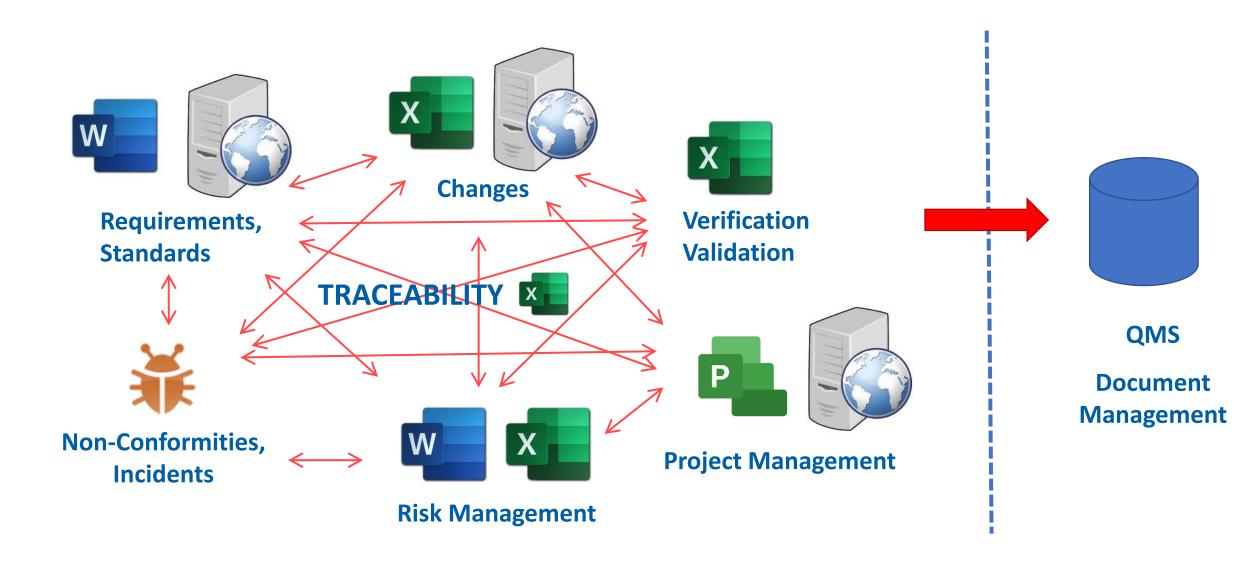
Problem Resolution

**Project Management** 

Agile SW Development & DevOps

Quality
Management &
Compliance

# Sometimes the existing landscape looks like this



### A UNIFIED DIGITAL PLATFORM IS A GAME CHANGER – AN ENABLER

**Product Management** & Roadmaps

**EVERYTHING IN ONE PLACE** 

**Change Management** 

**DOCUMENTS** (DHF) UPDATED ON THE GO

Risk Management **Requirements & Specifications** 

100 % AUTOMATIC
TRACEABILITY

**Verification & Validation** 

**Problem** Resolution

REUSE

Across projects

Develop common assets

**Product Architecture** & Design

TRANSPARENCY

QUALITY
PRACTISES **BUILT IN** 

**AUDIT** TRAIL

COLLABORATION - Across teams & disciplines - With external organizations

E-SIGN

**Project Management** 

**Agile SW Development** & DevOps

FAST CYCLES Quality Management & **Compliance** 

### **POLARION** TRULY UNIFIED PLATFORM – FOR LONG-TERM IMPROVEMENT

Product Management & Roadmaps

Risk Management Requirements & Specifications

Product Architecture & Design

"Polarion saves huge amounts of time, up to 80 %, especially in managing traceability and reusing information."

- *Innokas Medical* (Click to read!)

"Polarion enables us to create a clear process all the way from requirements to test cases."

– Planmeca (Click to read!)

**Change Management** 

Verification & Validation

**Problem** Resolution

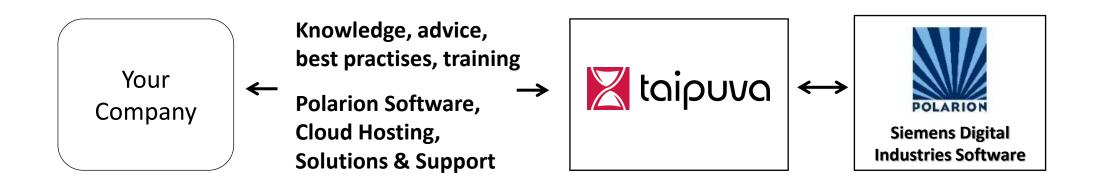
**Project Management** 

Agile SW Development & DevOps

Quality
Management &
Compliance

# 

We are a Smart Expert Partner for Siemens POLARION® — with a full range of services



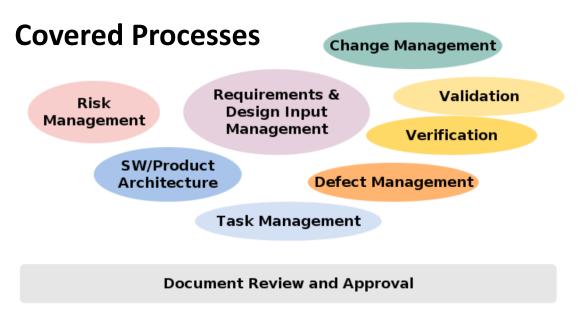
- Without knowledge a tool is just an empty shell!
- Taipuva has a ready-made Polarion solution for the medical industry (see next page). It compresses our experience how to simplify complex things.

#### SPEED | EFFICIENCY | QUALITY | COMPLIANCE



## Polarion Template for Regulated Industries

#### Ready-made process to get you going immediately!



#### **Risk Traceability Report**

Assessed Requirement(s)	Risk ID	Status	Risk Owner	Hazard	Possible Cause(s)	Harm	SEV	P1	P2			New P1			Mitigating Actions	Risk Actionee	Verification	Verification Result	Verification Comment
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. The severity is very risky for the user and detection is hard The mitigation is to detect the fault automatically, and then occurrence and detection rating get decent values.	Gauge is of bad quality	insulin pump will give wrong dosage and harm the patient	6	3	2	36	4	5	4	80	METE-698 - Reservoir gauge sensor self-diagnostics or warning logic	Carl User	METE-1407 - Verifies: Reservoir gauge sensor self- diagnostics or warning logic	Blocked 20210505- 0823 - Mitigations	Not testable test-case
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	Fault in error handling or signaling.	User may face health issues	5	3	2	30	5	1	1	5	METE-726 - Mitigate: Bolus dose delivery error not signaled - color of the insulin		METE-748 - Color of the insulin must be easily noticeable	<b>NOT RUN</b> 20201026- 1528 - Uusi	

#### 100 % Automatic Traceability Matrix – End-To-End

Starting Level	Dependent Items	Test Case	Latest Test Result
✓ METE-1354 - Insulin pump shall be easy to wear			No Records
			No Records
✓ METE-1410 - Reservoir design flexible to meet various market prefences		Test Case Missing!	
/ METE-1425 - Nytt krav för Abigo		Test Case Missing!	
✓ METE-1419 - Uusi käyttäjä vaatimus		Test Case Missing!	
✓ METE-1409 - Interchangeable reservoir for insulin It shall be possible to change the insulin		Test Case Missing!	
✓ METE-911 - Adjustable patterns for basal dose		✓ METE-1114 - Adjustable patterns for basal dose	▲ ✓ Passed (2020-11-03 15:48) 20201103-1546 - demo test
			No Records
	METE-637 - Adjusting basal dose patterns	METE-1116 - Adjusting profile's basal dose patterns	Passed (2020-11-03 15:48) 20201103-1546 - demo test
	METE-870 - Editor for adjusting the basal dose patterns	METE-1117 - Editor for adjusting the basal dose patterns	<b>✓ Passed</b> (2020-11-03 15:49) 20201103-1546 - demo test
✓ ⋒ METE-910 - Basal dose		Test Case Missing!	
		✓ METE-686 - Set basal dose	▲ ✓ Passed (2021-05-05 08:21) (  Deviations) 20210219-1020 - Usability Validation
✓ METE-913 - Delivering bolus dose		✓ METE-1115 - Delivering bolus dose	<b>XFailed</b> (2020-11-18 14:02) 20201118-1359 - Integration Test Run

#### **Includes:**

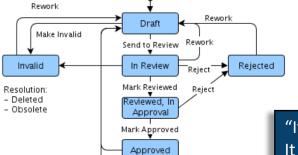
Workflows

Instructions

Reports

Information Model

Document Templates



Mark Done

Done

New Version

"Taipuva's process template on Polarion saved us weeks just in process design."

Radiometer Medical

"It took us 3 months to take into use. It was due to our priorities being at project work. We could have done it much faster." — <u>UNEEG medical</u>



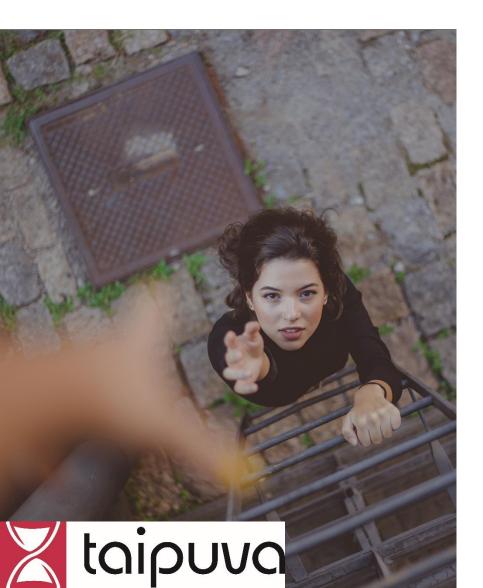
### You must have a hundred questions in your mind...

- How could this all help me in my special situation?
- Who are these Taipuva people anyway?
- It must be heavy stuff and only for huge companies?
- How to get going?
- How much time and resources would it take?
- What does it cost?
- Etc, etc...



### => This is exactly why ...

# We are happy to tell you more and to demonstrate!



- A live demo only takes 45 minutes of your time –
   to really see if our offering is relevant for you
- You get to benchmark your status against the state-of-the-art of other Nordic companies
- At least you will get some influences and ideas what is possible – outside your normal "bubble"
- If you are interested, we can help you with answering all you questions fast and easy for you!
- Feel free to contact us as the next step!

contact@taipuva.com OR www.taipuva.com/contact-us/

For Sweden

Tel. +46 725 255 665

**For Other Countries** 

Tel. +358 10 3180 777

# If you have some time **now** – see more details of the Siemens POLARION<sup>®</sup> solution...

### It is something very unique. Please note that POLARION is **not**

- document management
- issue tracker or ticketing system
- quality management
- project management

...but something that combines all of these together!



# Key Principles of Siemens POLARION®



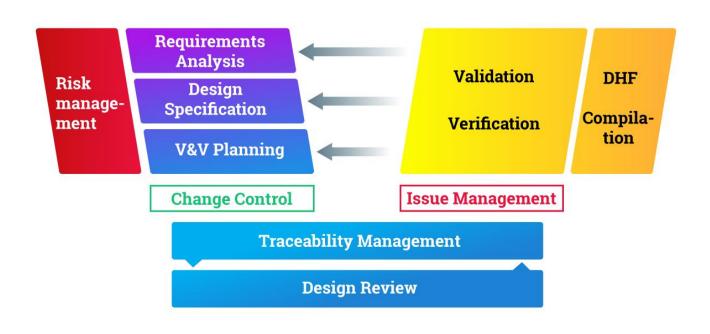
- LiveDoc<sup>TM</sup>
- History & Audit Trail
- Configurability & Flexibility

#### **Platform Approach**

= Have one tool as the backbone to evolve!



#1 – The biggest enabler of advantages is the **truly** unified principle – without separate components or different user interfaces



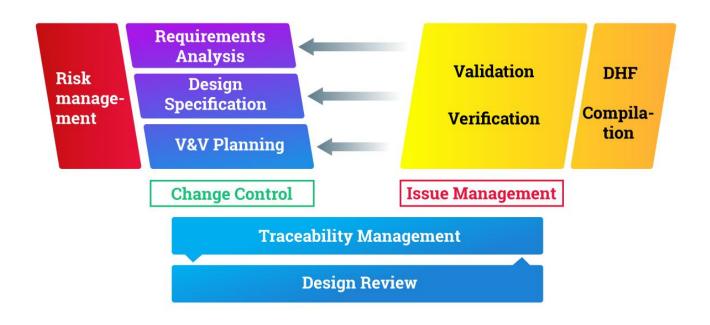
The needed process areas are in one tool, truly connected – enabling the following without any compromise:

- Traceability
- Collaboration & transparency
- Information reuse
- Full history and audit trail
- The status and integrity of all data at a given time point
- Reports and views of all interconnected data and its history



# #2 – Compelling Capabilities

There was a time, when different tools had to be chosen, because they were so much better in features. Not any more.



Polarion has been designed to have the right functionality for industrial product development and for regulated industries, covering:

- Requirements Management & Specifications
- Test Management
- Risk Management
- Change Management
- Issue/NC Management
- Project & Task Management
- Quality Management & Documents
- Custom workflow-driven processes

If you need to integrate Polarion with a wider spectrum of your IT landscape, it's very easy due to **open interfaces** and ready-made integrations.

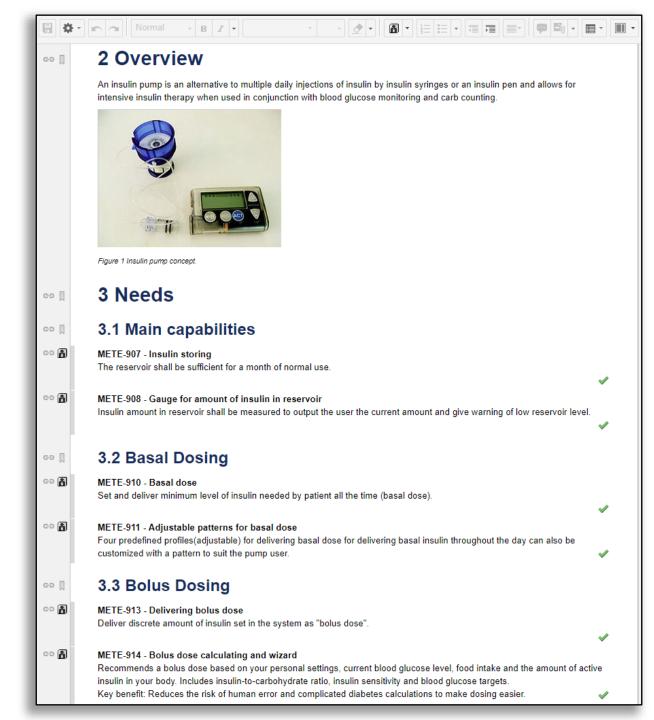


### #3 Live Document (patented)

- No more separate specification or other documents, because Polarion combines documents and traceable, identified objects into one!
- LiveDocs are not compilations or "exports" of selected items, but clear documents that very easy to read and edit – for anybody.
- LiveDocs are also not "wiki pages" that someone extracts objects from, but objects are live and they can be edited both within the document or as separate objects, and changes are reflected in both views.
- Documents have a status and workflow, so that they can reviewed and approved. Audits can be based on these documents, which makes it easily manageable.
- Comparison of document versions is intuitive and reportable.
- Quickly import your existing Word/PDF documents and information from Excel!
- LiveDocs are always online and you can even edit simultaneously with your colleagues.
- Free your imagination what you can do with LiveDocs!

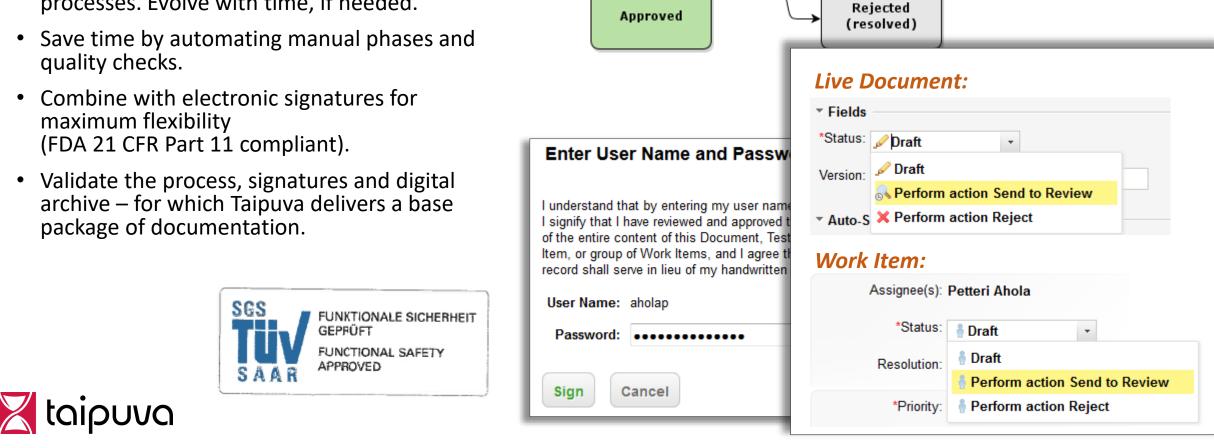
   Not only requirement specifications but quality manuals, instructions, SOPs, concept specifications, usability studies, design specifications, design reviews, meeting memos, etc.
- CLICK to see a 4-minute video of LiveDoc





## #4 Workflow & e-signature

- Guide your experts through processes with practical workflows. Program and instruct your SOPs within the tool!
- Connect the document workflow with that of the individual items for efficiency.
- Tailor the workflows of different areas to your processes. Evolve with time, if needed.



Draft

(initial)

Send for Approval

Waiting for

Approval

Approve

reject

Disapproved

reject

disapprove send for approval

reject



## **#5** Traceability

Many tools may claim that they can do traceability. However, consider that there are **many forms of traceability** — and in order to be complete enough, **all relevant inter-related process areas** need to be covered. Polarion has it all:

- **1.** Traceability between different objects to see dependency, justification and fulfilment and it needs to go down to the actual evidence
- 2. **Historic** traceability, or audit trail, in order to see that the process was followed and who did what, when and why
- **3.** Change traceability, in order to evaluate change impacts up front, manage change and to carry it out in a sure manner and again to record historic evidence of the process

The historic traceability can be tricky, if you have some parts of the process on different tools or data platforms.

Polarion it is based on a version control system (not a database) and thus all the data is versioned together. In addition, all changes are recorded – comparable and reportable. You can even go to a specific time in the history to see how things (and reports) were, with all the data as a whole.

With Polarion there are no compromises with the traceability and audit trail:

- Regulatory compliance is a no-brainer
- Save enormous amount of time and effort, when there is no manual traceability management needed
- Avoid quality issues, which might be due to wrong manual updates and not seeing the change impacts
- Everything is usable and clear unlike in solutions that do not have a tree view, filtering based on link meaning or custom reporting for your exact needs



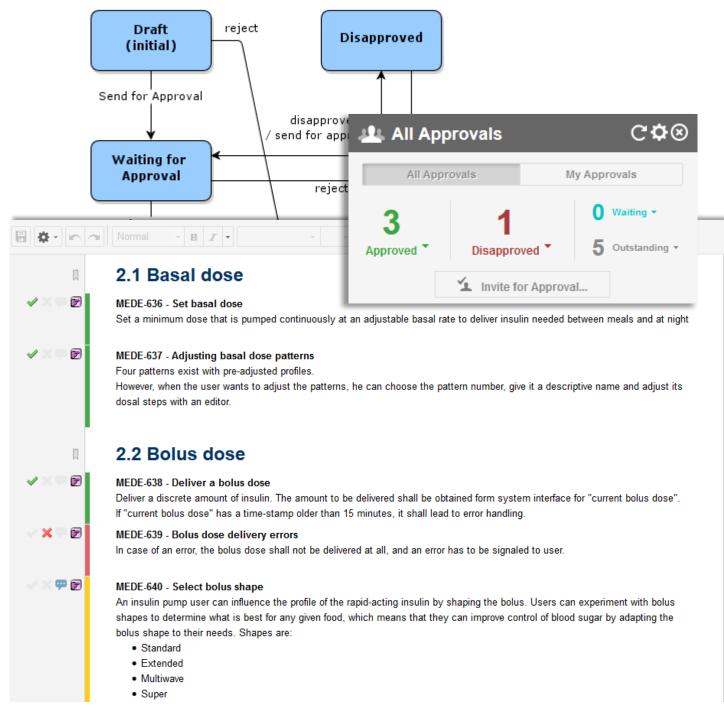
ID	Title	Status
▼ 🚮 METE-910	Basal dose	Approved
▼ <b>F</b> METE-636	Set basal dose	Approved
METE-686	Set basal dose	Approved
▼ 🚮 METE-911	Adjustable patterns for basal dose	Approved
▼ <b>F</b> METE-637	Adjusting basal dose patterns	Approved
	Editor for adjusting the basal dose patterns	🔑 Draft
▼ <b>METE-913</b>	Delivering bolus dose	Approved
▼ <b>F</b> METE-638	Deliver a bolus dose	Approved
METE-688	Set bolus dose	Approved
	Bolus dose delivery errors	✓ Approved

	METE-68	38	Set bolus dose	<b>✓</b> Appi	roved
	<b>ℱ</b> METE-639		Bolus dose delivery errors	<b>✓</b> Appi	roved
Starting Level	D	ependent	Items	Test Case	Latest Test R
✓ METE-911 - Adjustabasal dose			E-637 - Adjusting basal dose		
			METE-870 - Editor for adjusting the dose patterns		
✔ 🚹 METE-910 - Basa	al dose	<b>∕ 万</b> MET	E-636 - Set basal dose	✓ METE-686 - Set basal dose	Passed (2 02-11 22:53) Sys03 - S Verification
✓ METE-913 - Deliv	rering bolus dose		E-639 - Bolus dose delivery errors		
	•	<b>∕ 万</b> MET	E-638 - Deliver a bolus dose	✓ METE-688 - Set bolus dose	Passed (2 02-11 22:53) Sys03 - S Verification
		<b>∕ 万</b> MET	E-640 - Select bolus shape	✓ METE-754 - Select bolus shape	*Failed (20 11 22:54) \$\insup \text{Sys03 - S}\text{Verification}
				✓ METE-689 - Select bolus shape	Passed (2 02-11 22:53) Sys03 - S Verification
				✓ METE-688 - Set bolus dose	✓Passed (2

02-11 22:53)
Sys03 - System
Verification

# #6 Reviews and Approvals

- Facilitate reviews digitally, as part of the workflow.
- Improve efficiency by electronic collaboration and have meetings focusing on the content itself, with pre-processed most problematic points.
- Have all comments and history in one place without doing manual review memos.
- Capture the full history of what was changed and why, so that decisions behind the design can be understood after many years of development.
- Use the degree of formalism needed in your organization.
- Complement with digital signatures as needed.
- Review whole documents, only updated parts or individual objects – whatever suits your particular need.



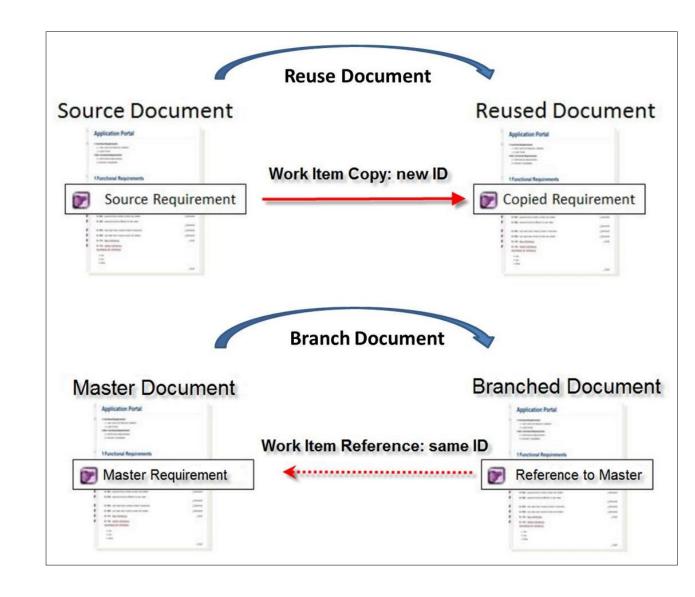


#### **#7** Reuse

Information reuse is not just a single feature checkbox, but there are <u>different areas of reuse</u>, for which there need to be <u>different mechanisms</u>. All the following are covered by Polarion (some mechanisms are depicted on the right):

- 1. "Simple" **reuse** (or duplication) from a project-to-project or from a product-to-product. However, it is not that simple anymore, if you need to reuse *structures* of different items. Imagine a tree of requirements and all test cases linked to them, and then risks linked with requirements, etc.
- 2. In a product family you would most likely want to **branch** different individual products from each other. Or if you need to maintain several product versions, which were originated from the same base.
- 3. In product line engineering there can be a big number of product **variants**, for which you need to have specific documentation of requirements, test cases, risks, etc. Polarion VARIANTS<sup>TM</sup> add-on or branch mechanism are very useful.
- 4. For reusing requirements based on standards, regulations and guidelines it a good practice to library them, release them for project use as different versions. For this purpose Polarion has a **derived reuse** mechanism.

Polarion makes use of its **live documents** in many of these mechanisms, which makes it understandable to follow the reuse scenarios. Otherwise it may become very confusing to see, which items or compilations of them were reused where and why.





# #8 Planning and Live Reports

Project management, product roadmaps and agile development – Combine these all in the same tool.

Many tools have support for one way to plan and manage projects. But the reality is "special" and mixed. You need to be able to run hybrid models, have nested plans and make it possible to change your way of working as it's evolving.

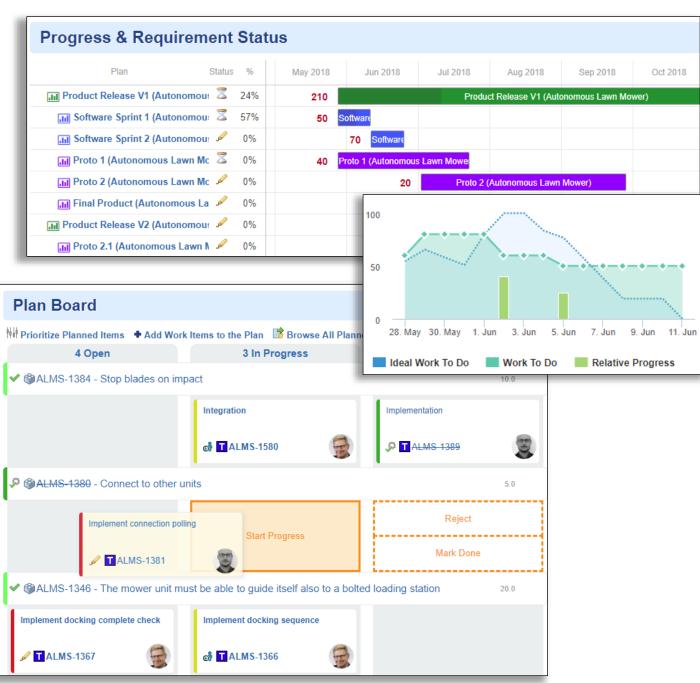
#### Polarion can do all this:

- Plan the product releases and connect all teams/disciplines to them – with their own ways of managing their progress.
- Use drag & drop Kanban boards or traditional methods to update and monitor status.
- Tailor the reports to serve your visibility needs thanks to the easy widgets (live reports), which you can even customize for special needs.

Polarion offers you the visibility and transparency to the big picture how the whole product is being developed – allowing teams to contribute their part, but not enforcing one "scrum" or "traditional" way of working for every team or discipline.

Connect to your favourite other tool(s), if you want! Having these capabilities in Polarion does not enforce you to use them.



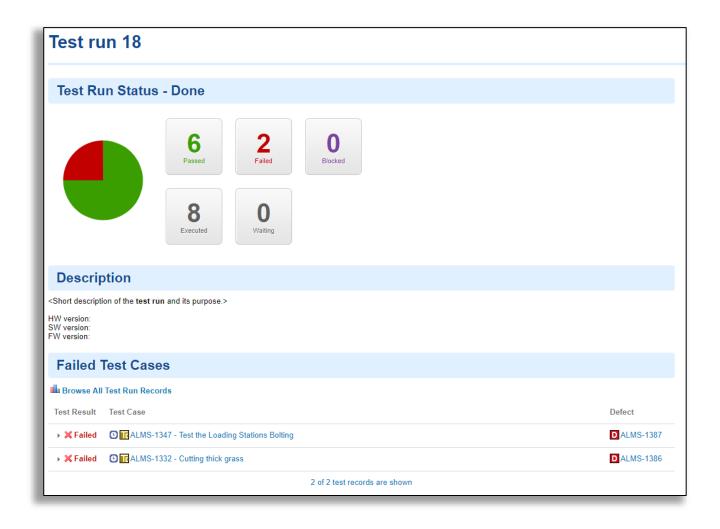


### #9 Test Management

This is "just" one of the process areas, but highly important for **verification and validation** to show evidence that requirements are met.

Polarion is a full-blown tool for quality assurance – an umbrella for all testing, verification and validation work. Unite all manual and automatic testing, and use easily configurable live reports to see the results.

- Compelling features for test management, quality checks and executing manual tests
- Report results online with Polarion or offline with excel
- Use live documents for test planning and specification (with review and approval)
- Import automatic test results, e.g. from RobotFramework or other automatic testing tools – integrate with xUnit or open interfaces
- See the results' full traceability against the tree of requirements, risk management/mitigation, etc.





#### **#10** Configuration Templates

Polarion is highly flexible to be configured according to your way of working. This is important, as the tool needs to adapt to the desired processes and not vice versa. Furthermore, we've seen that organizations want to work differently as their maturity grows.

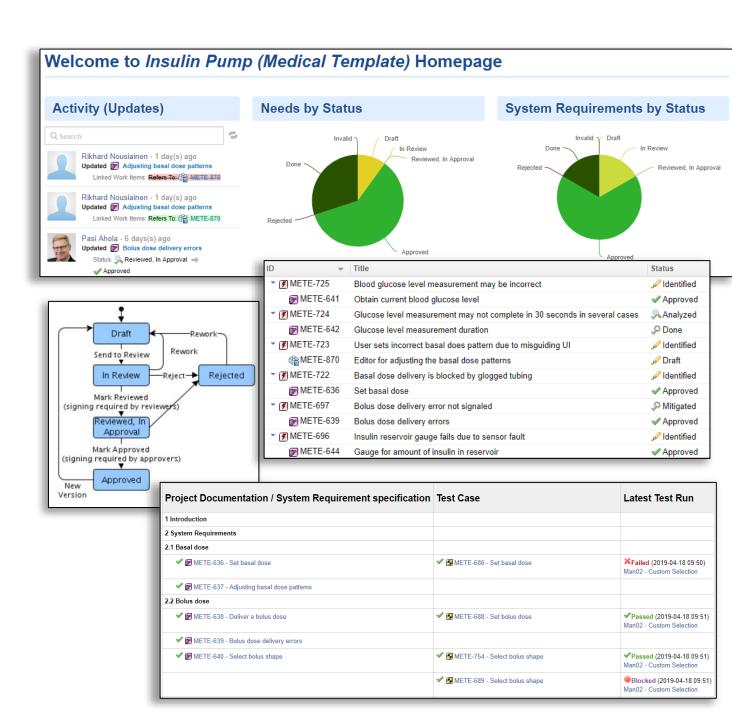
The tool shall enable that and Polarion does it perfectly. You can change the processes, and thanks to versioning both process configuration and data, the historic data stays readable.

To enable a jump start Taipuva, as a Smart Expert Partner of Siemens, offers **Regulatory Template** (some screen shots on the right)

- A suitable and proven way of working in the medical device industry
- Predefined process model for requirements management, verification & validation, risk management, defect management and task management
- Information model and workflows configured to contain proven best practices
- Review/approval process supported with or without electronic signatures (easy to choose, if you first want to continue using your document management system for official document approval)
- Reports that show end-to-end traceability effectively and with filtering capabilities
- Simple approach for an as-easy-as-possible start with, and to expand further as you go

Comment from Radiometer Medical about Taipuva's template: "This saves us weeks in just process design work!"





# Lots of features and possibilities in one tool... There might be again some questions:

#### Is it a heavy system and difficult to take into use?

Surprisingly not! When things are setup in a clear way, then using it just supports the desired way of working. Furthermore, you do not need to start with everything!
 XO Care took it into use in one week.

#### • Is it expensive?

No, the tool licensing cost is about 1 % of the user's salary cost,
 so when the efficiency gain is typically 20 % and higher, the payback is a no-brainer.

#### • Is it only for big enterprises?

Definitely not! There are lots of small companies and startups
 using Polarion, for example a Finnish startup <u>Photono</u> who think that it's worth it to have a good quality management system and have their product's technical file created efficiently from day one.
 Other examples of rather small companies are Danish <u>UNEEG Medical</u> and Finnish <u>Grundium</u>.

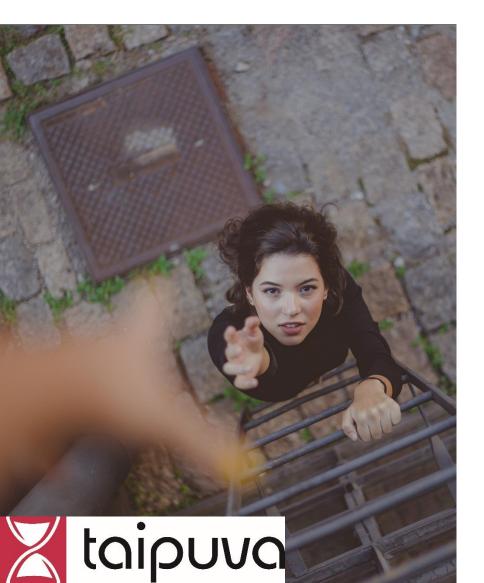
#### • There are lots of existing documentation. How to handle those?

- Migration from Word documents and Excel sheets is done by easy and fast import functionality.
- Migration from other systems can be supported with those, and/or by Polarion's open interface.
- Taipuva has lots of experience in various kinds of migration projects, so we can help you.



### => Have a short remote meeting with us to know more!

# It is Taipuva's priority to guarantee the success of our customers!



- Improving the ways of working in R&D and quality is a combination of process needs and digital tool capabilities – they affect each other (want or not).
- Your needs and culture are the most important starting point, and any tool implementation should adapt accordingly

   That is why Polarion is highly flexible.

- Process development is an evolution – continuous improvement.
- There might be more intensive phases, but it goes on. Processes and needs change, etc.
- This is why a long-term partner is important – willing and able to serve, when needed. Having understanding of industry, requirements, processes and best practices is of great value!

We are 101 % dedicated to serving our customers, so that you obtain the benefits you are looking for.
We are located in **Tampere** and **Stockholm**, with 10 years of experience in serving our customers via remote connections.
See what our customers say about us!

### Visit our website for <u>Customer Stories</u> and more!

