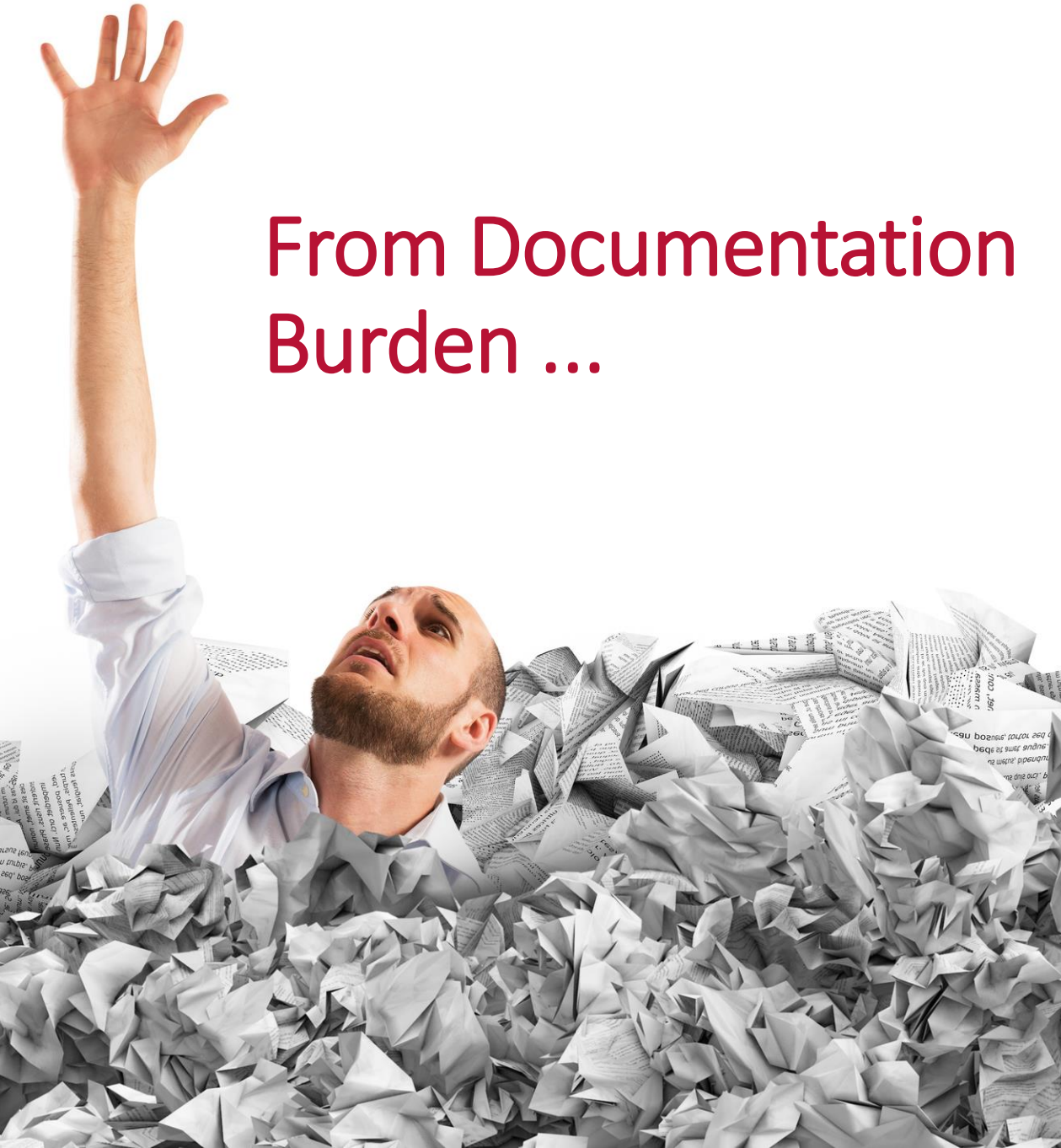


# From Documentation Burden ...



# ... To Agile Advantage





Taipuva Consulting  
was founded 10 years ago.

Vision: **“Help Finnish companies  
excel in R&D speed and efficiency”**





# We have been able to do that!

## From startups to global giants



## Now happy to be part of AHMED project

# Medical devices development *is* very **documentation oriented** – want it or not!

*According to what our medical device customers tell us:*




**> 70 % of medical software development is documentation**

TOTAL PROJECT

*“As a medical device manufacturer,  
we need to document **everything**.”*

– KaVo Kerr Group Finland



MANAGING  
**DOCUMENTATION  
TRACEABILITY** TAKES  
**20–25 % OF EFFORT**  
(when done manually)

Intended Use

Needs

Planning

Risk Management

Requirements

Architectural Design

Detailed Design

Config. & Change Mgt

Verification

Validation

Defect & NC Mgt

US FDA's analysis of medical device *recalls due to software failures* reveals that **79 %** were by changes after the initial development.



This is one reason why documentation and **traceability** are required.

The **purpose** is to ease change impact & risk analysis.

It may *feel* like a burden...

Can you turn this into your agile advantage?

– it is possible!

We want to share our learnings how to do this.

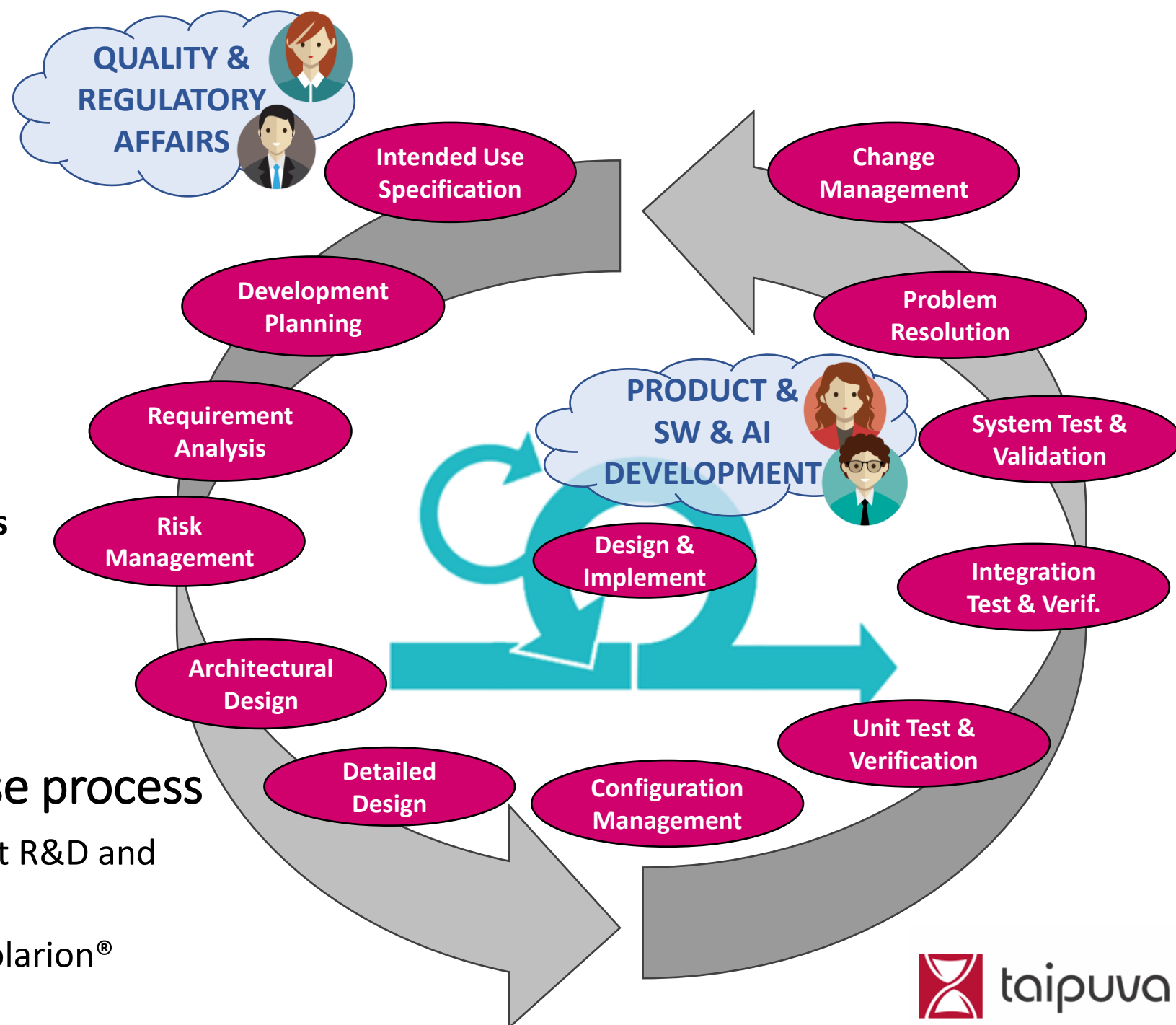


# Our Learning: Collaboration

- Prerequisite: the whole organization wants to achieve it together
- Quality and R&D need to agree on common ways of working – not just that quality adds documentation and processes on top of what R&D delivers
- The whole **integral circle of development & documentation needs to be agile together** – not just the product development (which may run faster cycles, too)
- The earlier this starts the better!

## Our development: ready-to-use process

- **Enables agile**: unites the worlds of fast R&D and quality documentation
- Runs on a digital platform, Siemens Polarion®





# Why using a digital platform as a backbone?

We did not want to re-invent the wheel for anyone, but to use **suitable technology available** – which has been **designed for regulated industries**.

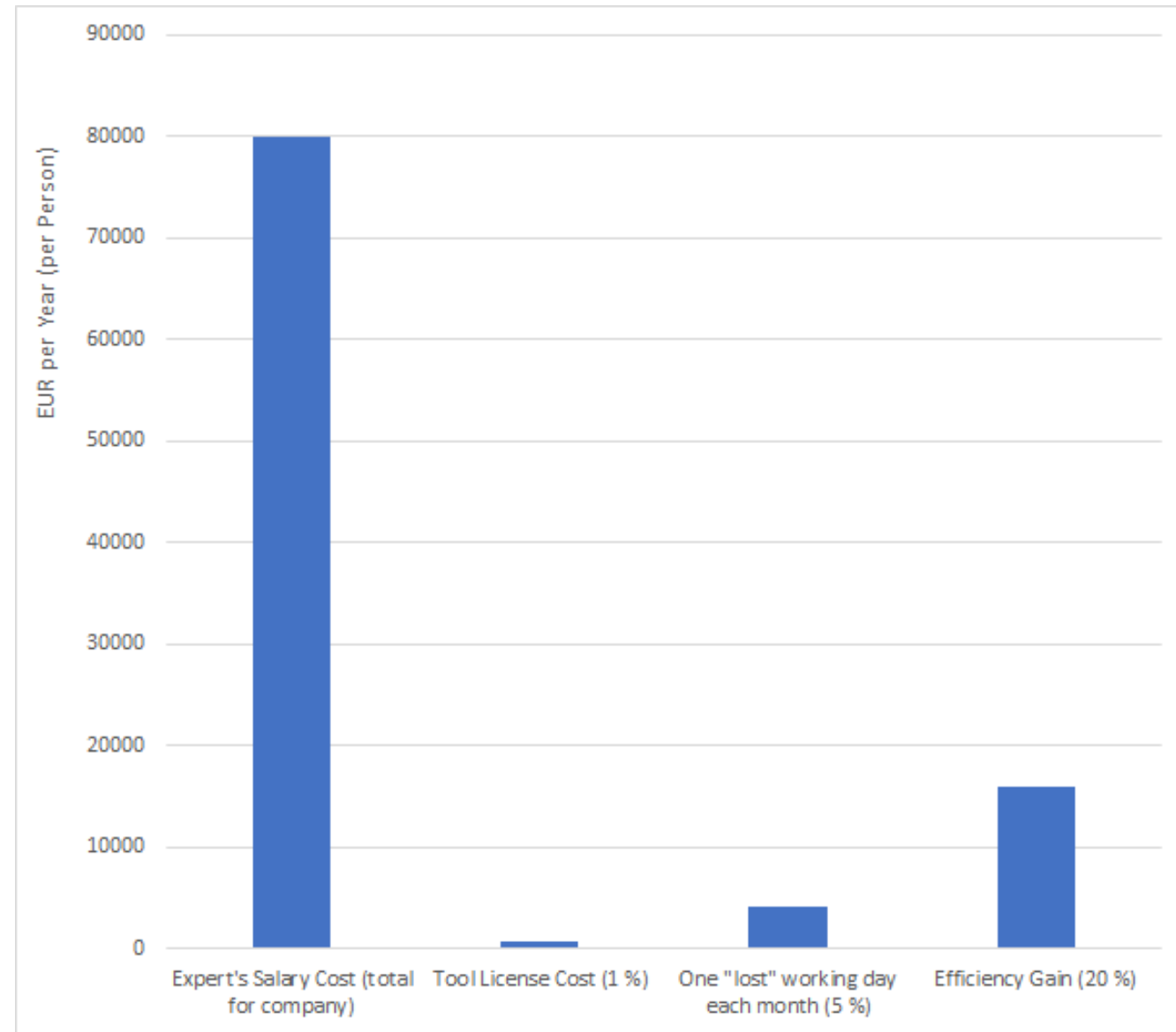
**The relevant questions for you are:**

- **Why not to** take the advantage of the ready technology out there? (your competition outside of Finland are sure doing that)
- **Why not to** have a strategy of minimizing the number of separate tools and interfaces?  
– Simplify and build the future on fewer, long-term IT platforms.

**Putting things into proportion:**

- How easy is it to lose your experts' time, say one day per month? How much does that cost?
- The cost of a tool is quite small, compared to your most valuable asset: human resources

**An investment in improvements shall yield the maximum possible efficiency gain.**

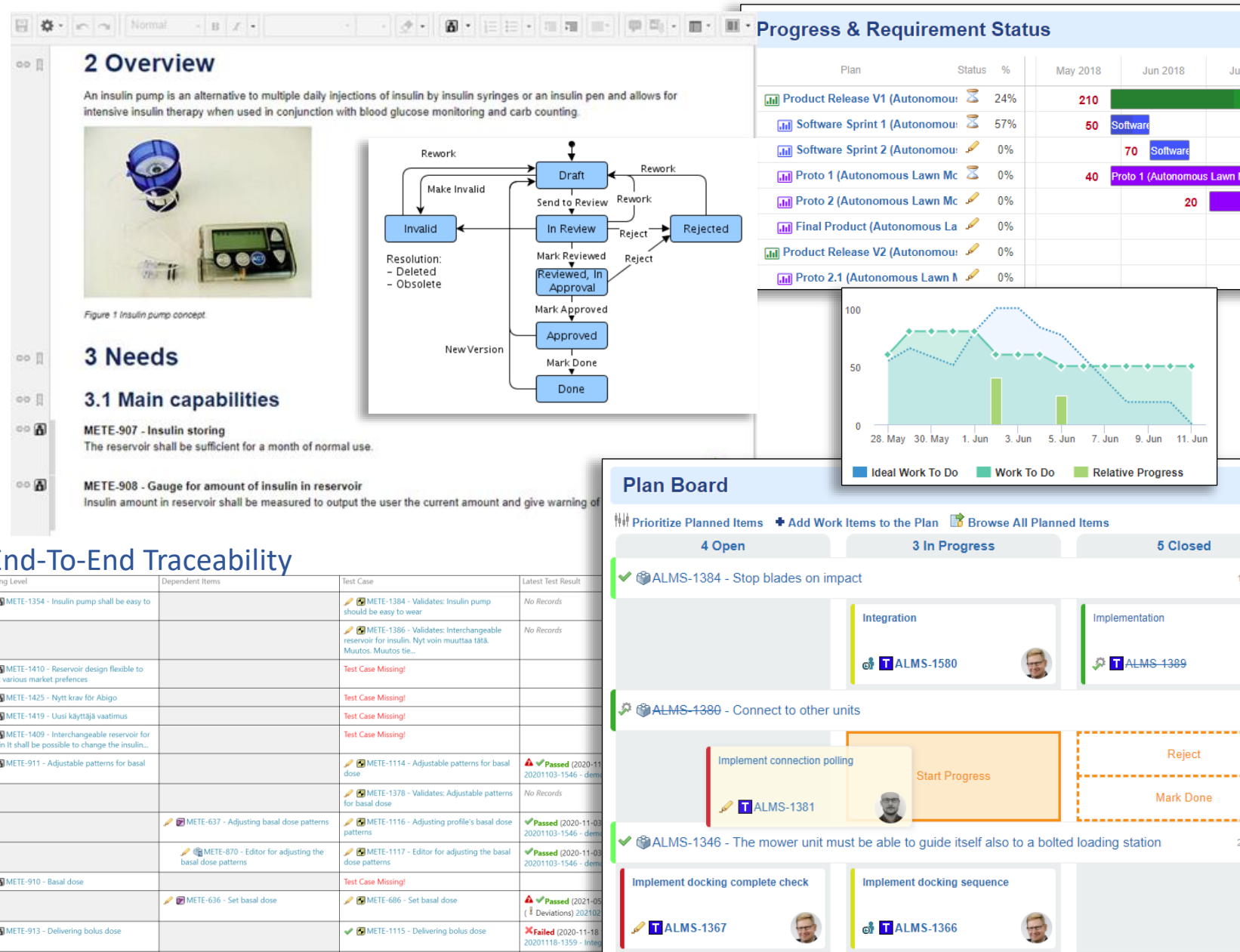




# Our Solution in a Nutshell – Already Available!

**Combining Taipuva's years of experience – on top of the leading platform *designed for regulated industries***

- Keep-it-simple principle!
- Easy to adjust to your specific ways of working
- Suitable for all types of products (actual devices, software, systems)
- Scales from micro companies to thousands of people
- Can be taken into use even in a week
- Import your legacy material from documents and spreadsheet
- Integrates with Jira and Azure DevOps (note: interfacing may sacrifice traceability and consistency)
- Connect to Git or SVN to trace to commits and code blocks – as well as test automation, CI and DevOps
- True collaborative online LiveDocs™ (not just wiki pages) that combine living objects and easiness of regular documents
- Easily extend to general quality management processes, quality manual, SOPs, etc. (outside of AHMED scope)



This 10-min intro was  
a scratch on the surface...

...Therefore,

- Learn more on our website  
[www.taipuva.com](http://www.taipuva.com)
- Or simply ask me directly!

AHMED project continues – Call  
for *your* needs and feedback!

Are you wondering, if your specific  
needs or use cases could be eased?

– **Throw us a challenge or an idea!**

I would be happy to hear from you!



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[LinkedIn](#) – Let's connect and build our networks!