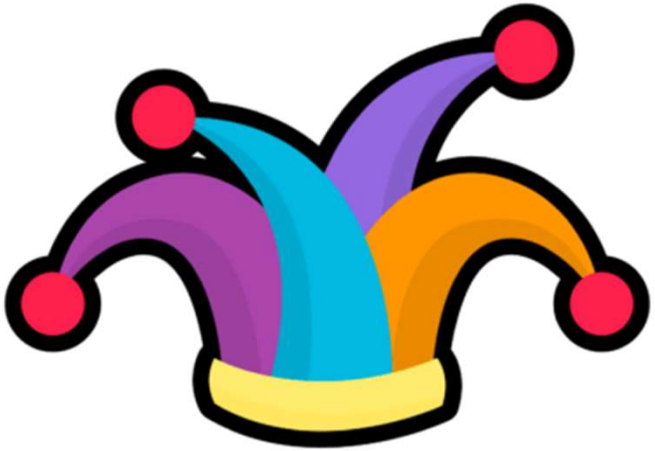
SWISSED24



A Fool with a tool is still a Fool

Case Study: implementation of a Design Control System at a Medical Device Manufacturer

Problem: How to achieve compliant documentation?

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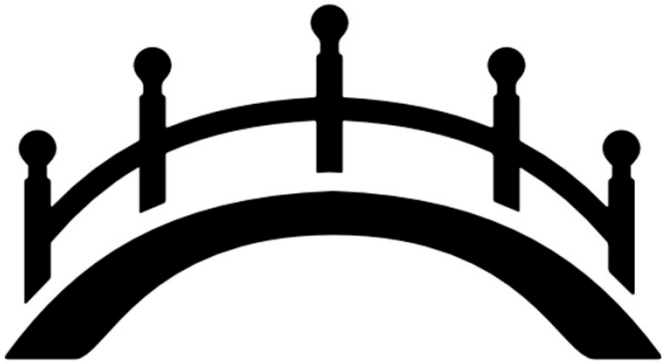
Engineering Talent



Medical Device Compliance

Situation at Grossenbacher Systeme AG

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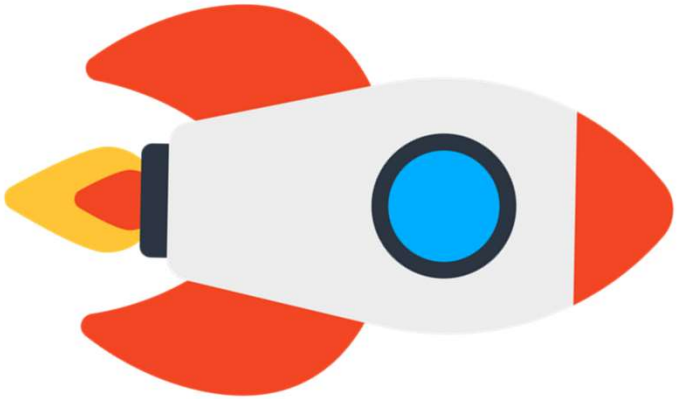
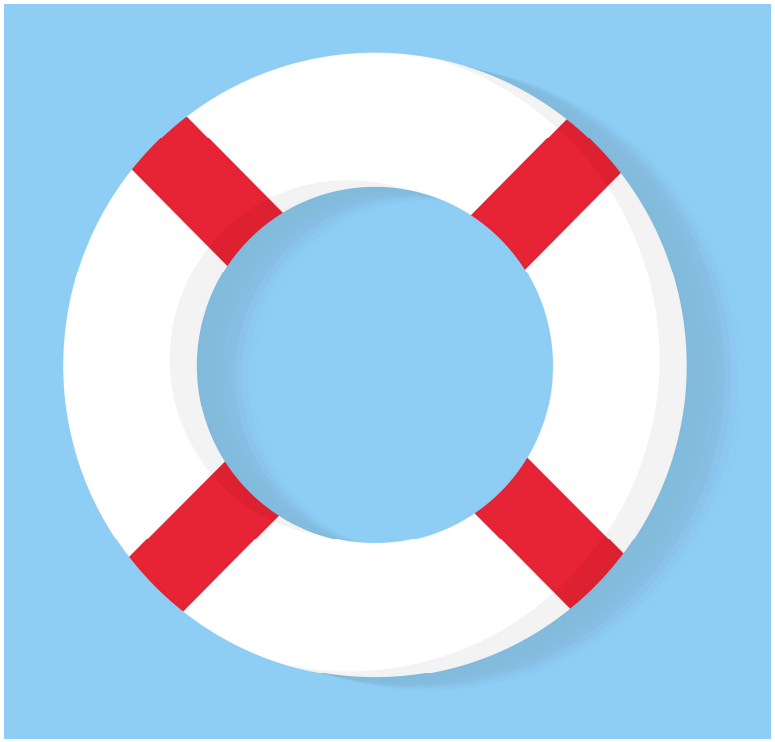
- Grossenbacher Systeme has long experience in
  - controls and displays
  - medical electronics
  - electronic engineering
  - manufacturing services
- ISO 13485 certified since 2008 (prod) / 2016 (dev)
- First own medical device starting 2017
- **Technical documentation was challenging**
- Bringing in consultants did not necessarily help
- Maybe a traceability tool helps?



Does a Design Control tool help?

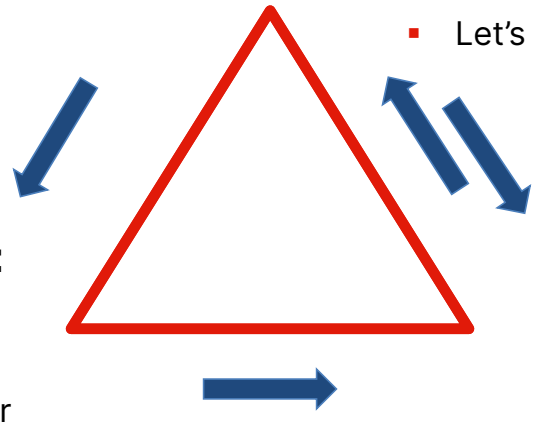
- Item centric, not Document centric
- Provides Traceability checks
- Manages inter-dependencies
- Manages Change control



The Participants

The Manufacturer: Grossenbacher Systeme AG

- OEM Manufacturer
- Engineering Company
- ISO 13485 certified
- Let's make a Medical Device!



The Tool Vendor: Aligned AG

- Software Vendor
- Design Control Software System provider
- Experts on flexible systems

The Compliance Firm: Keymkr GmbH

- Consultant firm
- Compliance Engineering
- Technical Documentation
- Experts on Design Control Structures

A highly Flexible ALM Software – a curse or a blessing?

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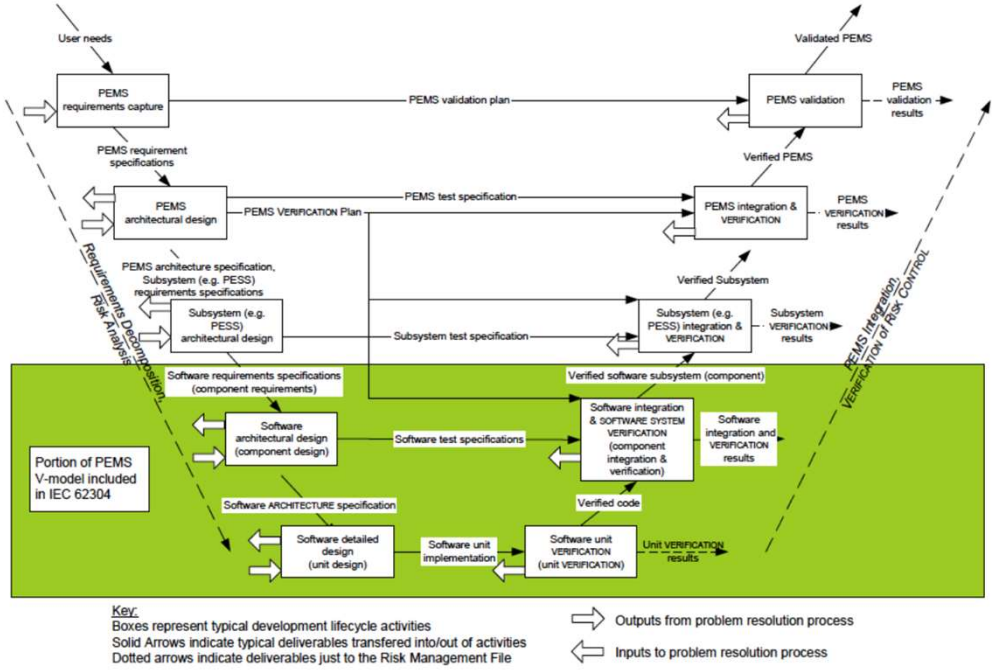
- A Design Control ALM Software models a Documentation traceability Structure

- The documentation structure is crucial for:
  - Documentation efficiency
  - Regulatory Compliance

- The structure can depend on:
  - The Medical Device product properties
  - The Device Classification
  - The Geographical Market
  - Applicable Standards

- The Documentation Structure is provided by the ALM Software user



Do we know where we are going?

- In a situation where:
  - Documentation Structure is not established
  - The user has limited compliance experience
  - Low confidence in Documentation Structure

- => The Design Control ALM Software does not have the input it needs to bring value, a.k.a “Garbage in, Garbage out”

Online Collaboration to achieve efficiency / compliance

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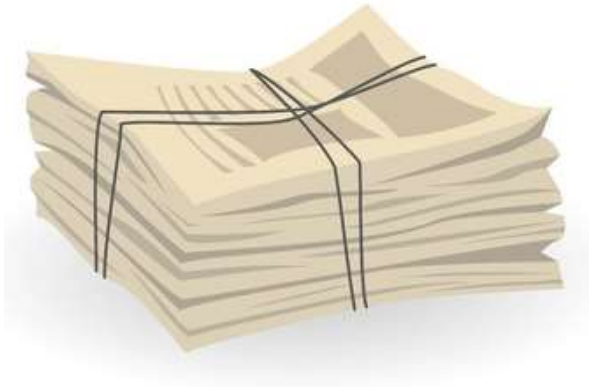
Keymkr GmbH provided:

- A Documentation Structure
- Documentation Services
- Documentation Compliance Training
- Compliance Support

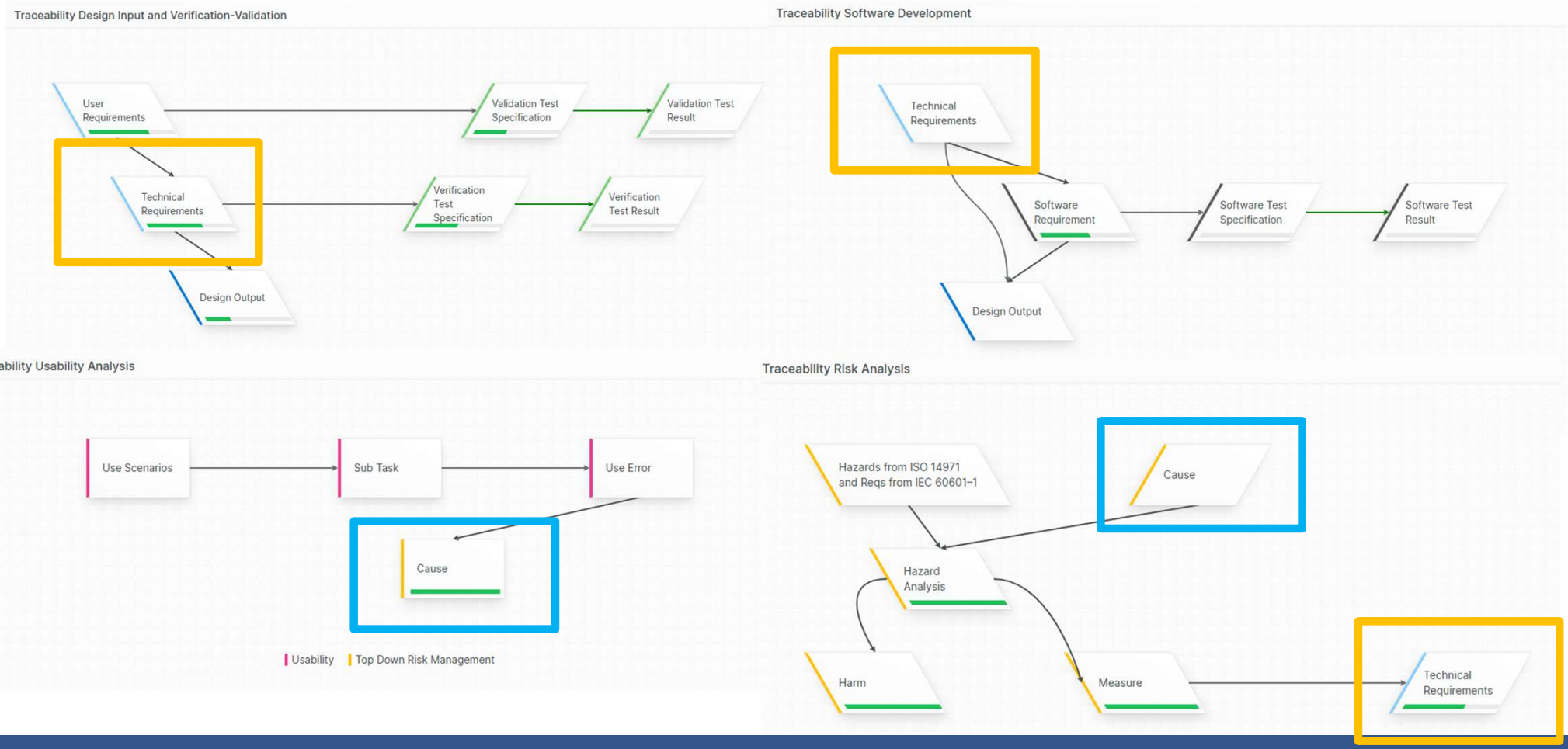
Aligned AG provided:

- The Desing Control ALM Software
- A Hosted Environment
- Technical Support
- Tool Integration Support

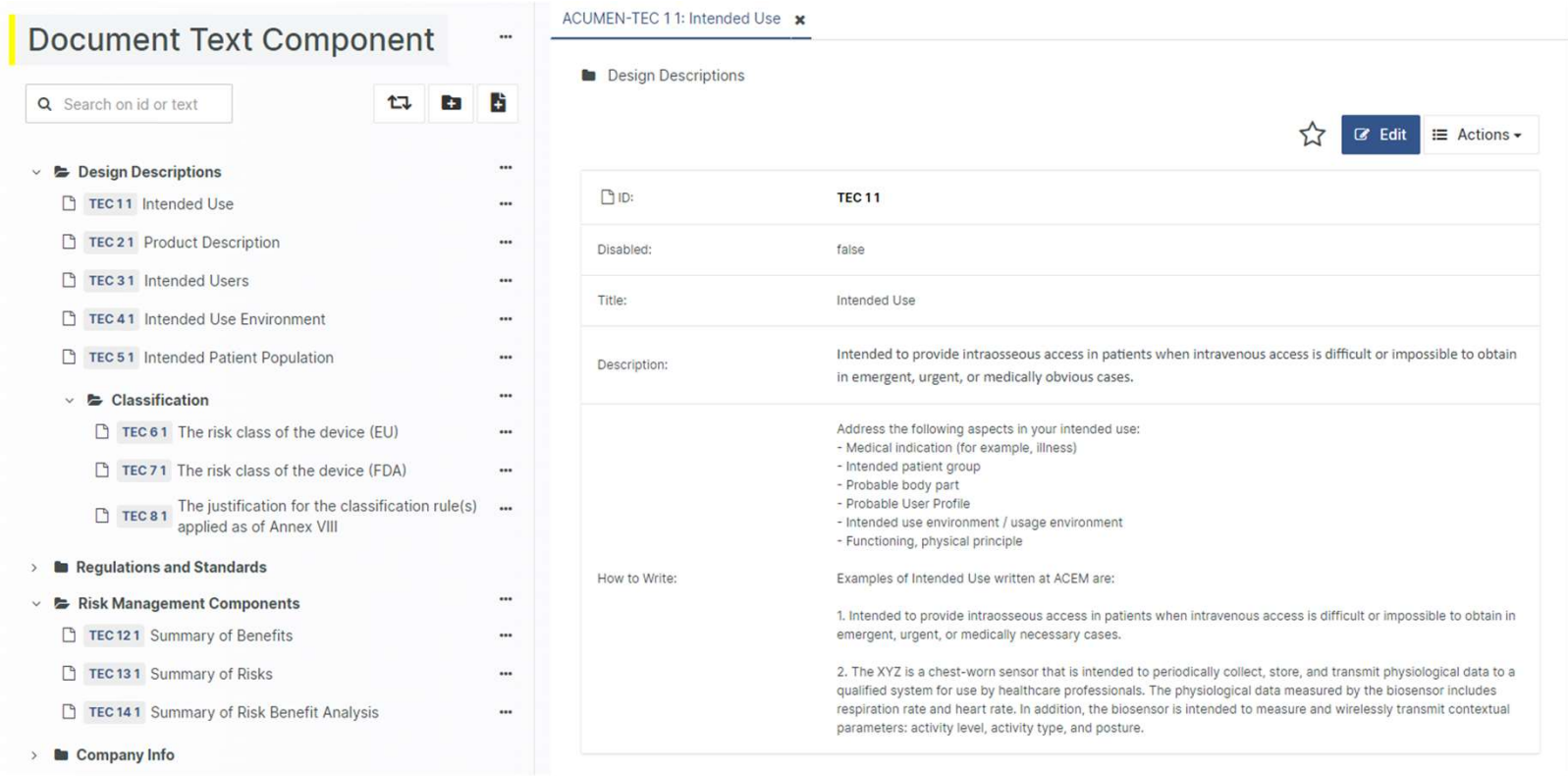


Compliant Documentation at Grossenbacher Systeme AG

Achieving a Design Control Structure



Interdependent Documents - Reusable Text Components



Conclusions

- Engineering Talent is not a guarantee for success in the medial device business
- Item-centric beats document-centric but…
- …Design control structure matters a lot
- A tool can not “repair” bad input or provide value without structure
- Why use a tool? Achieve efficiency and compliance at the same time

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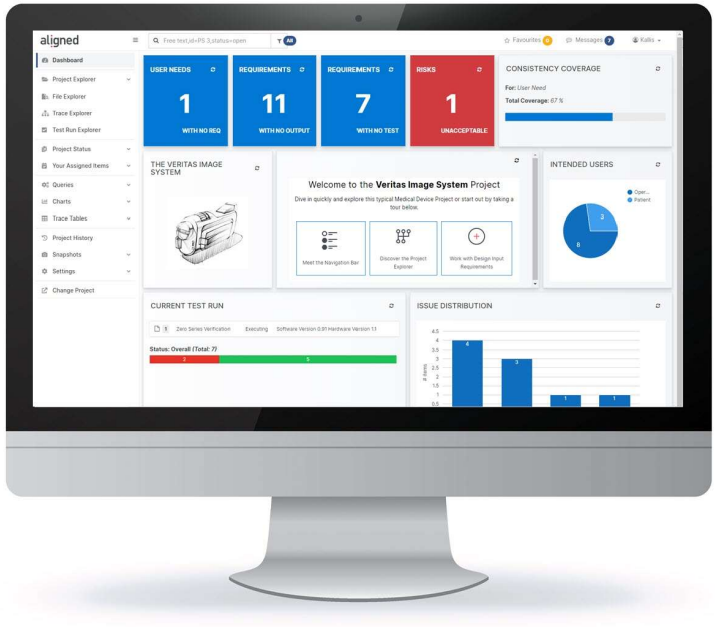

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