

A Fool with a tool is still a Fool

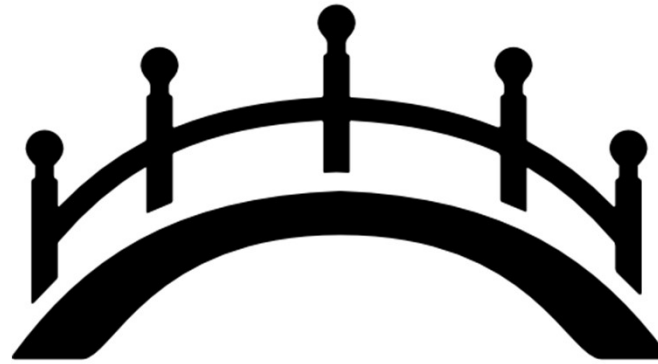
Case Study: implementation of a Design Control System at a
Medical Device Manufacturer

Problem: How to achieve compliant documentation?

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Engineering Talent

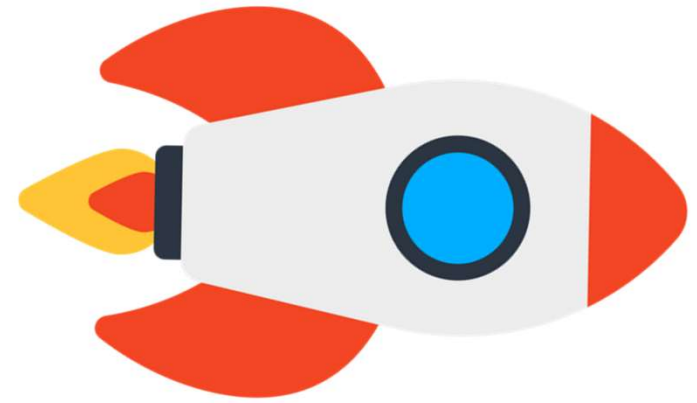


Medical Device Compliance

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?



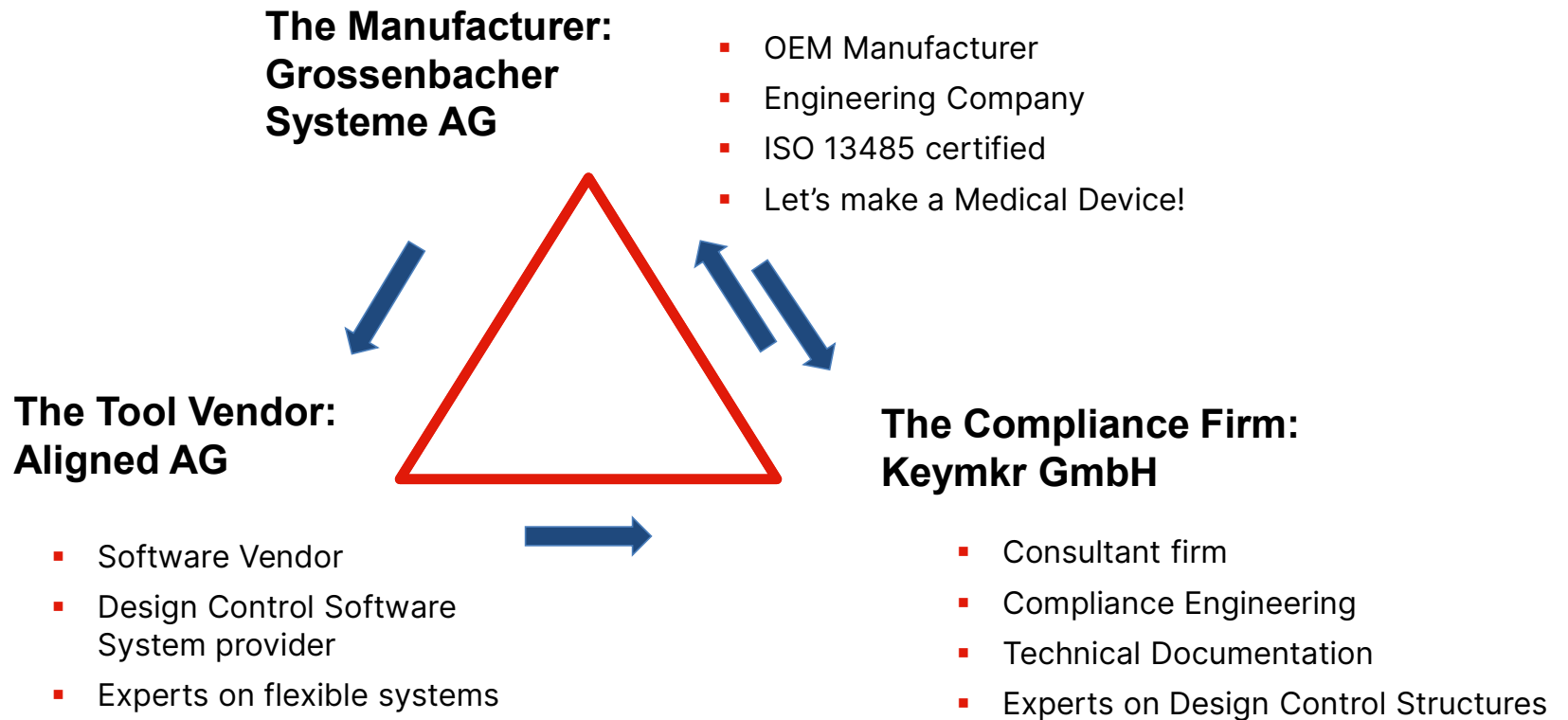
Does a Design Control tool help?

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

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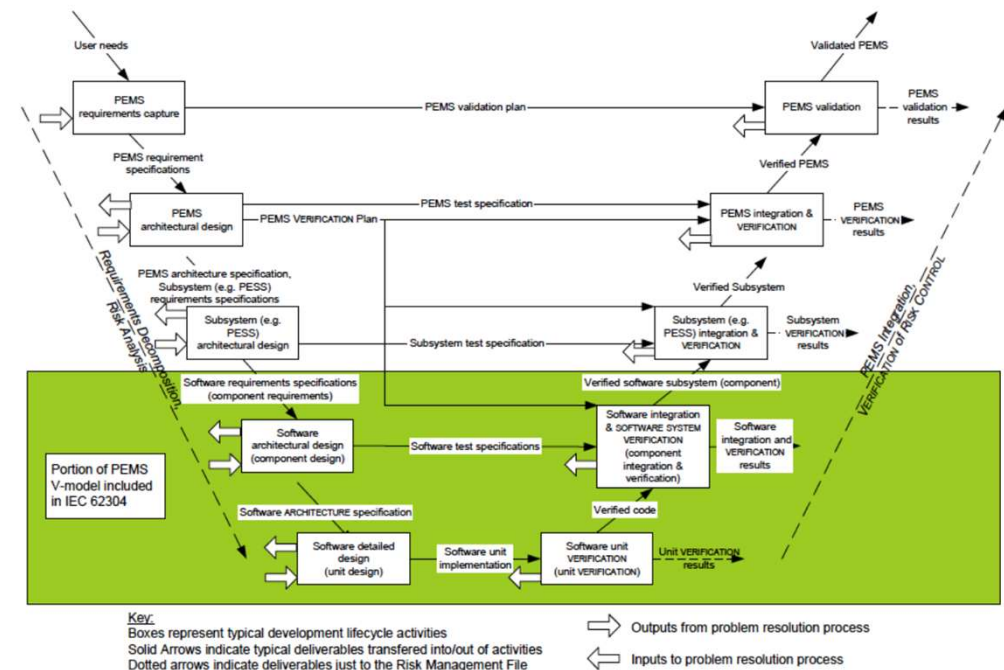
The Participants



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?

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- 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

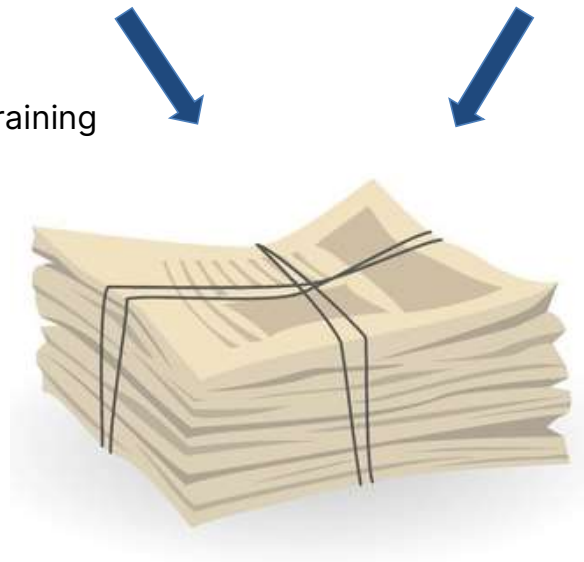
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Keymkr GmbH provided:

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

Aligned AG provided:

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



Compliant Documentation at Grossenbacher Systeme AG

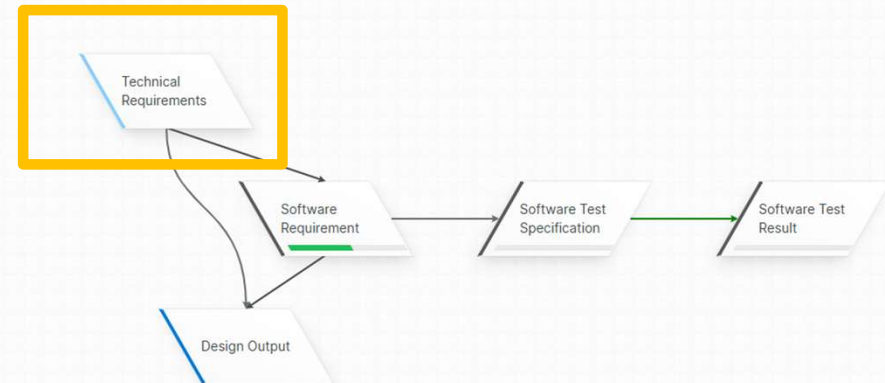
Achieving a Design Control Structure

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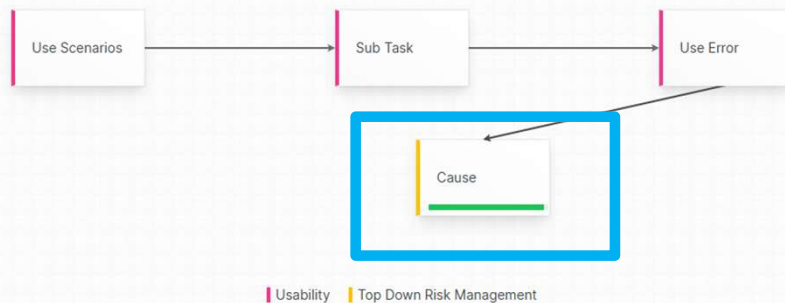
Traceability Design Input and Verification-Validation



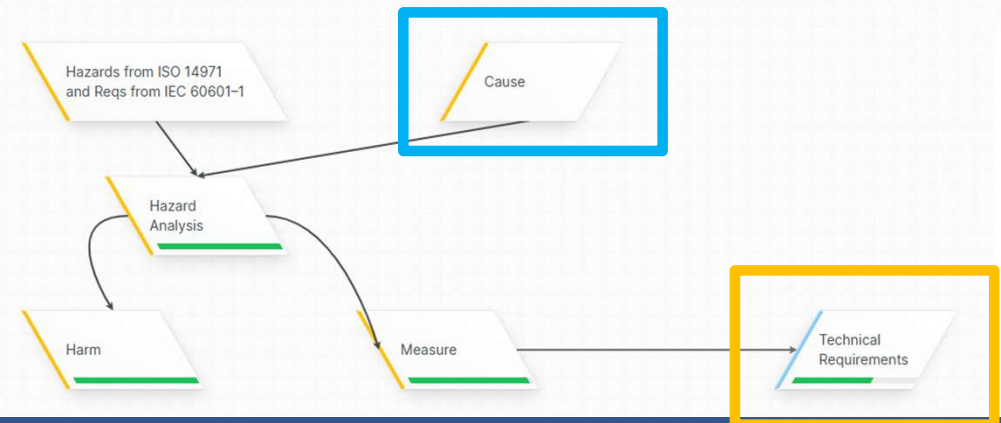
Traceability Software Development



Traceability Usability Analysis



Traceability Risk Analysis



Interdependent Documents - Reusable Text Components | aligned

Document Text Component

Search on id or text

Design Descriptions

TEC 11

Intended Use

TEC 21

Product Description

TEC 31

Intended Users

TEC 41

Intended Use Environment

TEC 51

Intended Patient Population

Classification

TEC 61

The risk class of the device (EU)

TEC 71

The risk class of the device (FDA)

TEC 81

The justification for the classification rule(s) applied as of Annex VIII

Regulations and Standards

Risk Management Components

TEC 121

Summary of Benefits

TEC 131

Summary of Risks

TEC 141

Summary of Risk Benefit Analysis

Company Info

ACUMEN-TEC 11: Intended Use

Design Descriptions

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Edit

Actions

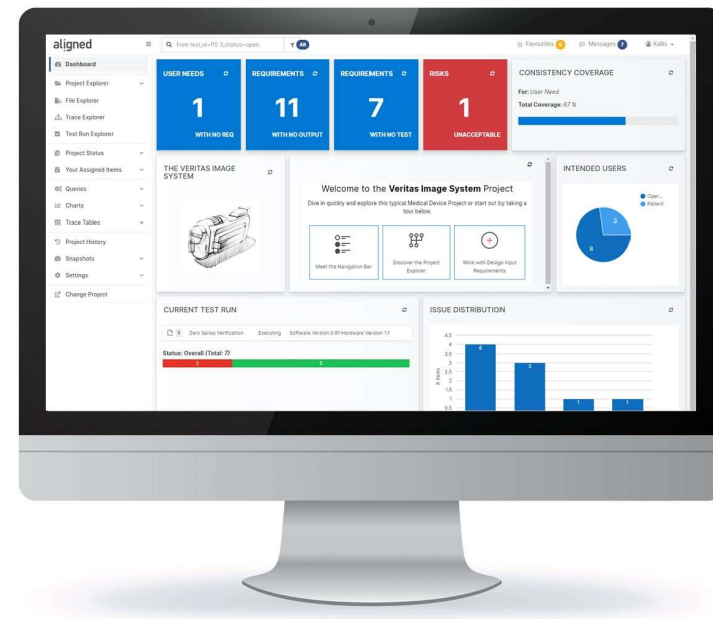
ID:	TEC 11
Disabled:	false
Title:	Intended Use
Description:	Intended to provide intraosseous access in patients when intravenous access is difficult or impossible to obtain in emergent, urgent, or medically obvious cases.
How to Write:	<p>Address the following aspects in your intended use:</p> <ul style="list-style-type: none">- Medical indication (for example, illness)- Intended patient group- Probable body part- Probable User Profile- Intended use environment / usage environment- Functioning, physical principle <p>Examples of Intended Use written at ACEM are:</p> <ol style="list-style-type: none">1. Intended to provide intraosseous access in patients when intravenous access is difficult or impossible to obtain in emergent, urgent, or medically necessary cases.2. The XYZ is a chest-worn sensor that is intended to periodically collect, store, and transmit physiological data to a qualified system for use by healthcare professionals. The physiological data measured by the biosensor includes respiration rate and heart rate. In addition, the biosensor is intended to measure and wirelessly transmit contextual parameters: activity level, activity type, and posture.

Conclusions



- Engineering Talent is not a guarantee for success in the medical 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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