



**MEDTECH  
MEETS  
DIGITAL**

19. – 20.03.2026 | Berlin - DIN e.V.



**MEDTECH  
MEETS  
DIGITAL**

**TAG 1 - SESSION C1  
FROM PRODUCT DESIGN TO SCALABLE MANUFACTURING**

# PRESENTERS

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# TAG 1 – SESSION C1

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## Von der Produktentwicklung zur skalierbaren Fertigung

Der Weg vom Produktdesign zur Serienfertigung ist ein komplexer Prozess, der eine nahtlose Integration über mehrere Systeme und Standorte hinweg erfordert. Zudem müssen die regulatorischen Anforderungen für diesen Prozess eingehalten werden.

In einer idealen Welt werden relevante Daten über zentrale Unternehmenssysteme wie bspw.

Teamcenter - PLM

SAP S/4HANA - ERP und

Opcenter - MES

zu einem einheitlichen Prozess verbunden. In dieser Session erfährst Du, wie Du eine fragmentierte IT-Landschaft harmonisierst, verschiedene Automatisierungsanforderungen bewältigst, die Validierung über mehrere Toolsets sicherstellst und gleichzeitig das Engineering Change Management, die regulatorischen Anforderungen sowie die hohen Qualitätsstandards einhältst.

# EXPECTATIONS?

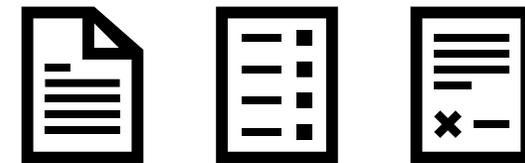
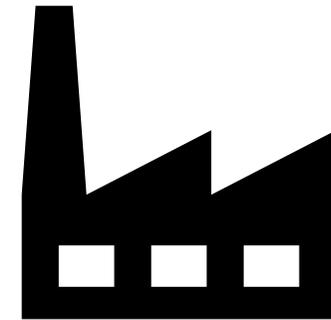
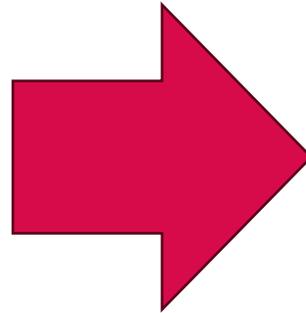
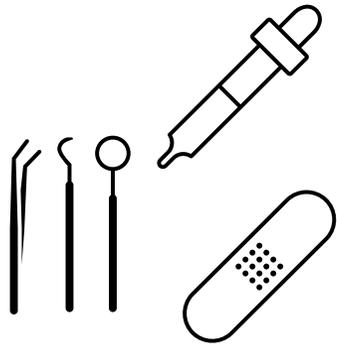
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Where do you stand with digitalization?

How would you assess your maturity of digital end-to-end processes?

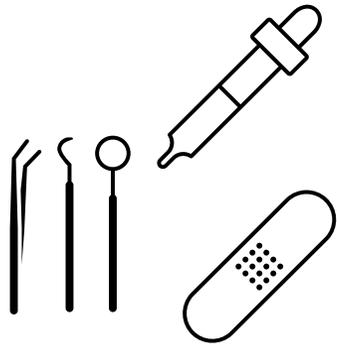
# FROM PRODUCT DESIGN TO SCALABLE MANUFACTURING

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# BUT FIRST ...

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# GOAL & CHALLENGE – EFFICIENT COMMUNICATION

ENGINEERING

Varianten

Stücklisten

Config. Management

Software-Updates

Design-Änderungen

Design Inputs &  
Outputs

**GoTo-Market:  
schnell / erfolgreich**

**Change**

Zulassungs- &  
Qualitätsvorgaben

Re-Validation

Impact Analysis

Re-Submission

MDR / FDA Updates

REGULATORY AFFAIRS



# WORKSHOP

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Questions to be discussed:

- In which area do we experience today the biggest inefficiencies and breaks between Engineering and Regulatory Affairs?
- What kind of information, documents or decisions aren't available end-to-end, although they are essential for effective collaboration?
- What is the impact of this shortcomings in regards to Quality, Compliance, producability, time line and market introduction?
- What part of the Engineering Change Management is specifically costly or risky?

**DIREKTE** VERBINDUNG ZWISCHEN REGULATORY & ENGINEERING  
**SCHNELLE** UMSETZUNG REGULATORISCHER ANFORDERUNGEN  
**SICHERE** COMPLIANCE IN JEDEM SCHRITT

Grösstes Infrastrukturprojekt der Schweiz: Gotthard-Basistunnel  
Nord-Süd Verbindung, 57 km Länge, 2 Röhren  
Lange Bauzeit, Nachhaltiger Impact

# GOTTHARD-BASE TUNNEL FOR CONFORMITY

ENGINEERING

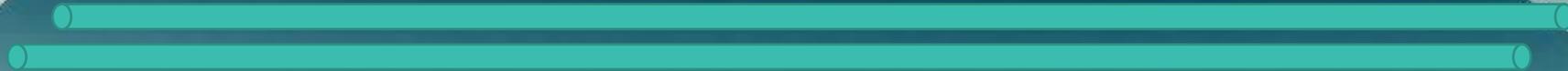
REGULATORY AFFAIRS

Automated  
information flow

Synchronized instead of  
sequential

Single Source  
of Truth

Regulatory  
Intelligence



# GOTTHARD-BASE TUNNEL FOR CONFORMITY

ENGINEERING

REGULATORY AFFAIRS

## Digital continuity

Automated information flow

Synchronized instead of sequential

Single Source of Truth

Regulatory Intelligence



Authoring



Teamcenter & Medical Device Solution

Single Source of Truth

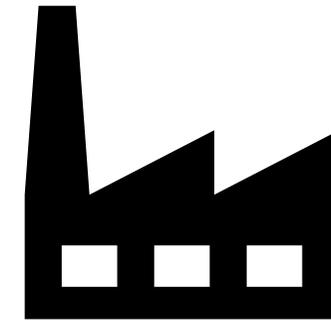
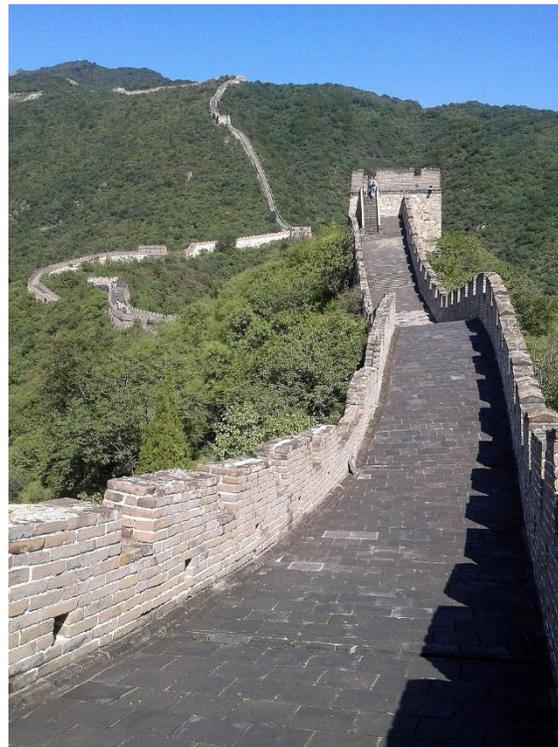
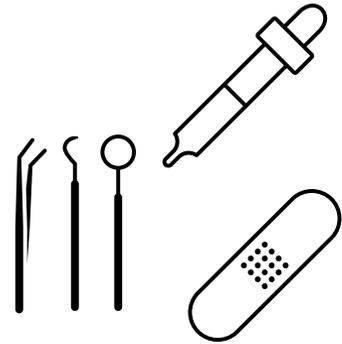


Submission Management

Regulator

# ONE PROBLEM SOLVED. BUT ...

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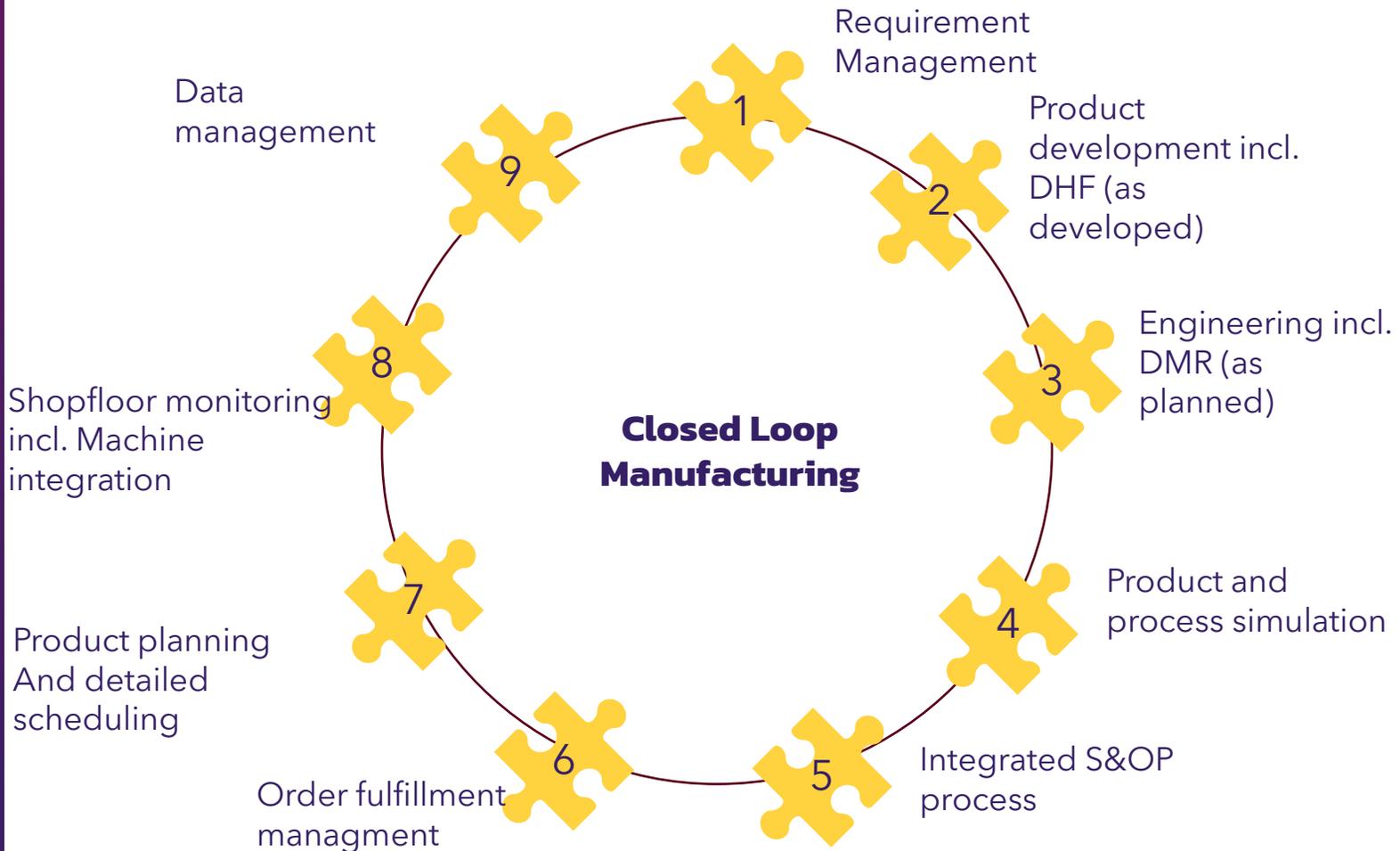


# CLM FRAMEWORK – THE WAY FORWARD

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# CLOSED-LOOP-MANUFACTURING (CLM)



## Benefits

- Seamless integration between sites
- Automated integration and data exchange between PLM-ERP-MES
- Integrated business process management with full integration of business and IT
- Constant process optimization based on live data (feedback loop)
- Advanced data analytics

## Target:

integrated digital framework in medical device industry

# SPECIFIC CHALLENGES FOR MEDICAL DEVICES



**Products**

**Documentation**

**Both must be perfect!**

- Document-centric work-approach creates high redundancy of data and reduces the possibility of traceability of objects and data
- The different markets has different requirements and norms for development, regulatory documentation and production
- The results of using paper are documentation errors, quality problems, increased costs and an increased risk
- Even if partially digitized, a lot of media disruption causes high effort and slows down any go-to-market

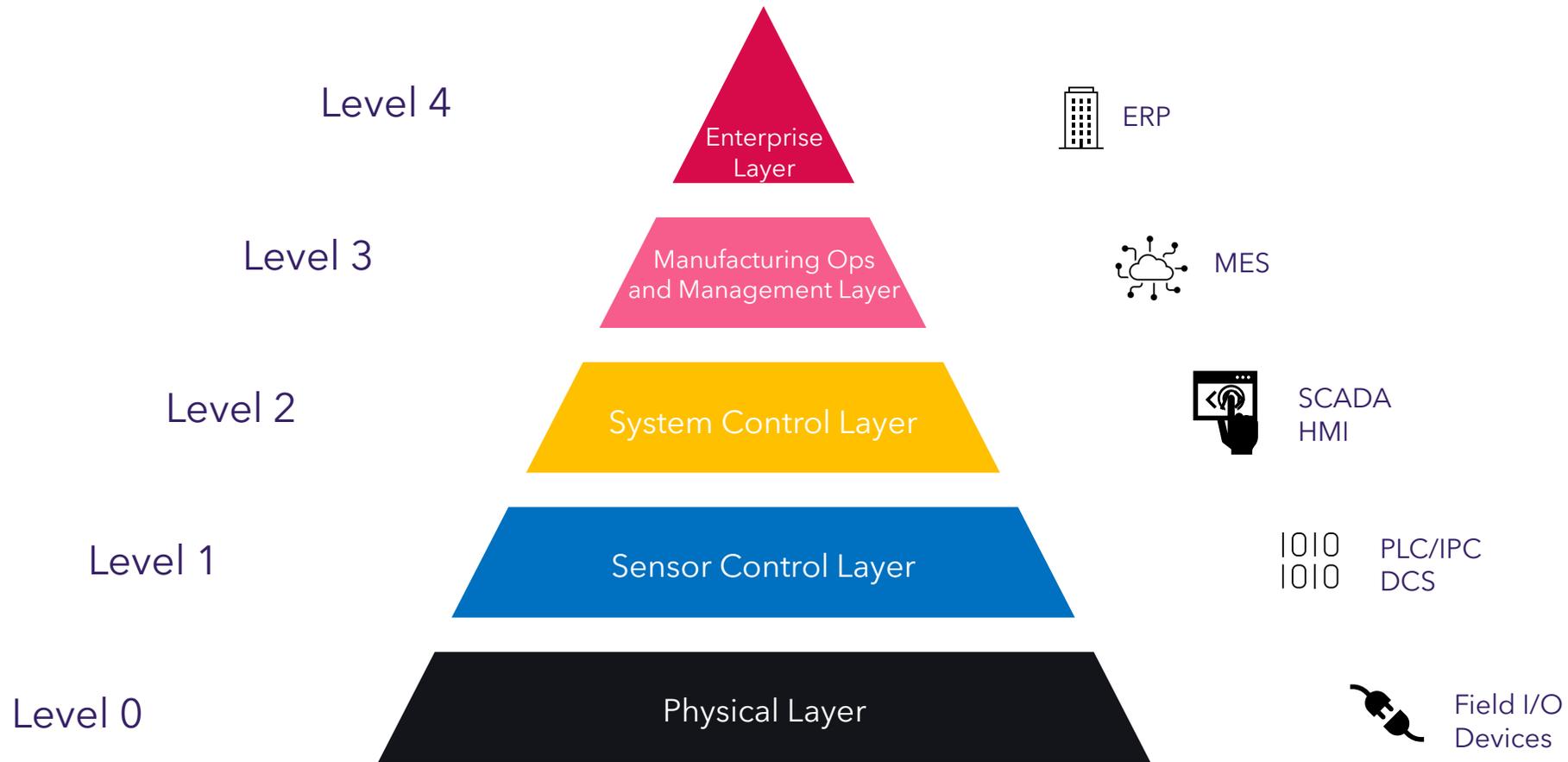
# WORKSHOP

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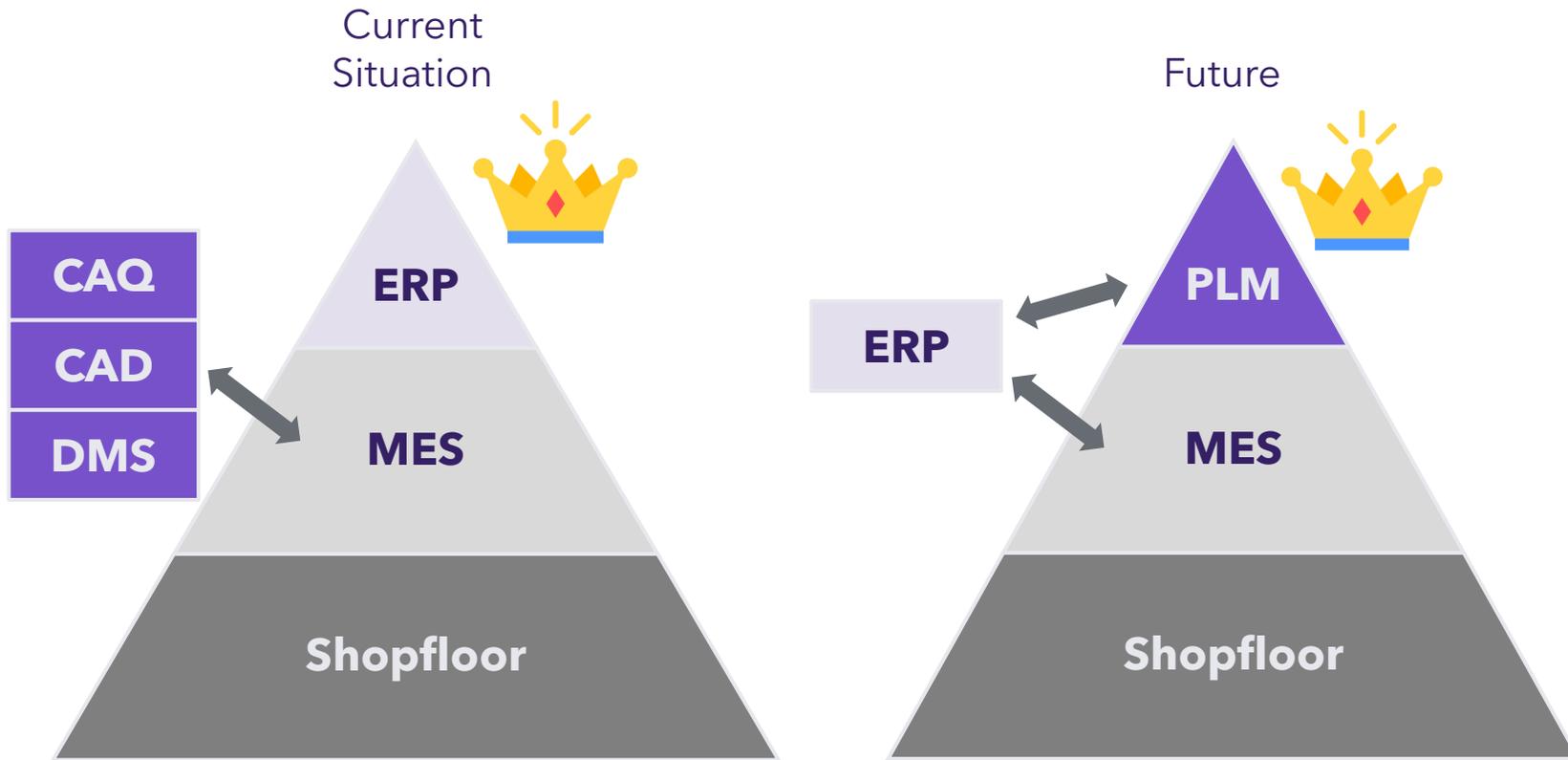
- Where do we lose today information, responsibilities or transparency in the end-to-end process?
- Where do we need more loops back from production, execution or data analytics, that we can improve R&D, regulatory and planning?
- To achieve a completely closed digital framework, which capabilities and integrations must we prioritize?

# ISA – 95 MODEL

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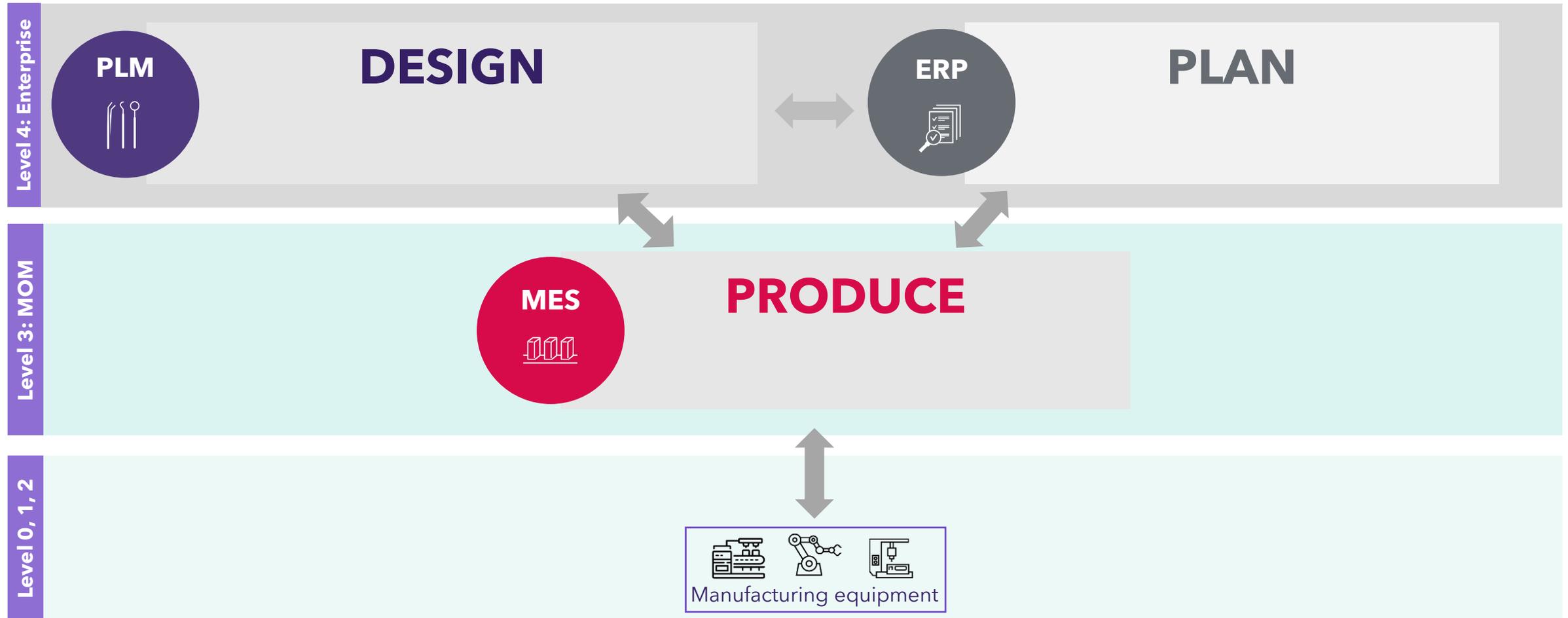
# THE KNOWN WORLD OF PRODUCTION IT



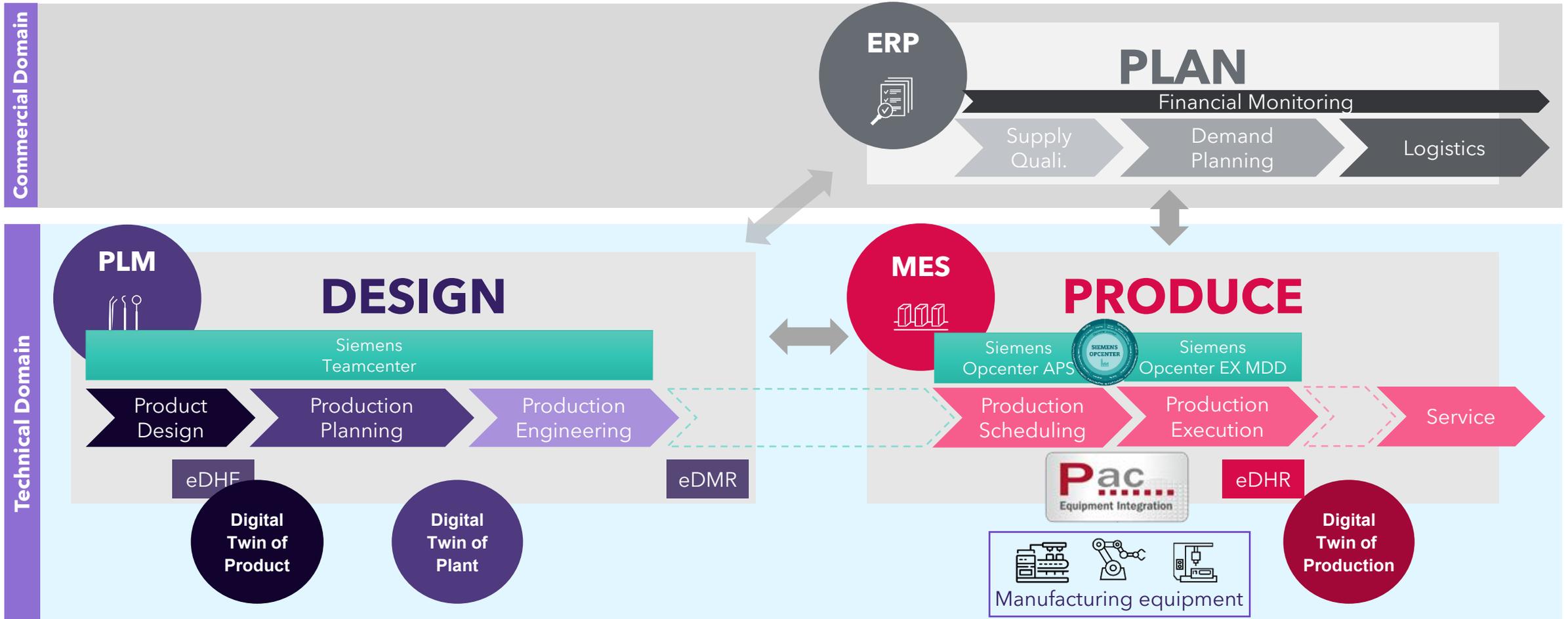
## Why

- PLM focuses on Products and the whole life cycle
- PLM centralizes requirements, regulatory affairs, CAD designs, Documents, BOM's, revisions
- ERP is financial centric
- ERP has no technical granularity
- ERP was exploited in the past to drive production
- Usability of ERP in shopfloor is not given → therefore paper
- Today documents are stored in folders → totally decentralized

# TYPICAL PRESENTATION OF MAGIC TRIANGLE – USING ISA 95 MODEL



# BETTER WITH COMMERCIAL AND TECHNICAL DOMAIN



# WORKSHOP

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## How is your actual status?

- When an auditor asks, 'Where do you see evidence of implementation?' - where do you look first?
- How do you see the role of ERP in your company?
- How does the design transfer to manufacturing and back work actual and how long does it take?
- How do you ensure that the BOM, Work Plan and inspection are consistent? (Directing the documents)
- Is Manufacturing Execution already a consideration in your design process from a data flow perspective?

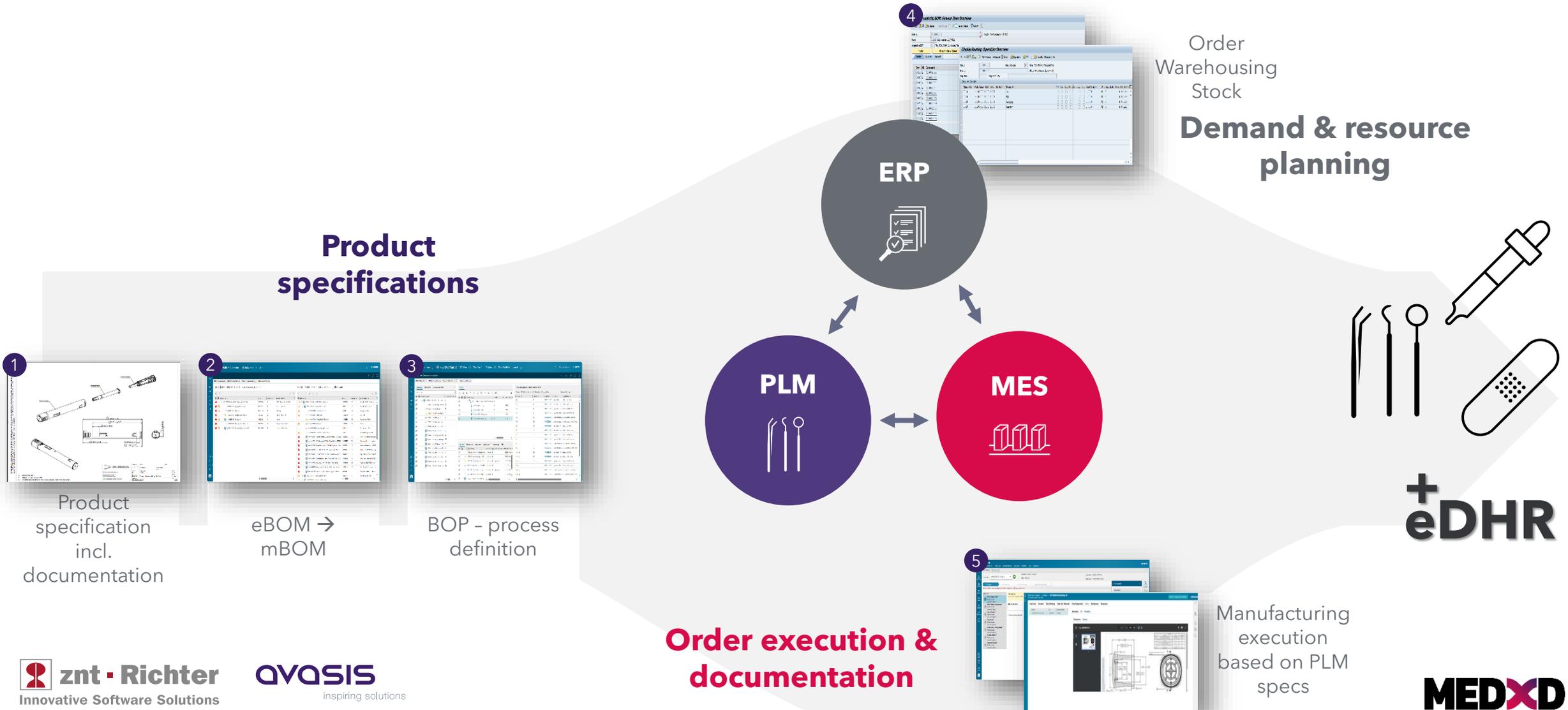
## Which benefits do you see, with such an approach?

- If your ERP System goes down today, can you still keep production running?
- What kind of system you would need to be sure of what you're allowed to produce?
- What would you need to get there?
- What's holding you back?

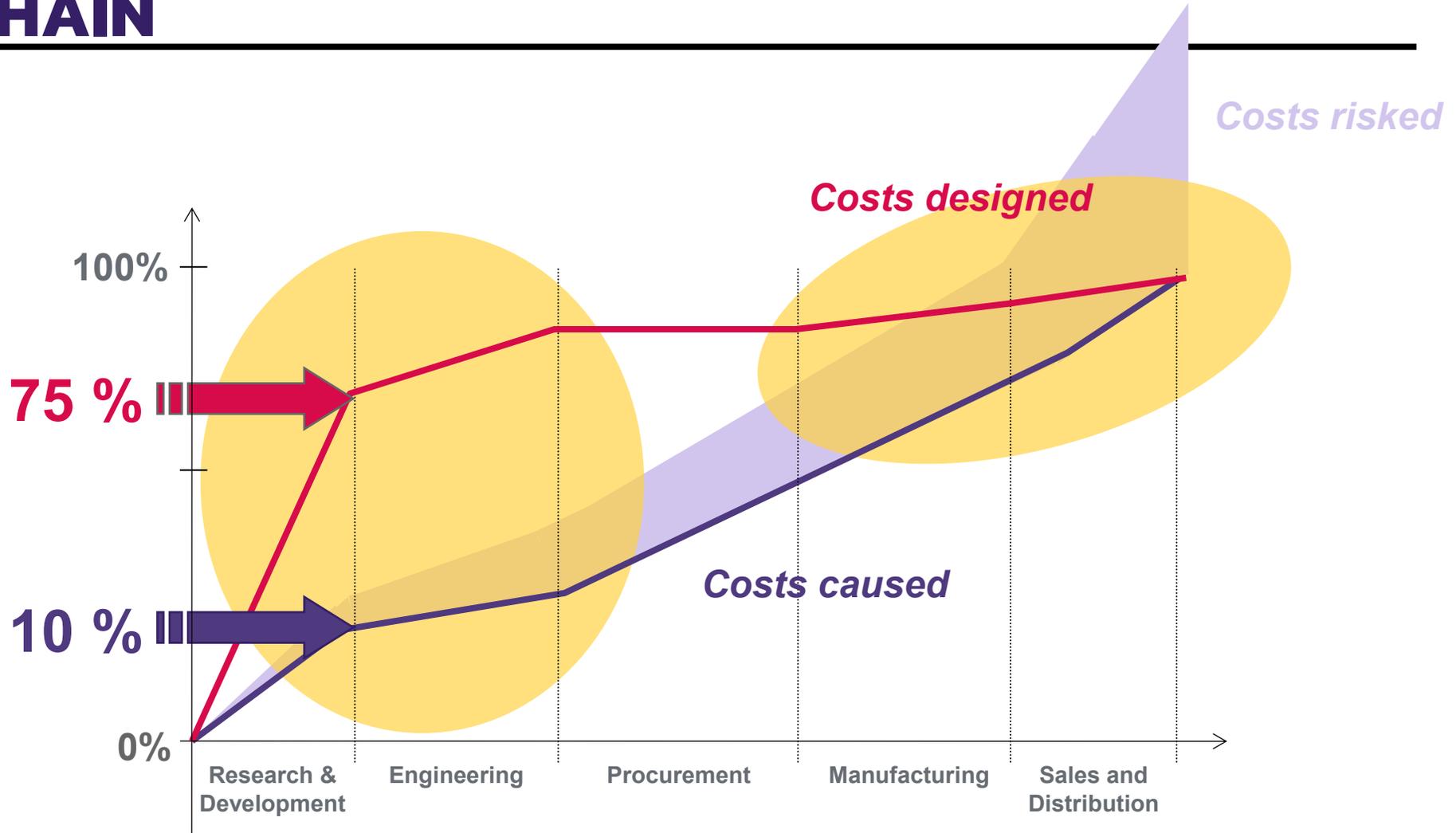
## Where are your challenges / problems?

- Do you have Data Silos? Media Breaks?
- Are there organizational challenges between the different stakeholders and how do you overcome these?
- How big is the amount of paperwork you generate?
- Who is responsible for correctly implemented design change?

# THE CLM „MAGICAL TRIANGLE“ IN WORK

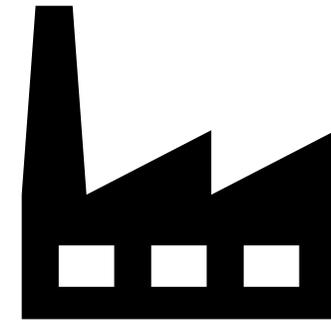
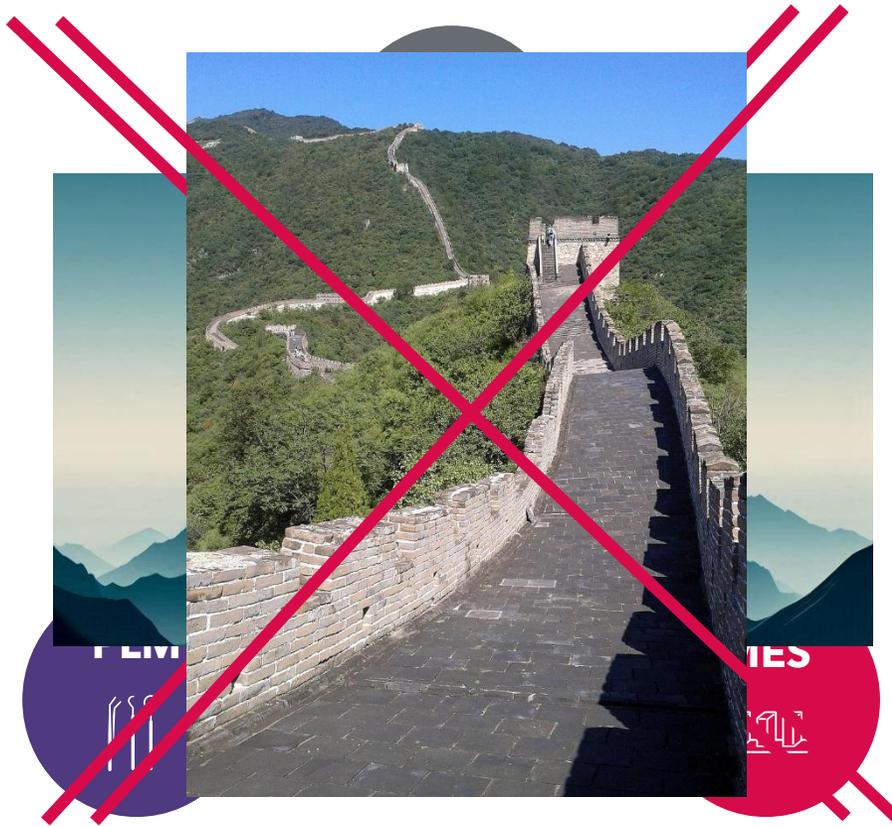
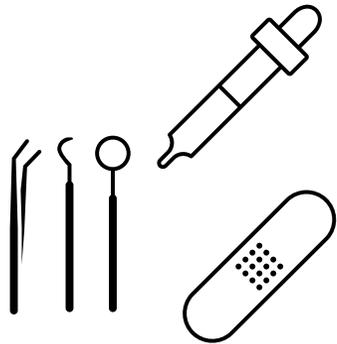


# COST OPTIMIZATION – COST IMPACT ALONG THE VALUE CHAIN



# FROM PRODUCT DESIGN TO SCALABLE MANUFACTURING -> CLM!

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# SUCCESS STORY: SHL MEDICAL AG



**Enabling our growth & sustainability goals  
3X manufacturing sites – global footprint**  
Seamless integration between sites and automated data exchange between PLM-ERP-MES

**Challenge**  
Digitally connect varying operational processes and siloed business systems to enable location independent manufacturing.

**Solution**  
Teamcenter (TC), Polarion (PLN), Easy Plan, TCMDS (Medical Device Solution) by avasis, TC-PLN interface by avasis, Active Integration Gateway (T4S, CN4T), Opcenter EX Medical Device & Diagnostics, Opcenter APS, Tecnomatix Plant Simulation

“By leveraging Siemens' integrated solution suite alongside our SAP S/4HANA ERP, we are breaking down silos and digitally connecting our operational processes across the entire value chain. This powerful ecosystem will enable us to achieve true location-independent manufacturing by synchronizing design, engineering, planning, and execution. The result is a seamless digital thread that drives agility, transparency and optimization from concept to production — regardless of where our teams or assets are located.

- Fabian Hoefler & Harsh Bafna, SHL Medical

 **AVASIS SIEMENS**

Find out more: [SHL Medical goes paperless with Siemens' manufacturing planning and simulation solutions \[VIDEO\] - Teamcenter Manufacturing](#)



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# RESULTS OF WORKSHOPS



Vielen Dank für die Diskussion!



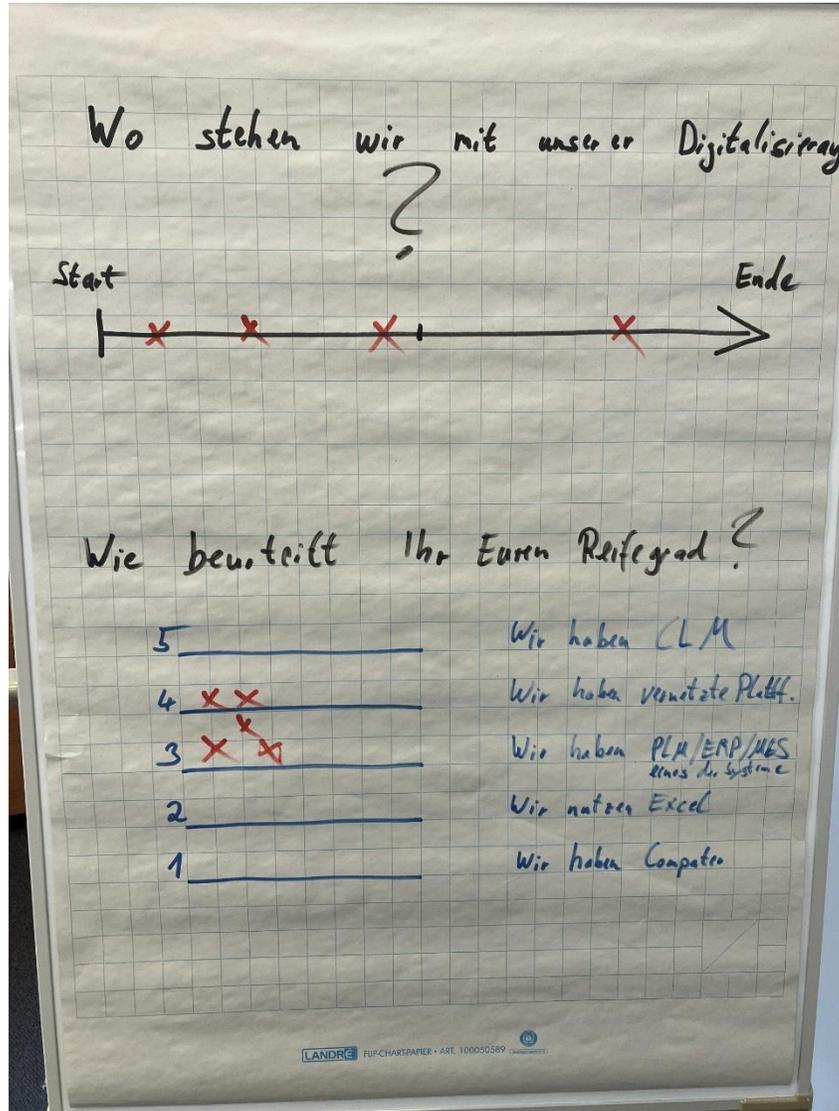
# EXPECTATIONS?

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Where do you stand with digitalization?

How would you assess your maturity of digital end-to-end processes?

# OPENING QUESTIONS



## Conclusion

Die Teilnehmer sind überwiegend mitten in der Digitalisierung und haben einen fortgeschrittenen Reifegrad, aber jedoch noch nicht komplett vernetzt.

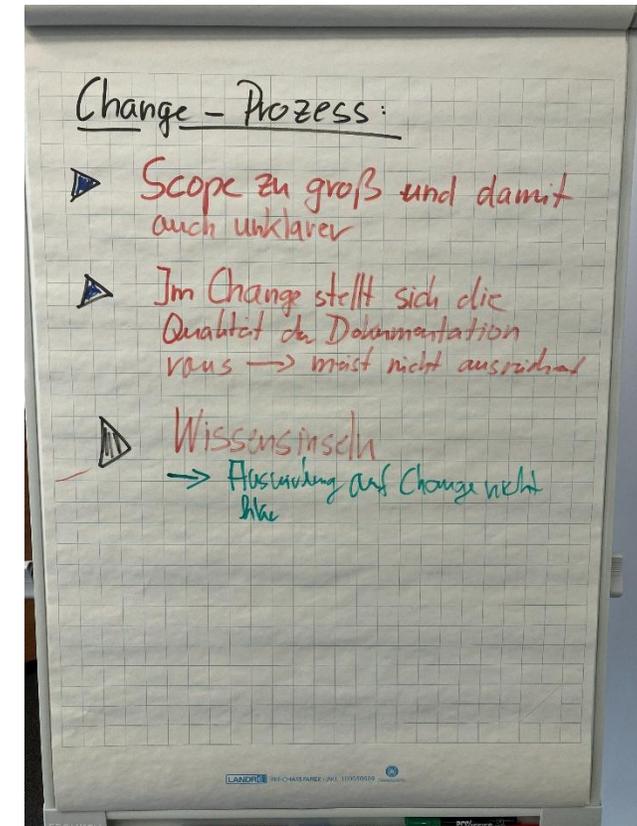
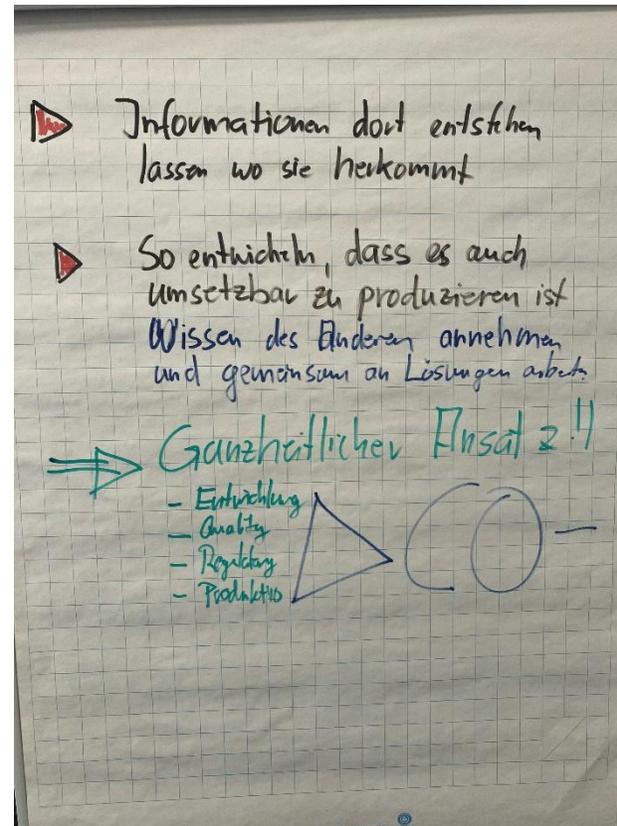
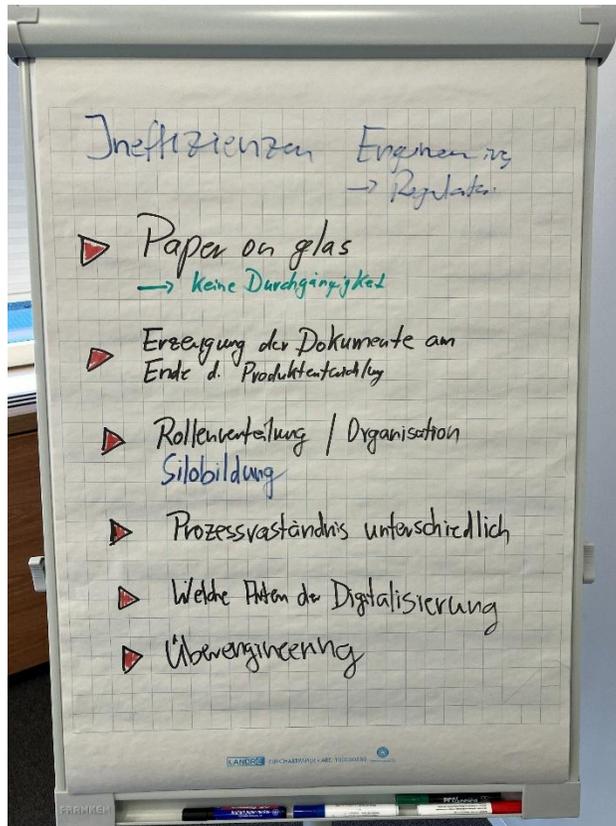
# WORKSHOP – PART 1

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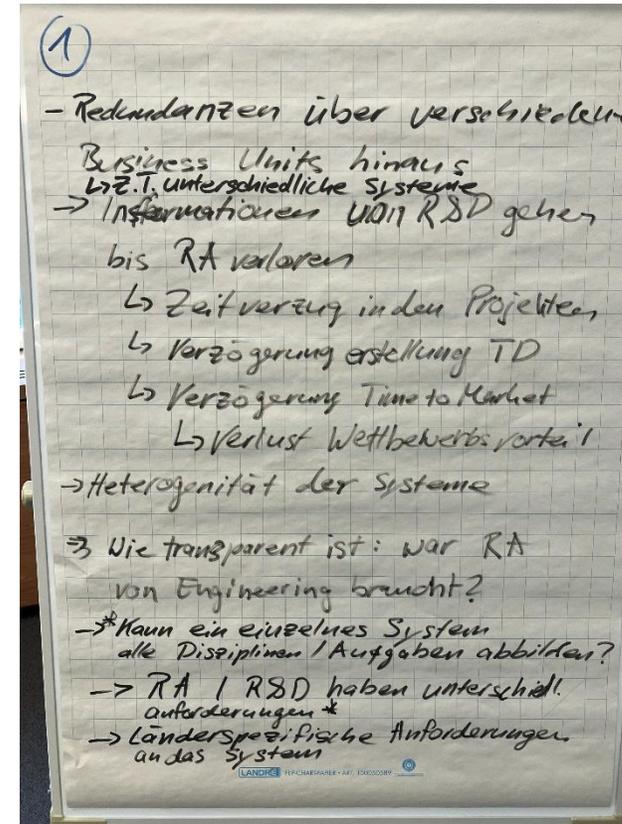
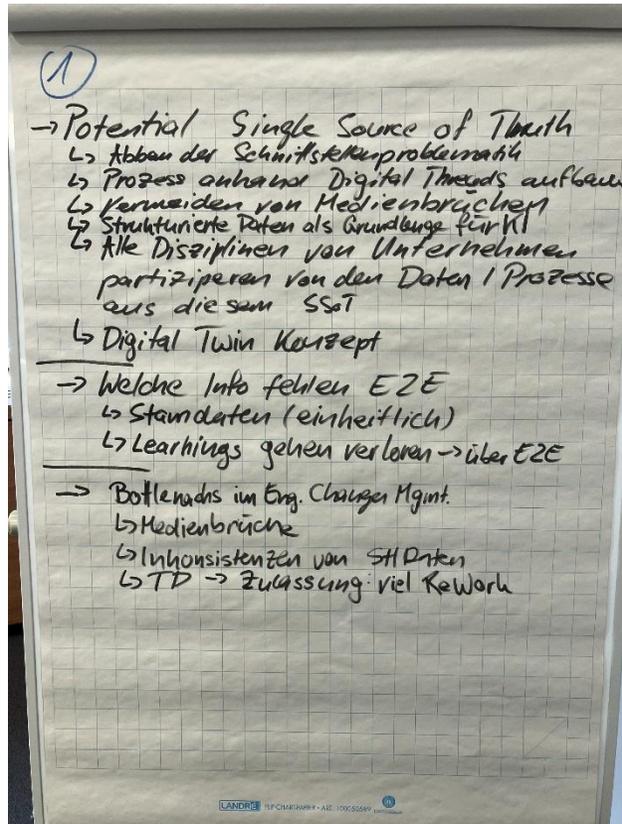
# WORKSHOP PART 1



## Conclusion

Digitalisierung des bestehend Prozesses, unterschiedliches Prozessverständnis und Silos führen zu den größten Ineffizienzen. Diese „Wissensinseln“ werden auch im Change deutlich - die Auswirkungen sind schwer abzuschätzen.

# WORKSHOP PART 1



## Conclusion

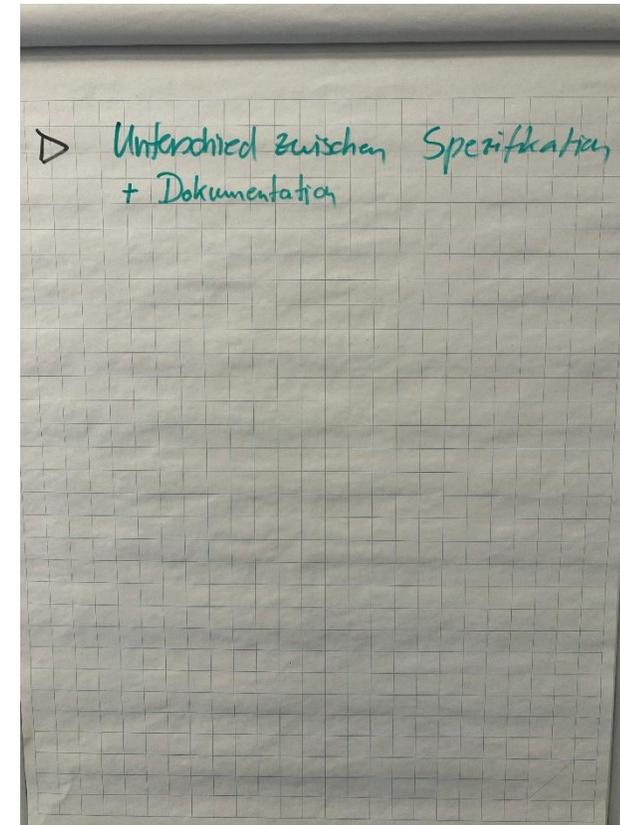
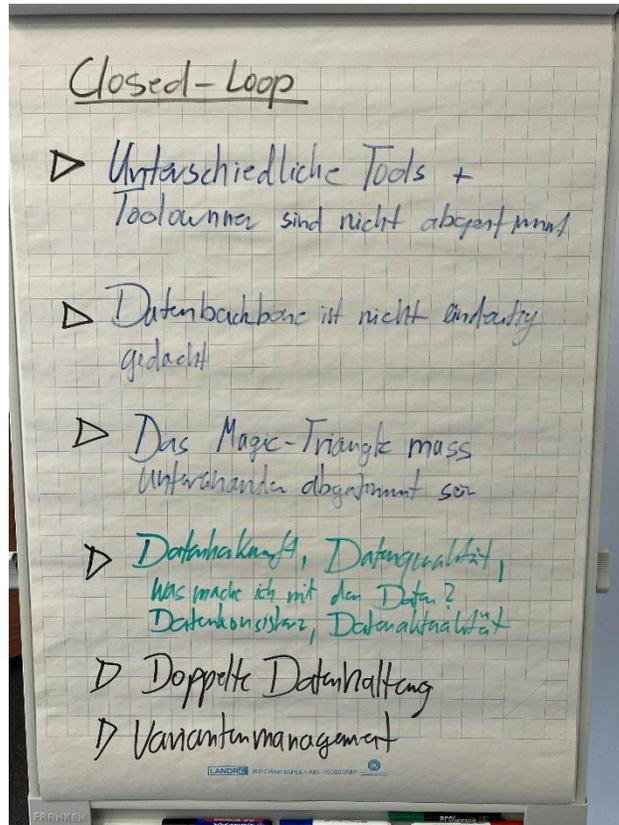
Single Source of Truth unterstützt den Prozess und ermöglicht Digital Twins. Die Herausforderung sind Redundanzen über Business Units und Informationsverlust. Damit wird der Change zum Bottle Neck, da hier die Medienbrüche besonders deutlich werden.

# WORKSHOP – PART 2

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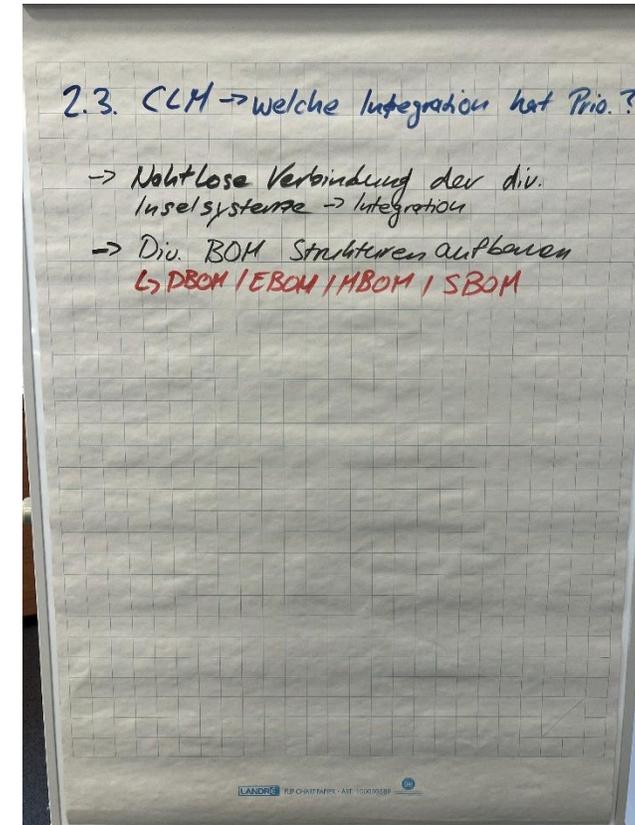
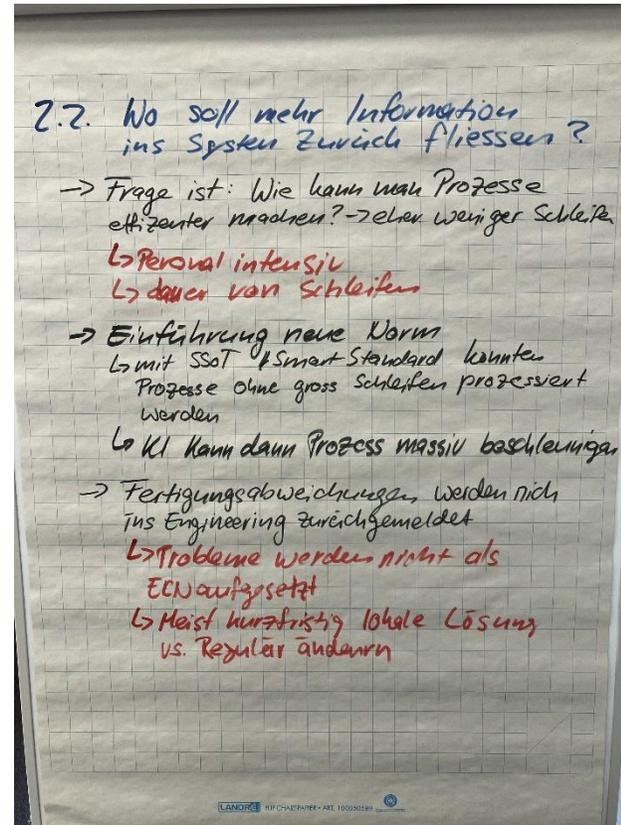
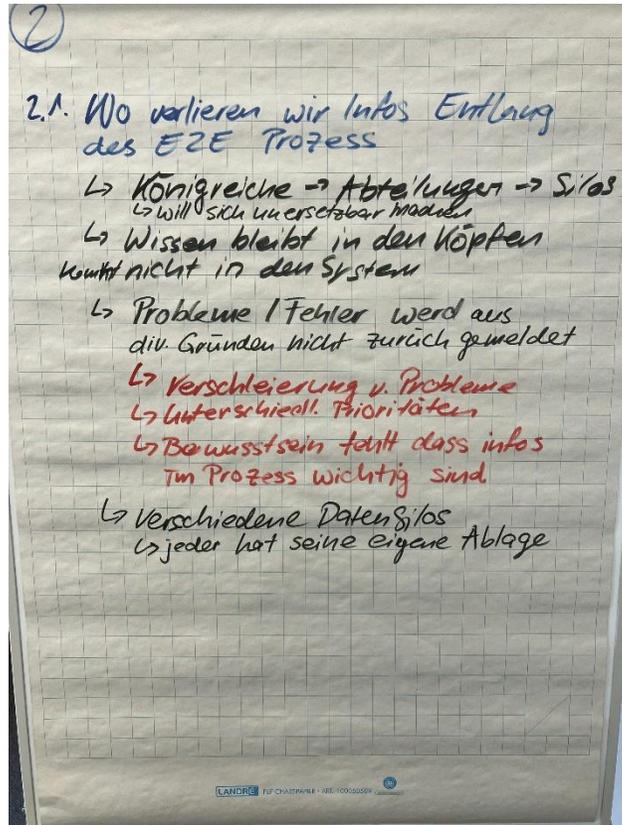
# WORKSHOP PART 2



## Conclusion

Der Verlust an Information passiert durch die Verwendung unterschiedlicher Tools, nicht abgestimmter Datenstrukturen und fehlender Datenqualität. Das führt primär zu Unterschieden von Spezifikationen und Dokumentation.

# WORKSHOP PART 2



## Conclusion

Information werden durch „Königreiche“ nicht ausreichend transportiert und verbleiben in den Köpfen anstatt im System zu landen. Generell sollten aus allen Bereichen Schleifen zurück gebildet werden, KI kann hier helfen. Informationen müssen verbunden und strukturiert werden.

# WORKSHOP – PART 3

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## How is your actual status?

- When an auditor asks, 'Where do you see evidence of implementation?' - where do you look first?
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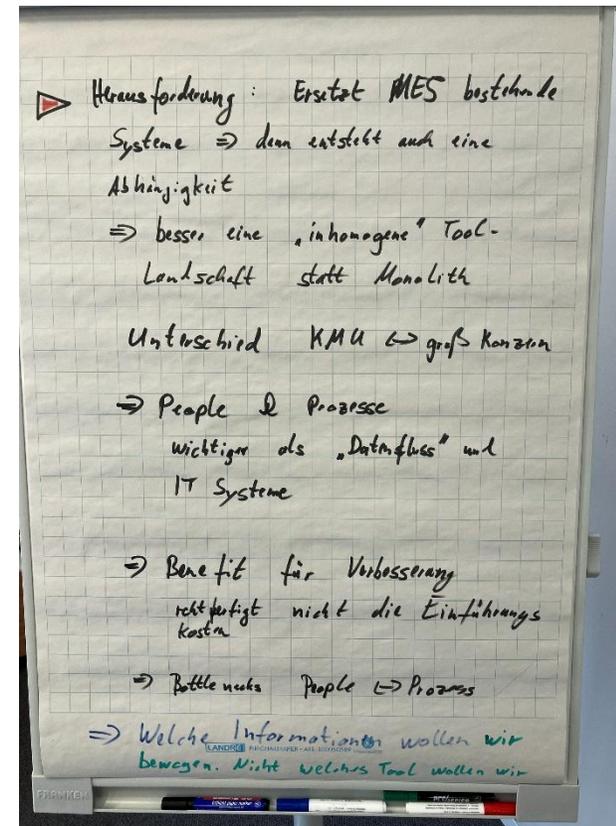
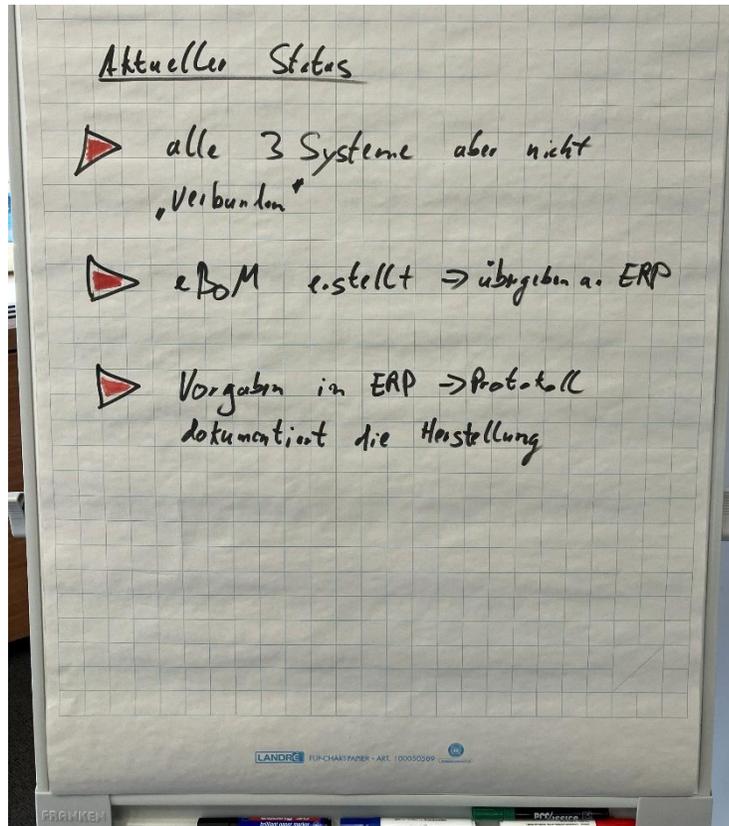
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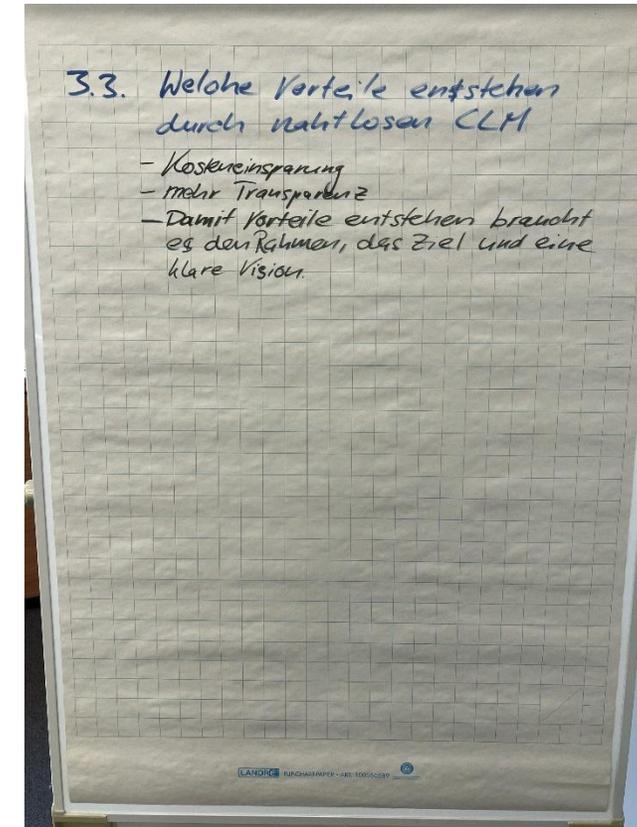
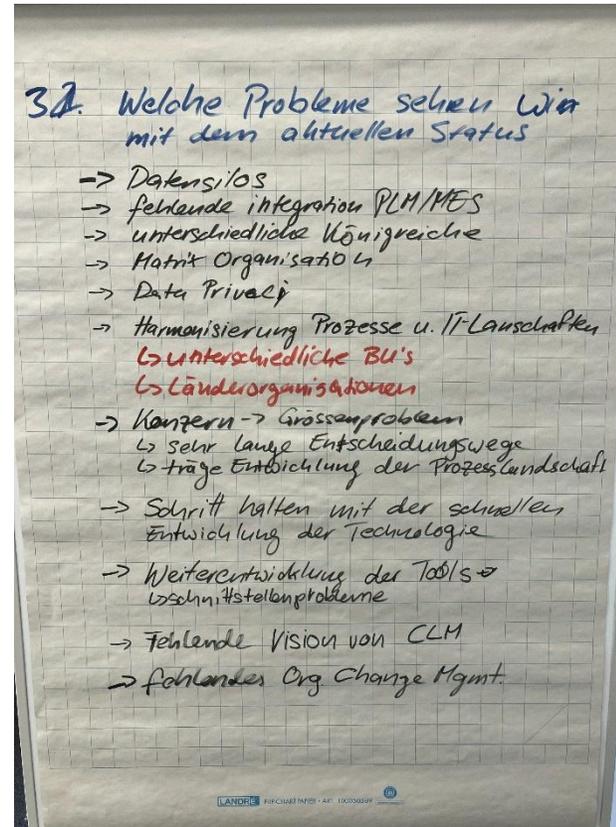
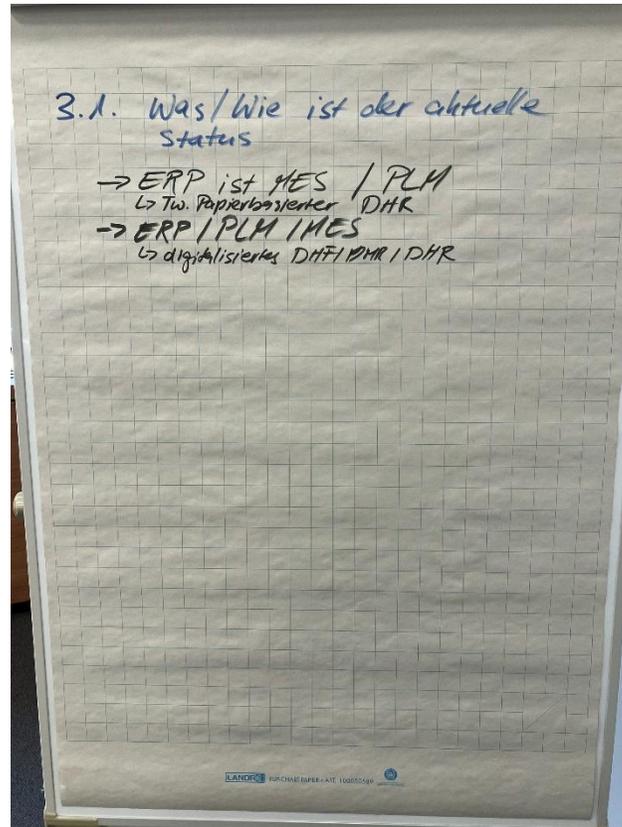
# WORKSHOP PART 3



## Conclusion

PLM, ERP, MES sind häufig vorhanden, aber nicht vernetzt, BOMs werden ohne Link übergeben. People & Prozess sowie welche Informationen bewegt werden sollen, sollen im Mittelpunkt stehen, nicht das Tool/Systeme.

# WORKSHOP PART 3



## Conclusion

ERP erfüllt die Aufgabe von MES und PLM, damit entstehen Datensilos und Skalierungsprobleme, welche durch fehlende Vision und unvollständigen Org-Change Mgmt unterstützt werden. Damit können die Kosteneinsparung und Transparenz von CLM nicht realisiert werden.