



Intelligente Dokumentation

Vorteile durch dein Einsatz von ALM/PLM Tools

Fachtagung „Digitale Tools zur Optimierung von QM & MDR Prozessen“, Innsbruck, 6. Februar 2020

Vorstellung avasis

avasis 1997
2017
20 years inspiring PLM solutions



- 1997 **Gründung** in Diepoldsau (Schweiz)
- 2001 Aufnahme Tätigkeiten in **PDM/PLM** (Teamcenter)
- 2011 Unterstützung **Medizintechnik** mit Teamcenter
- 2016 Siemens OEM Partner «**Medical Device Solution**»
- 2017 Siemens «**Smart Expert Partner**»
- 2018 Unterstützung **Medizintechnik** mit Polarion (ALM)
- 2019 Lösungen für die digitale Technische Dokumentation, Development, Risk Management, Usability, Clinical Evaluation

SIEMENS



Seit 1997 Partner von
Siemens bzw. deren
Vorgänger Unternehmen



Vorstellung avasis

avasis 1997
2017
20 years inspiring PLM solutions

Solution
Partner
PLM

SIEMENS

Smart Expert
Channel



Ihr Nutzen:
Langjährige Partnerschaft & Kontinuität
Durchgängige Lösungen aus einer Hand
Smart Expert Partner von Siemens – zukunftssicherer Partner
Kompetente, engagierte Berater und Spezialisten mit Fach- und Branchenwissen

Medizintechnik: Lifecycle – Entwicklung & Produktion

Maschinenbau: Geräte-, Werkzeugbau, Automotive

Solution Partner

- NX
- Teamcenter
- QMS
- Polarion

Dienstleistungen:

- Beratung
- Implementierung
- Schulung

Eigenprodukte für

- Technical Doc.
- Risk Management
- Usability
- Clinical Evaluation

Team



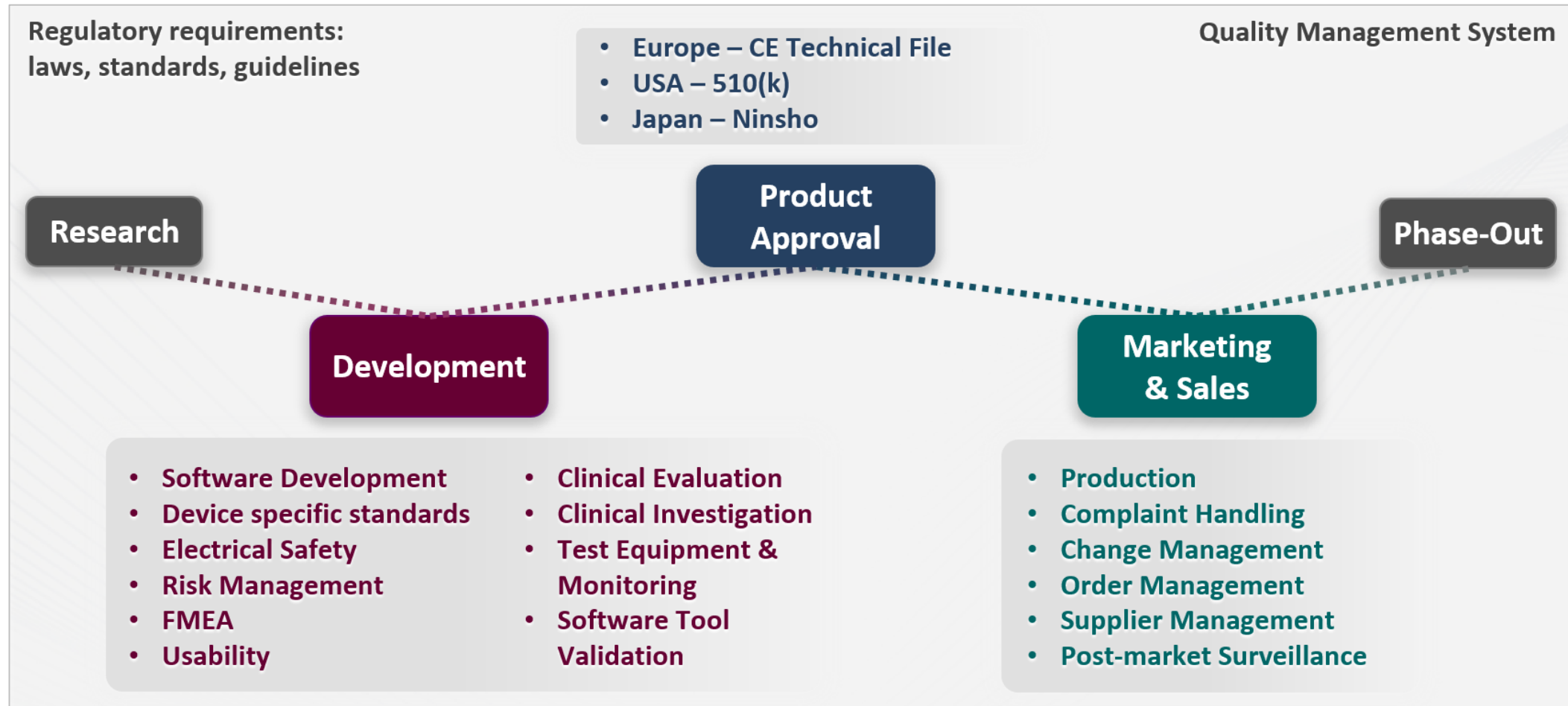


Herausforderungen Medtech

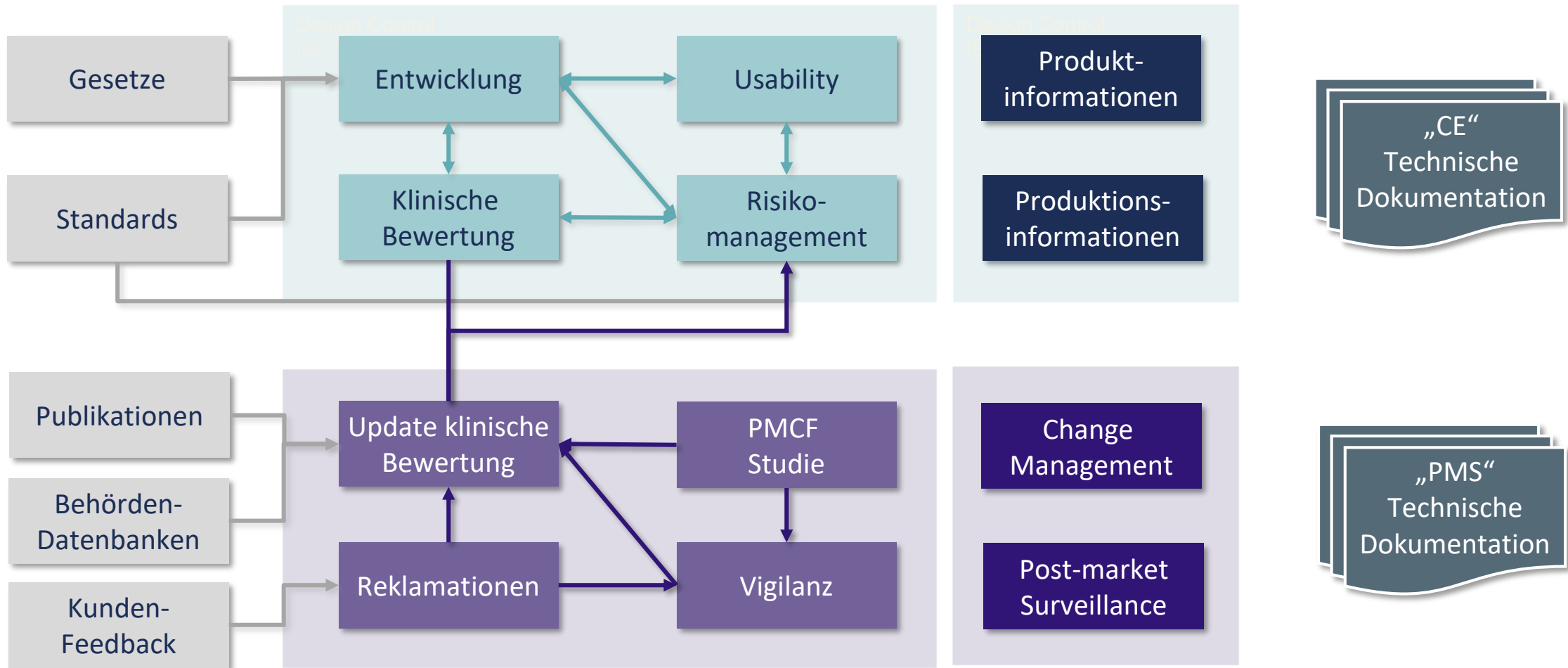
Komplexität von Informationen

AVASIS

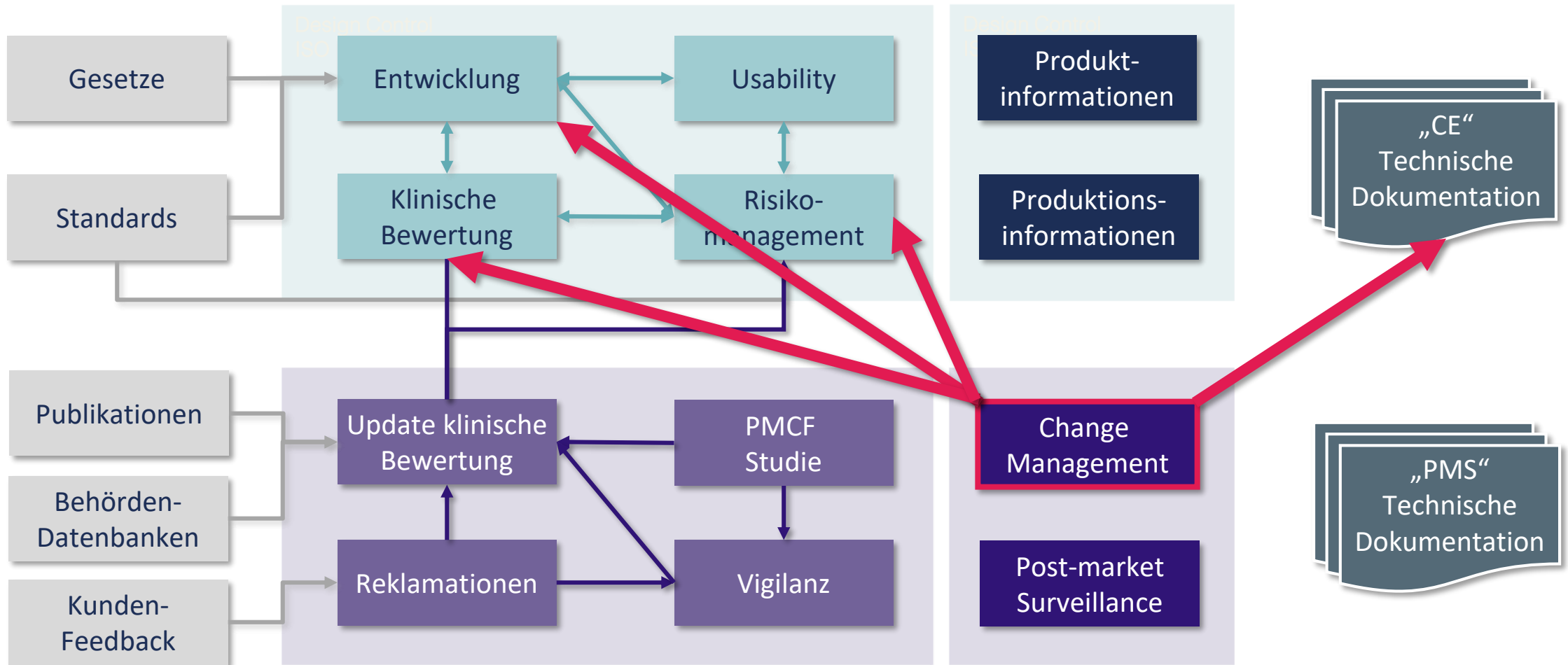
inspiring PLM solutions



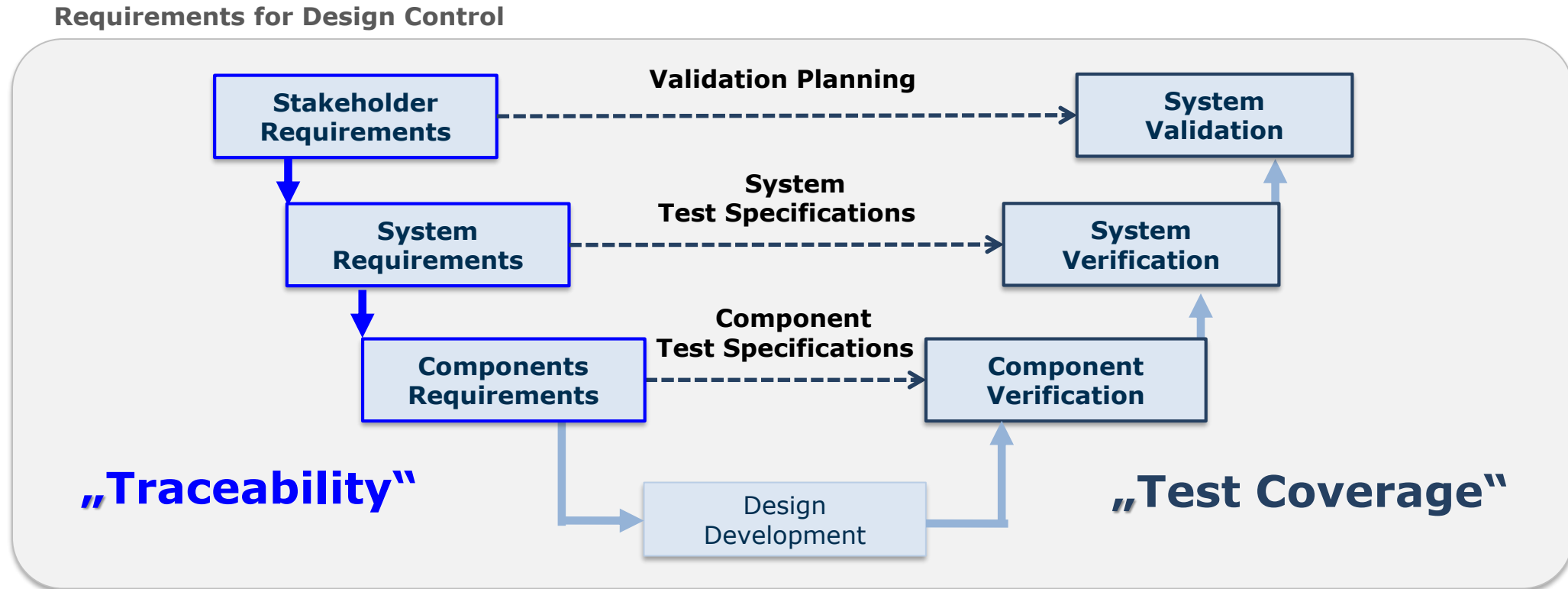
Komplexität von Informationen – Prozesse



Komplexität von Informationen – Prozesse

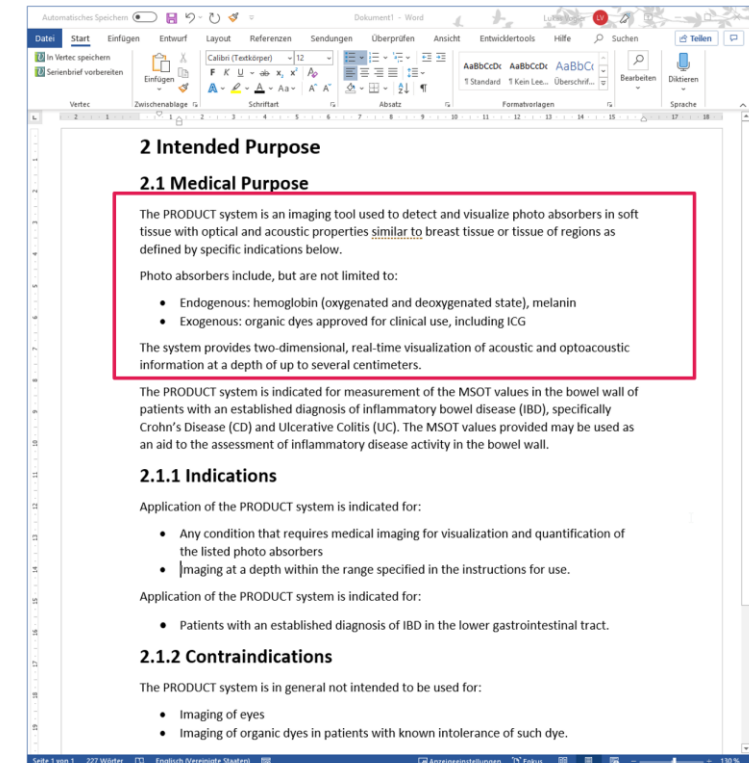


Beispiel: Entwicklungsprozess



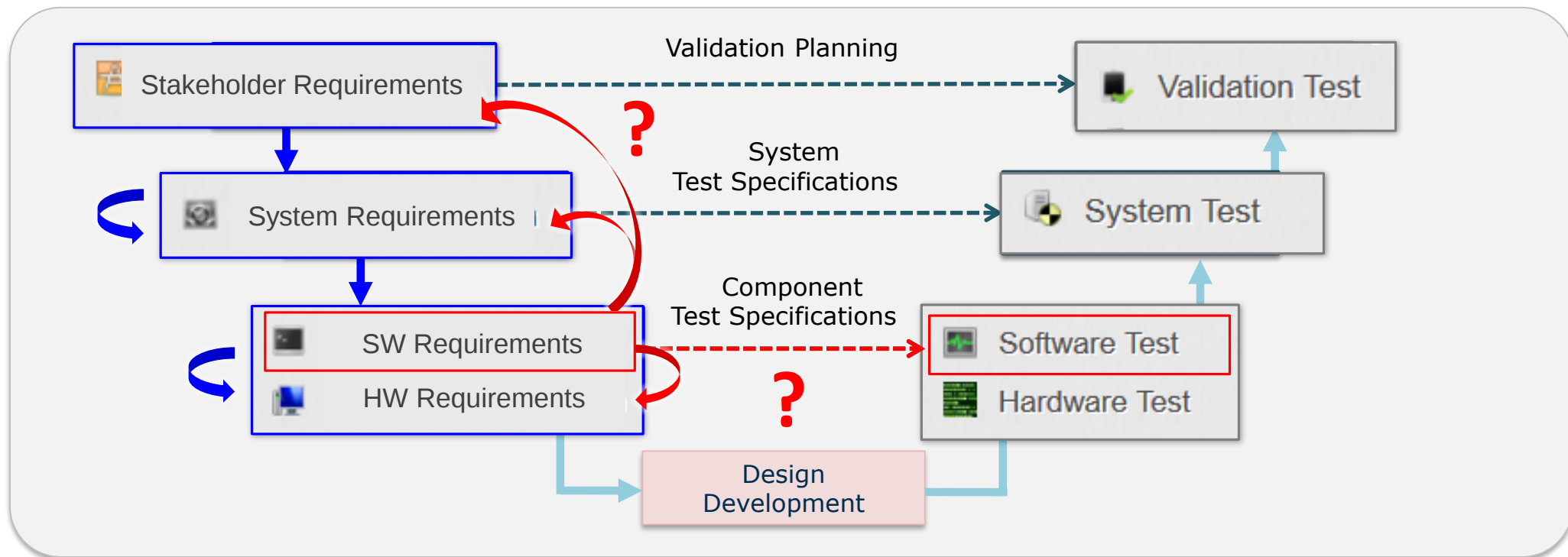
Beispiel: Entwicklungsprozess

- ❌ Status einzelner Anforderungen:
Fehlende Information? Offene Fragen? Im Review? Freigegeben?
- ❌ Verantwortlichkeiten?
- ❌ Darstellung und Pflege von Abhängigkeiten?
- ❌ Vollständigkeit von Traceability und Test Coverage?
- ❌ Reihenfolge von Freigaben, Prozesskonformität?
- ❌ Konsistenz?
- ❌ Wiederverwendung?

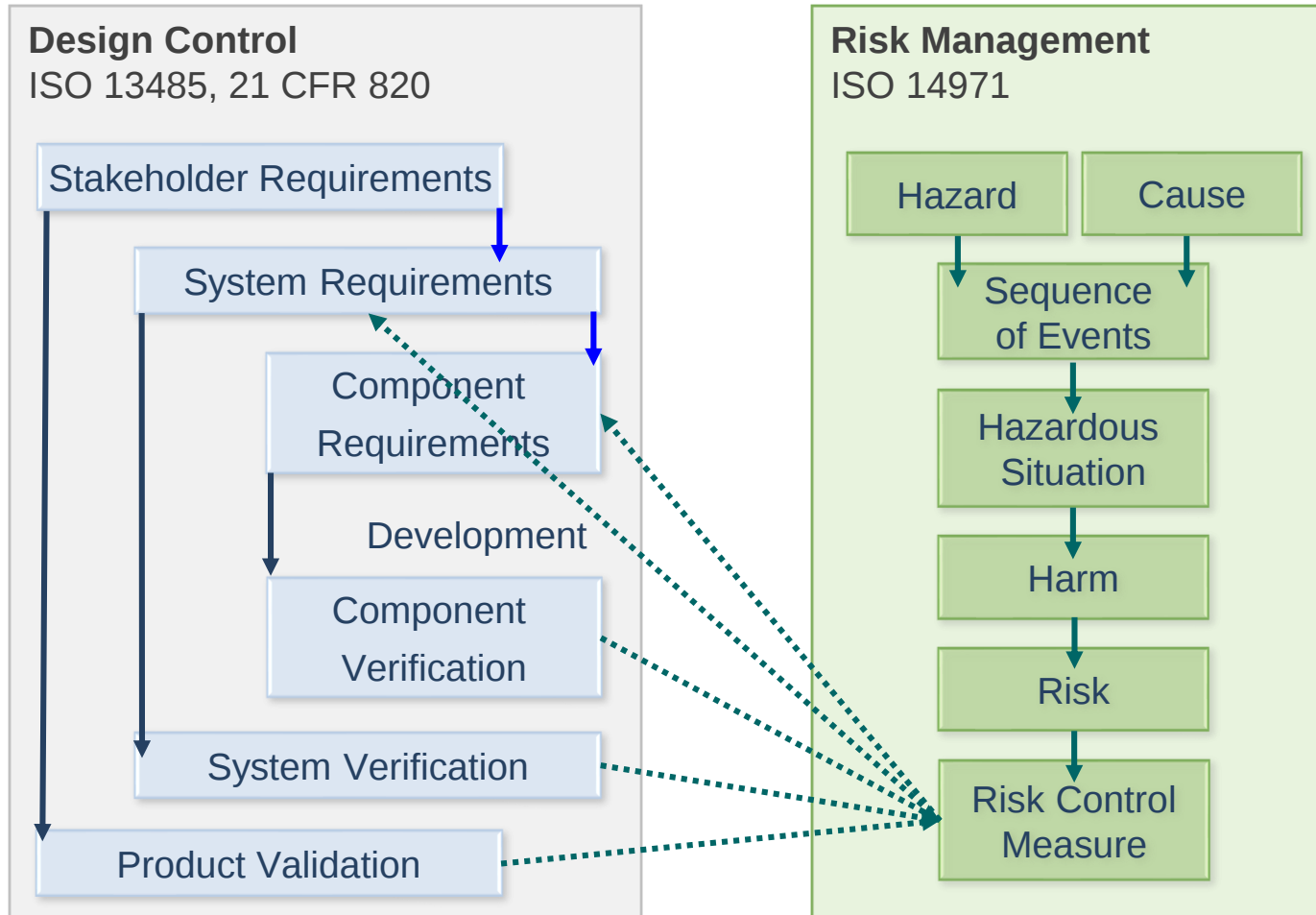


Beispiel: Entwicklungsprozess - Änderungen

Requirements for Design Control



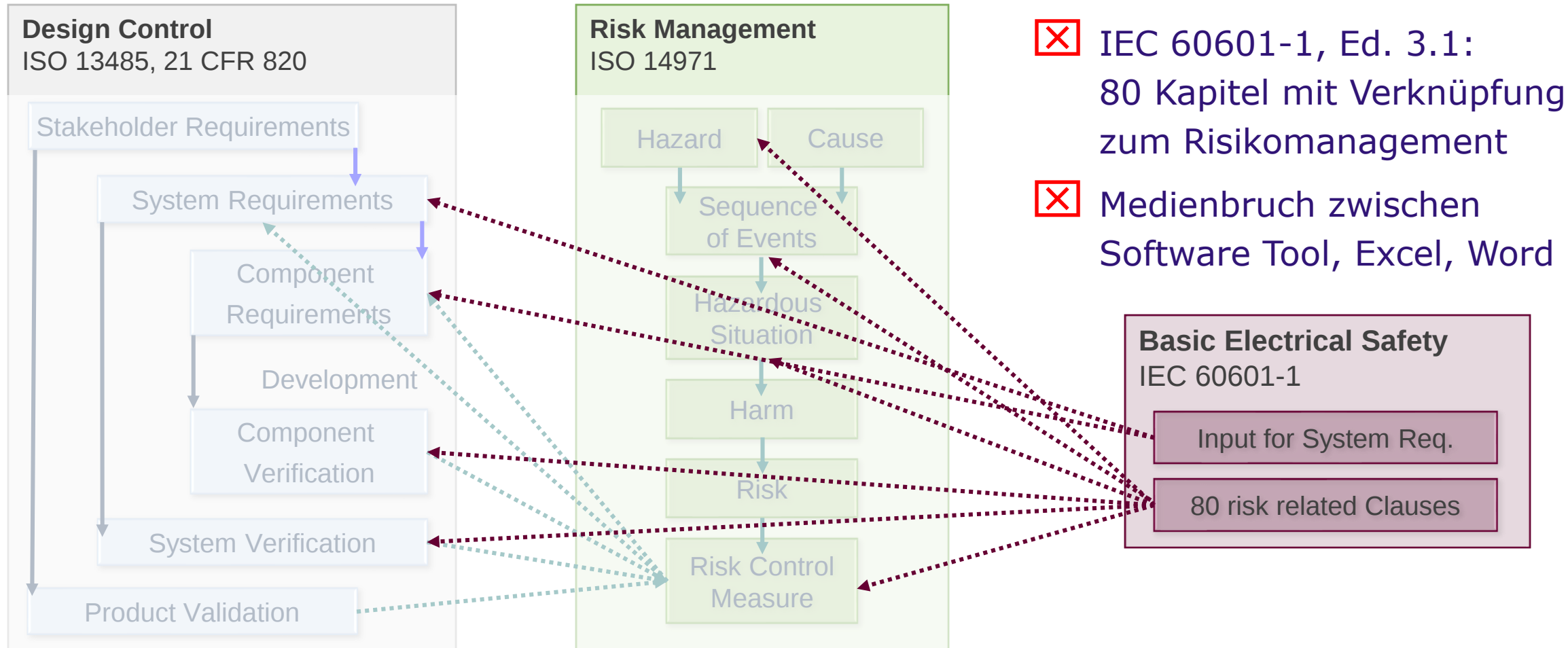
Beispiel: Risikomanagement (ISO 14971)



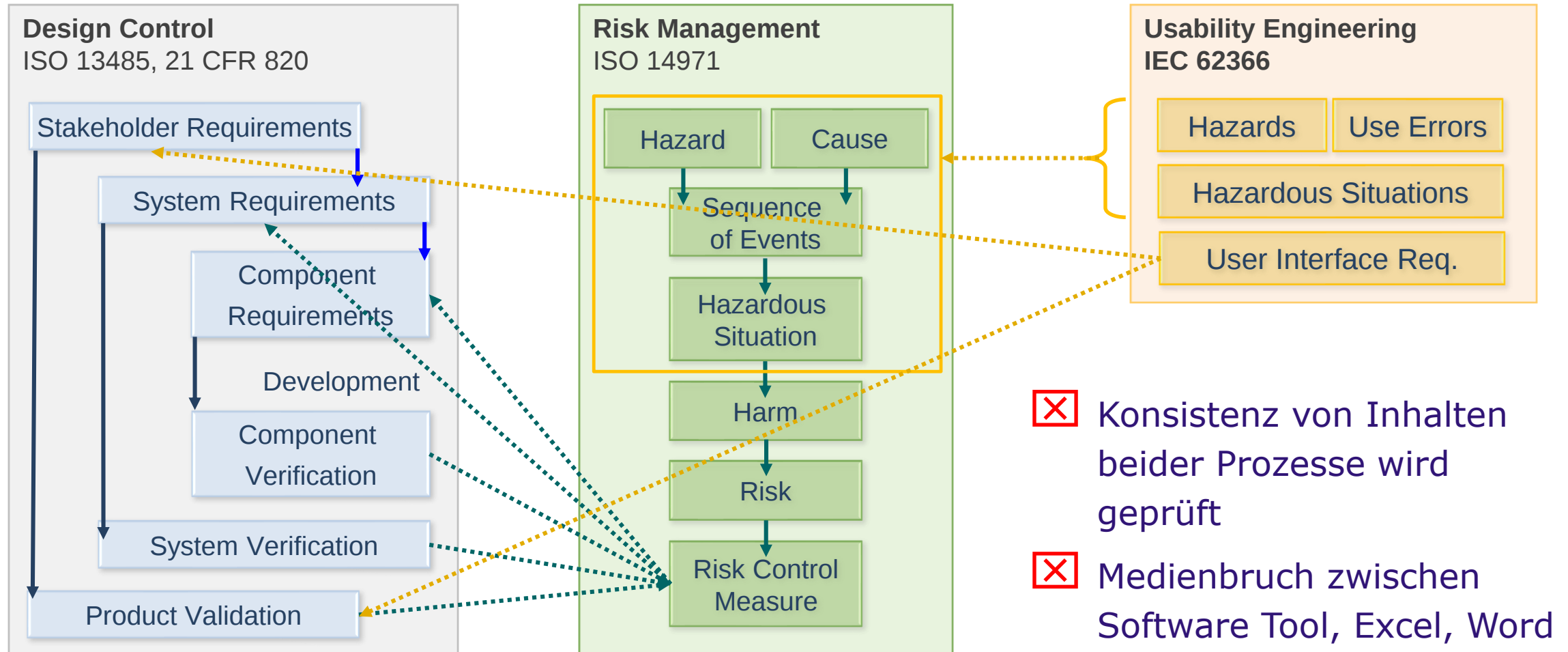
Risk Analysis		Risk Analysis		Risk Analysis		Risk Control		Risk Control		Final Risk Evaluation	
Hazard	Unfavorable sequence of events	Cause (event)	Hazardous situation	Harm	Risk	Risk Control Measure	Residual Risk	Risk Control Measure	Residual Risk	Final Risk Evaluation	Final Risk Evaluation
H1: System operation	Use of system for non-intended purpose (e.g., use of system for non-intended purpose)	Use of system for non-intended purpose (e.g., use of system for non-intended purpose)	Use of system for non-intended purpose (e.g., use of system for non-intended purpose)	Use of system for non-intended purpose (e.g., use of system for non-intended purpose)	Use of system for non-intended purpose (e.g., use of system for non-intended purpose)	Use of system for non-intended purpose (e.g., use of system for non-intended purpose)	Use of system for non-intended purpose (e.g., use of system for non-intended purpose)	Use of system for non-intended purpose (e.g., use of system for non-intended purpose)	Use of system for non-intended purpose (e.g., use of system for non-intended purpose)	Use of system for non-intended purpose (e.g., use of system for non-intended purpose)	Use of system for non-intended purpose (e.g., use of system for non-intended purpose)
		Use of system for non-intended purpose (e.g., use of system for non-intended purpose)	Use of system for non-intended purpose (e.g., use of system for non-intended purpose)	Use of system for non-intended purpose (e.g., use of system for non-intended purpose)	Use of system for non-intended purpose (e.g., use of system for non-intended purpose)	Use of system for non-intended purpose (e.g., use of system for non-intended purpose)	Use of system for non-intended purpose (e.g., use of system for non-intended purpose)	Use of system for non-intended purpose (e.g., use of system for non-intended purpose)	Use of system for non-intended purpose (e.g., use of system for non-intended purpose)	Use of system for non-intended purpose (e.g., use of system for non-intended purpose)	Use of system for non-intended purpose (e.g., use of system for non-intended purpose)
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- ❌ Unhandliche Tabellen
- ❌ Redundante Informationen
- ❌ Aufwendige Änderungen
- ❌ Medienbruch Design Control und Risk Management
- ❌ Vollständigkeit???

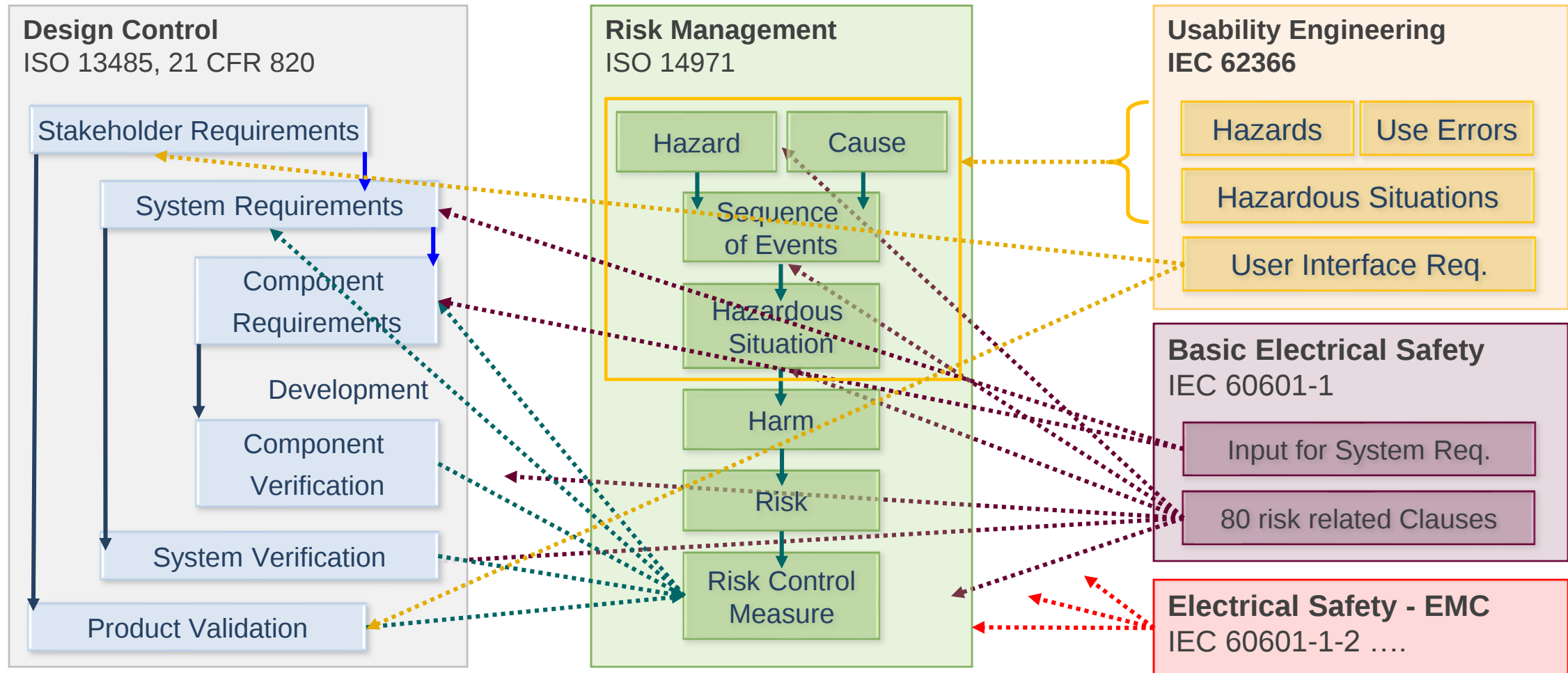
Beispiel: Elektrische Sicherheit (IEC 60601-1)



Beispiel: Usability (IEC 62366-1)



Zukunft: weitere Schnittstellen!



Wiederverwendung von Informationen

Automatisches Speichern Dokument1 - Word

Datei Start Einfügen Entwurf Layout Referenzen Sendungen Überprüfen Ansicht Entwicklertools Hilfe Suchen Teilen

Calibri (Textkörper) 12

AaBbCcDc AaBbCcDc AaBbCcDc

1 Standard 1 Kein Lee... Überschrift...

Bearbeiten Diktieren

Vertec Zwischenablage Schriftart Absatz Formatvorlagen Sprache

2 Intended Purpose

2.1 Medical Purpose

The PRODUCT system is an imaging tool used to detect and visualize photo absorbers in soft tissue with optical and acoustic properties similar to breast tissue or tissue of regions as defined by specific indications below.

Photo absorbers include, but are not limited to:

- Endogenous: hemoglobin (oxygenated and deoxygenated state), melanin
- Exogenous: organic dyes approved for clinical use, including ICG

The system provides two-dimensional, real-time visualization of acoustic and optoacoustic information at a depth of up to several centimeters.

The PRODUCT system is indicated for measurement of the MSOT values in the bowel wall of patients with an established diagnosis of inflammatory bowel disease (IBD), specifically Crohn's Disease (CD) and Ulcerative Colitis (UC). The MSOT values provided may be used as an aid to the assessment of inflammatory disease activity in the bowel wall.

2.1.1 Indications

Application of the PRODUCT system is indicated for:

- Any condition that requires medical imaging for visualization and quantification of the listed photo absorbers
- Imaging at a depth within the range specified in the instructions for use.

Application of the PRODUCT system is indicated for:

- Patients with an established diagnosis of IBD in the lower gastrointestinal tract.

2.1.2 Contraindications

The PRODUCT system is in general not intended to be used for:

- Imaging of eyes
- Imaging of organic dyes in patients with known intolerance of such dye.

Seite 1 von 1 227 Wörter Englisch (Vereinigte Staaten) Anzeigeeinstellungen Fokus 130 %

Automatisches Speichern Dokument2 - Word

Datei Start Einfügen Entwurf Layout Referenzen Sendungen Überprüfen Ansicht Entwicklertools Hilfe Suchen Teilen

Calibri (Textkörper) 12

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Bearbeiten Diktieren

Vertec Zwischenablage Schriftart Absatz Formatvorlagen Sprache

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Seite 2 von 5 440 Wörter Englisch (Vereinigte Staaten) Anzeigeeinstellungen Fokus 140 %

Automatisches Speichern Dokument2 - Word

Datei Start Einfügen Entwurf Layout Referenzen Sendungen Überprüfen Ansicht Entwicklertools Hilfe Suchen Teilen

Calibri (Textkörper) 12

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Bearbeiten Diktieren

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Seite 3 von 5 440 Wörter Englisch (Vereinigte Staaten) Anzeigeeinstellungen Fokus 140 %

Automatisches Speichern Dokument2 - Word

Datei Start Einfügen Entwurf Layout Referenzen Sendungen Überprüfen Ansicht Entwicklertools Hilfe Suchen Teilen

Calibri (Textkörper) 12

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1 Standard 1 Kein Lee... Überschrift...

Bearbeiten Diktieren

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Seite 4 von 5 440 Wörter Englisch (Vereinigte Staaten) Anzeigeeinstellungen Fokus 140 %

Automatisches Speichern Dokument2 - Word

Datei Start Einfügen Entwurf Layout Referenzen Sendungen Überprüfen Ansicht Entwicklertools Hilfe Suchen Teilen

Calibri (Textkörper) 12

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1 Standard 1 Kein Lee... Überschrift...

Bearbeiten Diktieren

Vertec Zwischenablage Schriftart Absatz Formatvorlagen Sprache

2 Intended Purpose

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Photo absorbers include, but are not limited to:

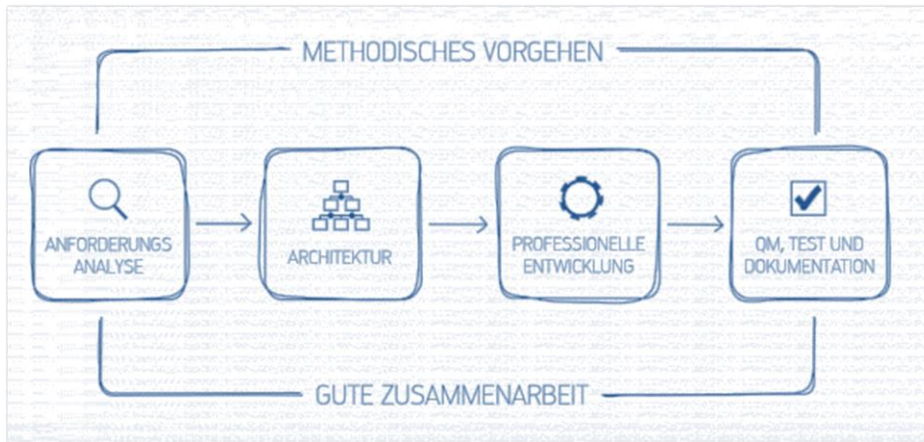
- Endogenous: hemoglobin (oxygenated and deoxygenated state), melanin
- Exogenous: organic dyes approved for clinical use, including ICG

The system provides two-dimensional, real-time visualization of acoustic and optoacoustic information at a depth of up to several centimeters.

Seite 5 von 5 440 Wörter Englisch (Vereinigte Staaten) Anzeigeeinstellungen Fokus 140 %

Verknüpfung zwischen Entwicklung & Produktion





Wünsche:

- Effiziente Dokumentenerstellung, Review und Freigabe
- Transparenz, Nachvollziehbarkeit
- Dokumentierte Entscheidungen
- Verknüpfen von Prozessen/Informationen
- Unterstützung von Abläufen
- Individual anpassbar, leichte Bedienung
- Einfacher Zugriff / jederzeit verfügbar
- Langfristig reduzierter Aufwand

Unterstützen statt ausbremsen



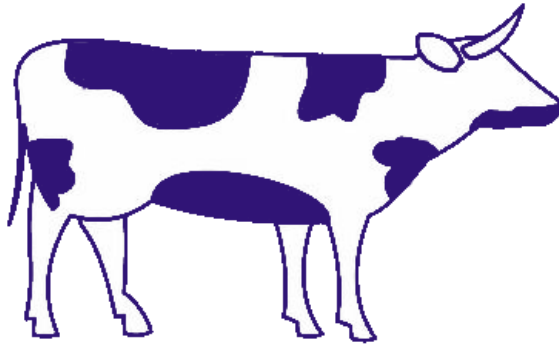
Digitale Zukunft: Knowledge Units

Dokumentenübergreifende Verknüpfung von Informationen

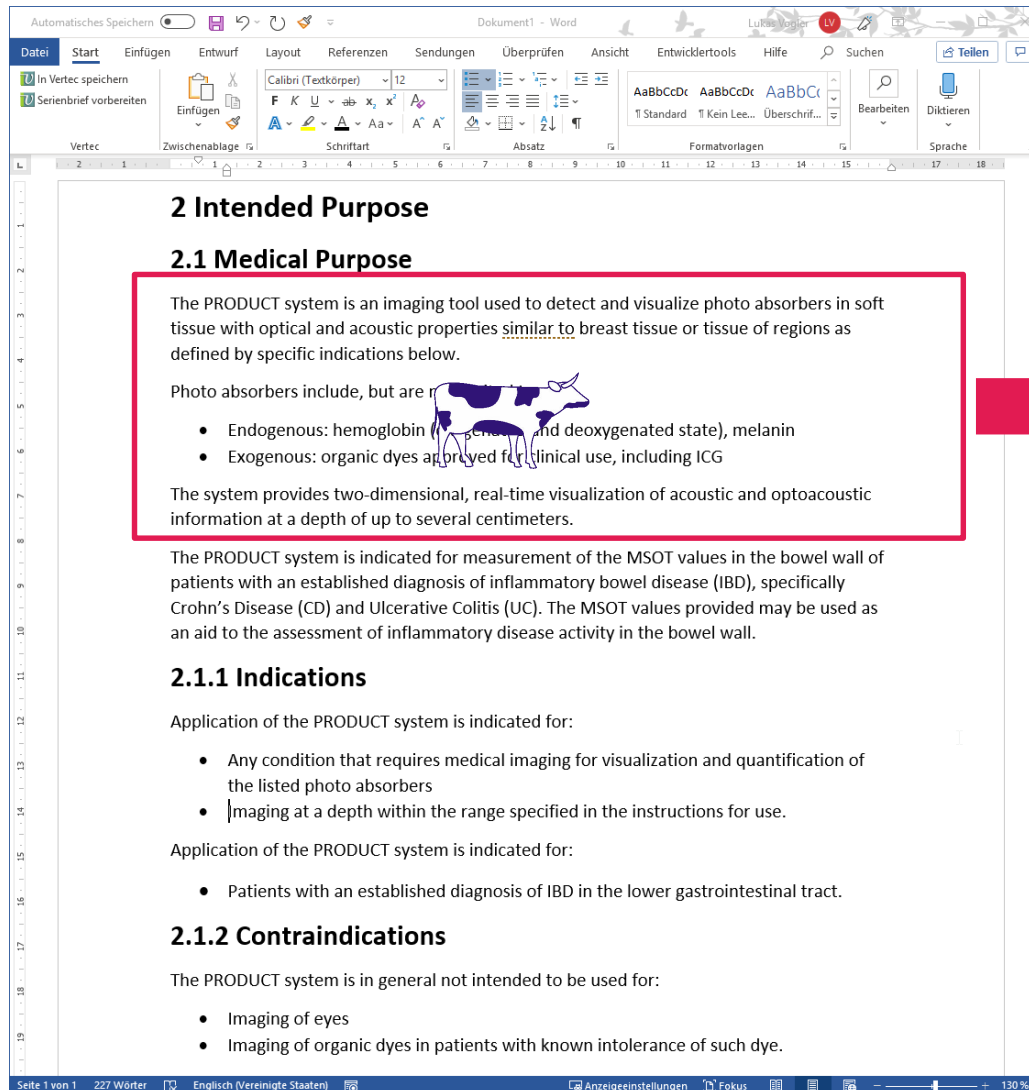
AVASIS

inspiring PLM solutions

Die Knowledge Unit = KU



- Einzelne, identifizierbare Einheit
- Ist Bestandteil eines/mehrerer Dokumente
- Wird potentiell wiederverwendet
- Hat Attribute für Kategorien/Zuordnung
- Eigener Lebenszyklus
- Digitale (zentrale) Verwaltung



Intended Purpose < 01 - Stakeholder > +

localhost/polarion/#/project/ProductDevelopment/wiki/StakeholderLevel/Intended%20Purpose

Apps HTML Color Picker Open AIR Secure File Exchange 8 Tips to Capture B... TechWell | How to... www.incose.org/chi... Writing Software R... Sophist Blog OTS/SOUP Softwar... Weitere Lesezeichen

Normal B I Arial 10

2 Intended Purpose

2.1 Medical Purpose

PDT-9396 - The PRODUCT system is an imaging tool used to detect and visualize photo absorbers in soft tissue with optical and acoustic properties similar to breast tissue or tissue of regions as defined by specific indications below.

Photo absorbers include, but are not limited to:

- Endogenous: hemoglobin (oxygenated and deoxygenated state), melanin
- Exogenous: organic dyes approved for clinical use, including [ICG](#)

The system provides two-dimensional, real-time visualization of acoustic and optoacoustic information at a depth of up to several centimeters.

Intended Purpose, Medical Purpose, 2

2.1.1 Indications

PDT-9397 - Application of the PRODUCT system is indicated for:

- Any condition that requires medical imaging for visualization and quantification of the listed [photoabsorbers](#)
- Imaging at a depth within the range specified in the instructions for use

Intended Purpose, Indication, 1

2.1.2 Contraindications

PDT-9415 - The PRODUCT system is in general not intended to be used for

- Imaging of eyes
- Imaging of organic dyes in patients with known intolerance of such dye

Intended Purpose, Indication, 1.0

Properties

ID: PDT-9396

*Status: [Draft](#)

Knowledge Unit Category: [Intended Purpose](#)

Knowledge Unit Sub Category: [Medical Purpose](#)

Version: 2.0

Last Approval: 2019-09-22 14:23

Links

[Edit Links](#)

has parent

[MSOT-9263 - Medical Purpose](#)

Documents

This Work Item is contained in [Intended Purpose \(this document\)](#) and referenced in:

- [Risiko Management Plan Example](#)

Entwicklungsprozess – Traceability von Anforderungen

„Analog“
mit Word

		Software Traceability Report		Record No.	Version
Research & Development				<wwmdd>	<xx>

6 Traceability and Test Coverage Report – Software Requirement Level

Design Input ID	Software Requirement	Software Test	Rational for missing traceability
DI-1	SWRS-11-1	SWTEST-1	-

Digital

Source Document			
Document(s)	Status	Revision / Date	Traceability Status
 Product Requirements	Draft	1125 DRAFT 2016-02-17 15:01	Work Items total: 113 Valid Traceability: 99 Missing Traceability: 14
Linked Specification(s)			
Document(s)	Status	Revision / Date	
 System Specification	Draft	1107 DRAFT 2016-02-17 13:49	

Entwicklungsprozess – Traceability von Anforderungen

Product Requirements Traceability

Project/Product: cMSOTv1
Revision: 18250 **DRAFT**

Record Changes

Revision	Date	Author	Changes
6566	2016-07-27	Polarion (Sarah Panten)	Update of 1st Version (Polarion revision 11698)
16655	2017-07-12	Sarah Panten	Update with new revision of Product Requirements
18250	2017-10-03	DRAFT	

Requirements Document

Document(s)	Status	Revision / Date	Traceability
Product Requirements	✓ Approved	19388 2017-11-09 17:30	Work Items Valid: Invalid:

Relevant Specification(s)

Document(s)	Status	Revision / Date
System Specification	✓ Approved	16650 2017-07-12 13:31

Traceability Report

Requirement Work Item	Linked Work Items	Document(s)	Documentation Status	Compliance Status
3 Product Requirements				
3.1 Intended Use				
3.1.1 General Intended Use				
✓ c1-18 - Imaging tool used as support for diagnosis	✓ c1-1253 - Generation of optoacoustic signals	System Specification	Valid	✓
	✓ c1-1256 - Detection of optoacoustic signals	System Specification	Valid	
	✓ c1-1259 - Generation of images and image sequences	System Specification	Valid	
	✓ c1-4745 - Display and analysis of acquired images/image sequences	System Specification	Valid	
	✓ c1-2205 - Multispectral image (Examination)	System Specification	Valid	
✓ c1-19 - Provision of anatomical information	✓ c1-2205 - Multispectral image (Examination)	System Specification	Valid	✓
✓ c1-21 - Provision of molecular information: molecular probes, non-targeted contrast agents	✓ c1-1342 - Multispectral image (Analysis)	System Specification	Valid	✓
✓ c1-25 - Patient population: Gender, age	No linked Work Item(s)	-	-	✗

Entwicklungsprozess – Test Management

Requirement	Test Case	Test Record	Test Compliance Status
 c1-5054 - Requirement with valid test records	 c1-5057 - Valid Test Result	Passed Date: 2015-12-29 12:20 Tester: Project Management Test Run: Demo Test Run (testRunTemplate)	✓
 c1-5055 - Requirement without valid test records	 c1-5059 - Test Case Changed!	Invalid: Test Case Changed! Date: 2015-12-29 12:20 Tester: Project Management Test Run: Demo Test Run (testRunTemplate)	✗
	 c1-5060 - Requirement Changed	Passed Date: 2015-12-29 12:20 Tester: Project Management Test Run: Demo Test Run (testRunTemplate)	
	 c1-5061 - Never planned or executed	Invalid: Never Executed! ---	
	 c1-5062 - Planed but not executed	Invalid: Planned for execution	
 c1-5063 - Requirement changed after test execution	 c1-5060 - Requirement Changed	Invalid: Requirement Changed! Date: 2015-12-29 12:20 Tester: Project Management Test Run: Demo Test Run (testRunTemplate)	✗
 c1-5082 - Requirement without a test case	No Test Cases found!		✗

Entwicklungsprozess – Test Management

Executed Test Runs

Test Run	Status	Revision/Date	Test Cases	Current Results
 Component - Laser Verification	✓ Done	19171 2017-10-26 10:38	Planned: 22 Waiting: 0 Executed: 22	Passed: 22 Failed: 0 Blocked: 0
☐ SW - Verification - HW related - Laser	✓ Done	19171 2017-10-03 20:31	Planned: 6 Waiting: 1 Executed: 5	Passed: 5 Failed: 0 Blocked: 0

Requirements having invalid Test Results

Requirement Work Item	Test Cases	Document	Last Test Result
✓  c1-1192 - Operating temperature	 c1-4750 - Standard - IEC 60601-1 (Electrical Safety)	System Verification - Test Spec - Safety & Labeling	Invalid: Never executed!
✓  c1-3418 - Laser output energy	✓  c1-3921 - Laser Configuration	SW - Test Spec - HW Related Functionality	Invalid: Requirement changed

Open Anomalies

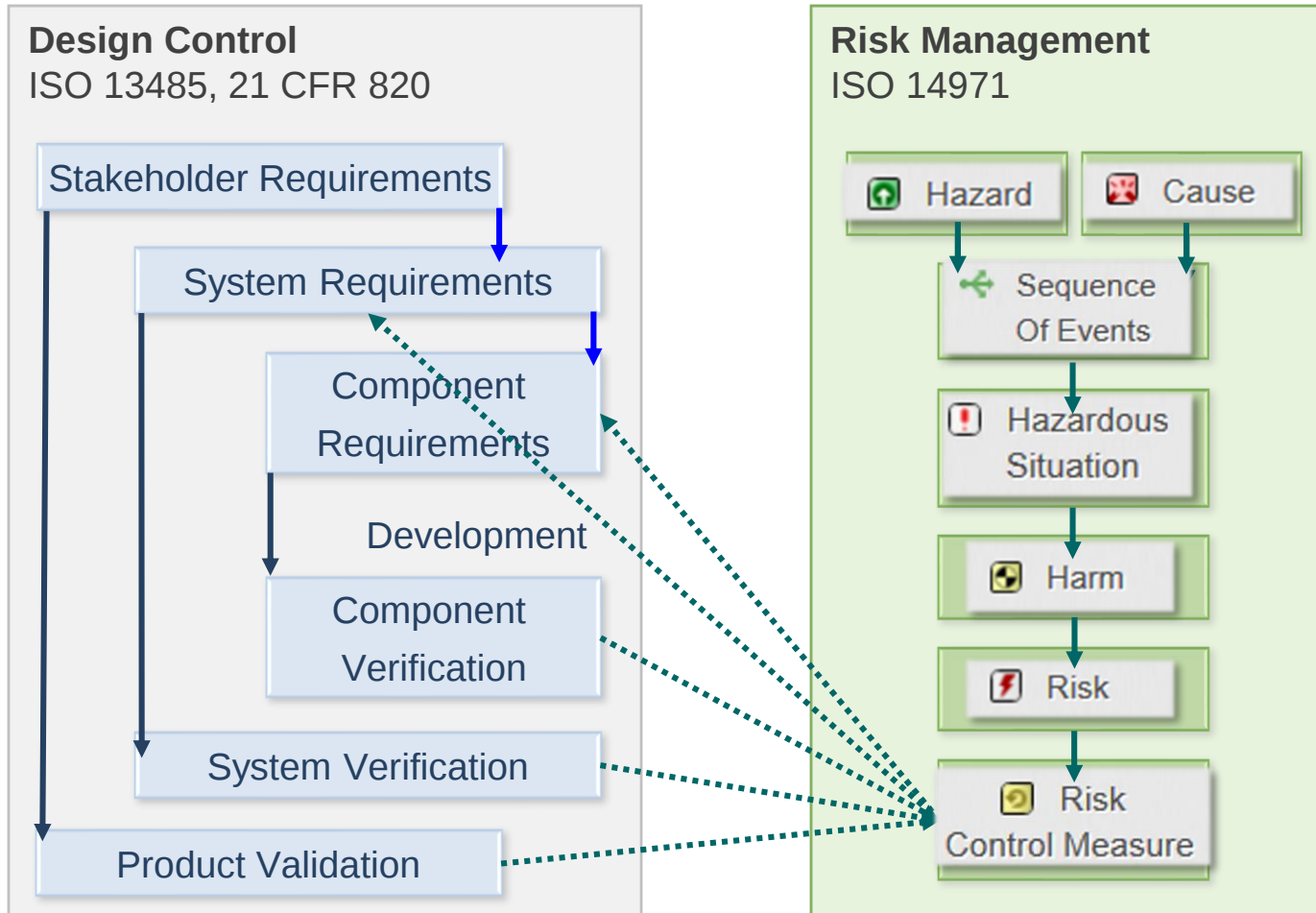
Anomaly	Status	Test Case
All anomalies have been evaluated and closed		

Summary of test results

Change Control: Any changes of requirements or test cases are pointed out

Evidence, that no unresolved test cases exist

Risikomanagement (ISO 14971)



- ✓ 1x Eingabe, x-fach verknüpfen
- ✓ Kein manuelles "Tracking"
- ✓ Verlinkung zu Spezifikationen und Test Ergebnissen
- ✓ Individuelle Anpassung von Übersichten
- ✓ Erstellung von Reports
- ✓ Übersicht der Vollständigkeit

Risk Analysis and Control Table

This report shows all initial risks and their complete paths from the root cause over mitigation(s) to the final assessment

[Show Sequences of Events Table](#) •
 [Show Risk Control Table](#) •
 [Show Risk Control Matrix](#) •
 [Show Risk Detail Report](#)

[Export Risk Table to Excel](#)
[enable / disable](#)

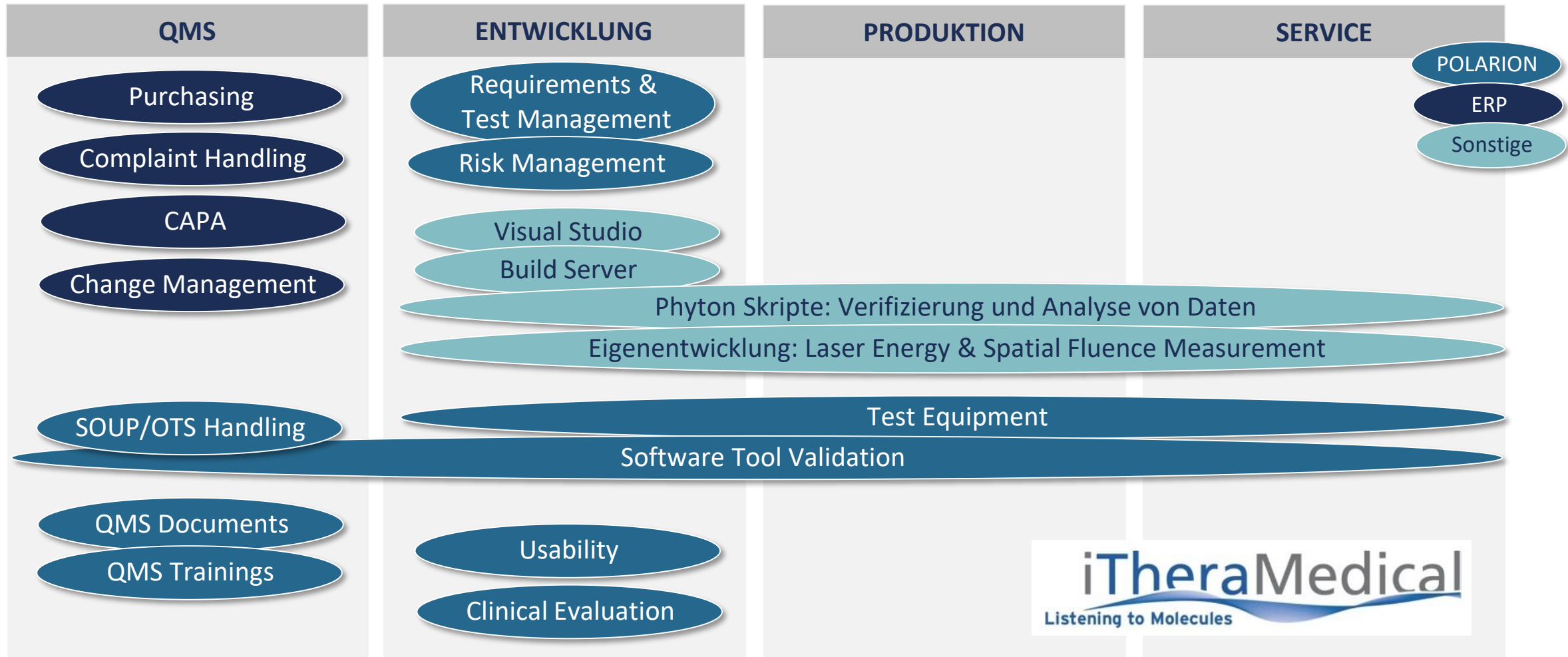
#	Sequences of Events				
	Hazard / Reg. Requirement	Sequence of Events	Hazardous Situation	Cause	Category
1	 c1RM-365 - Protective earthing of moving parts	 c1RM-707 - protective earth connection of moving part breaks - > voltage carrying conductor has contact with moving part -> voltage on moving part	 c1RM-706 - Person is exposed to voltage	 c1RM-716 - Repetitive movement of part damages protective earth connection	HW Failure
2	 c1RM-15 - Pathogenic germs and other stuff	 c1RM-173 - Inappropriate reprocessing for specific device application -> residues from previous device application -> contamination with pathogenic germs	 c1RM-180 - Person is exposed to pathogenic germs	 c1RM-69 - User not reprocesses devices according to provided reprocessing information	Use Error



Initial Risk Assessment				
Risk ID	Harm	Harm Severity	Risk Probability	Acceptance Level
 c1RM-717 - Risk for electrical shock due to damage of protective earth connection	 c1RM-23 - Serious injury or death by electrical shock	critical	remote	 Not accepted
 c1RM-228 - Risk for infection: contamination with pathogenic germs due to inappropriate reprocessing for device application	 c1RM-46 - Infection with pathogenic germs	serious	remote	 Further Investigation

Customization of displayed information according to specific work flow or personal preferences

Lösungsansatz: Einsatz von Tools für Prozesse



Zukunft: Aufbau eines KU Repositories



**MDD
Produktakte**

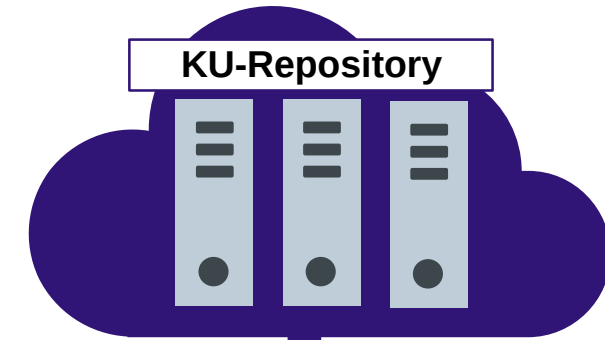


**MDR
Produktakte**

1. Identifizieren von **Knowledge Units (KU)**
2. Knowledge Unit Klassifizierung
3. Vorlagen werden um KU Platzhalter ergänzt



- Dokumente können bestehen aus:**
- Vorhandenen Knowledge Units
 - Produktspezifische Inhalte



KU-Repository

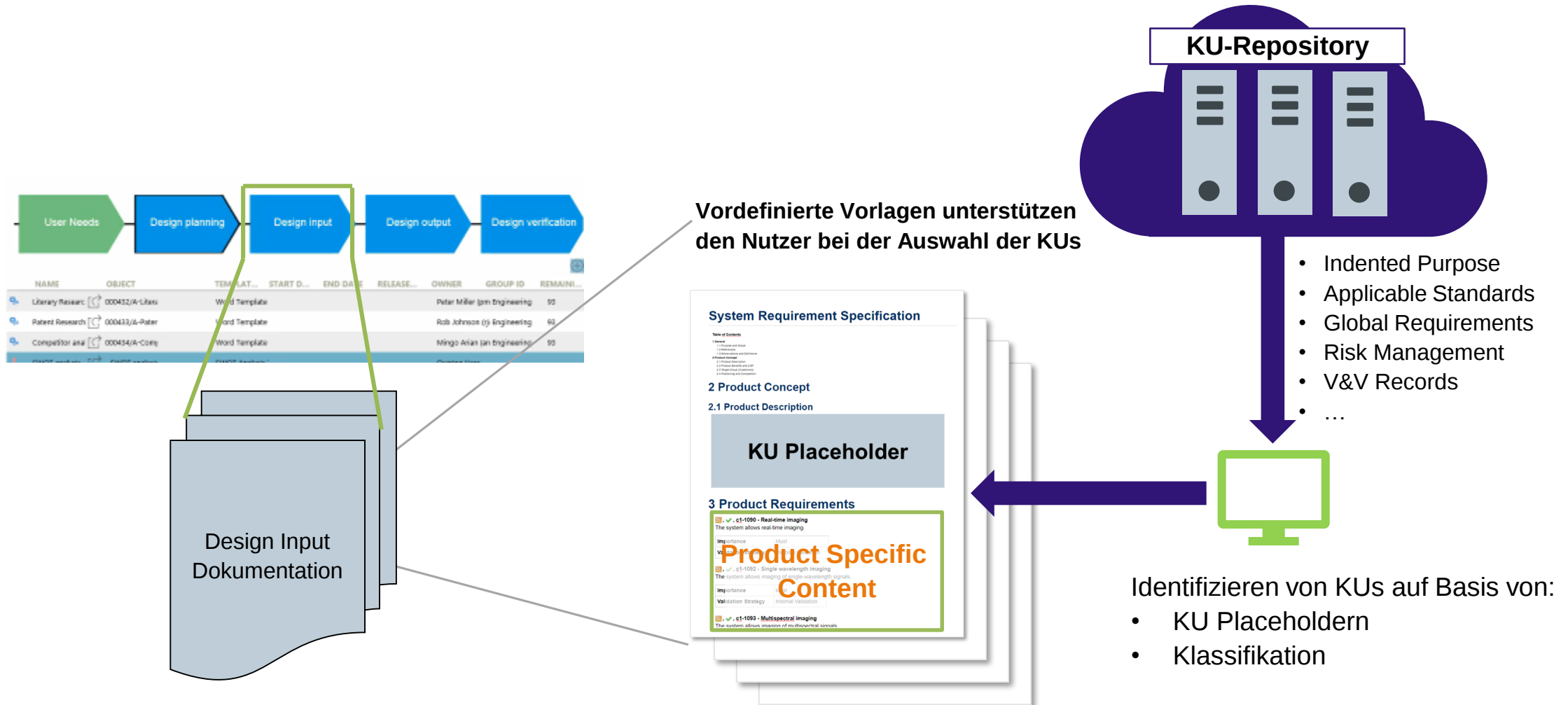
- Indented Purpose
- Applicable Standards
- Global Requirements
- Risk Management
- V&V Records
- ...



Identifizieren von KUs auf Basis von:

- KU Platzhalter
- Klassifizierung

Wiederverwendung von KUs bei Neuentwicklung oder Dokumentation: Zeitersparnis und Qualitätsverbesserung



Nutzen

- Reduzierter Aufwand für Erstellung und Pflege von KUs in Dokumenten
- Sichtbarkeit von Abhängigkeiten in mehreren Prozessen
- Zentrale Verwaltung in KU Datenbanken möglich
- Wiederverwendung statt Neuerstellung

Herausforderungen

- Gesamtüberblick erforderlicher KUs fehlt
- Fehlende Definitionen/Klassifizierungen
- Welche Dokumente brauchen welche KUs?
- Welche KUs brauche ich für eine Zulassung?
- Digitale Infrastruktur erforderlich
- Aufbau von KU Datenbanken

Veranstaltungsreihe

MDR als Chance zur digitalen Transformation

Wechsel von Dokumenten zu Informationseinheiten

21. April 2020, 9-17 Uhr

Veranstaltungsort: Zühlke Engineering
Landshuter Allee 12, 80637 München

Interessiert?

Kontakt: info@avasis.biz

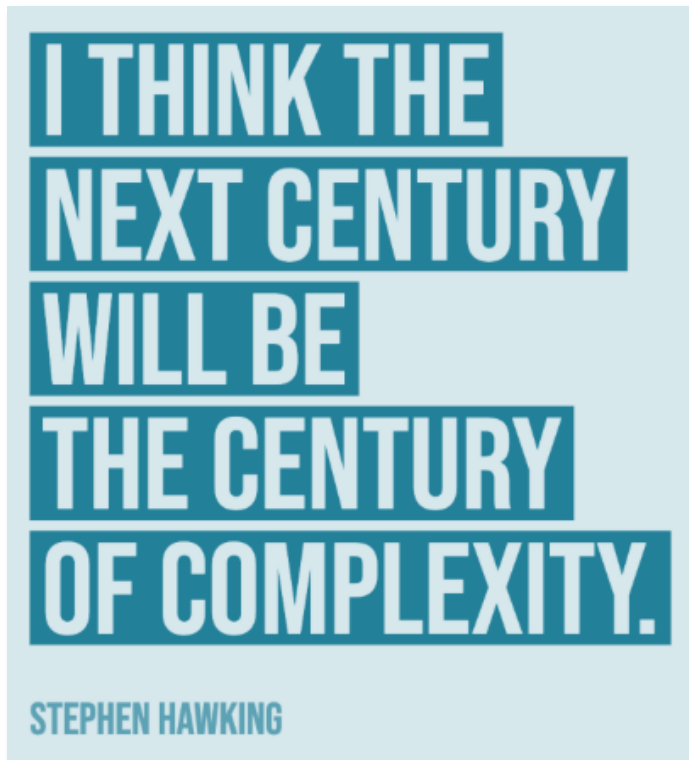
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- **Benannte Stelle TÜV SÜD:** Aktueller Stand der Digitalisierung beim TÜV SÜD
- **Knowledge Unit Konzepte & Workshops:** Vorstellung und Diskussion der KU Konzepte für Entwicklung, Risikomanagement, Usability und Klinische Bewertung
- **Case Studies:** Vorträge von Firmen mit Beispielen für die digitale Umsetzung von Prozessen und Dokumenten

Prozessen und Dokumenten
Beispielen für die digitale Umsetzung von
Firmen mit

„Knowledge Units: A smart way to manage complexity?!“



**WIR GLAUBEN,
DIE MDR IST EINE
CHANCE – MIT DER
„KU“ ALS HEBEL
FÜR DIE
DIGITALISIERUNG
DER
TECHNISCHEN
DOKUMENTATION**



Herzlichen Dank!

Interesse an der Mitarbeit
beim Knowledge Unit Konzept?
Kontakt: Sarah.panten@avasis.biz

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