

Digitalizing lifecycle processes
in the Medical Device Industry
with inspiring solutions

four®

Rick Stroot – Medische Elektronica – 6 feb 2024

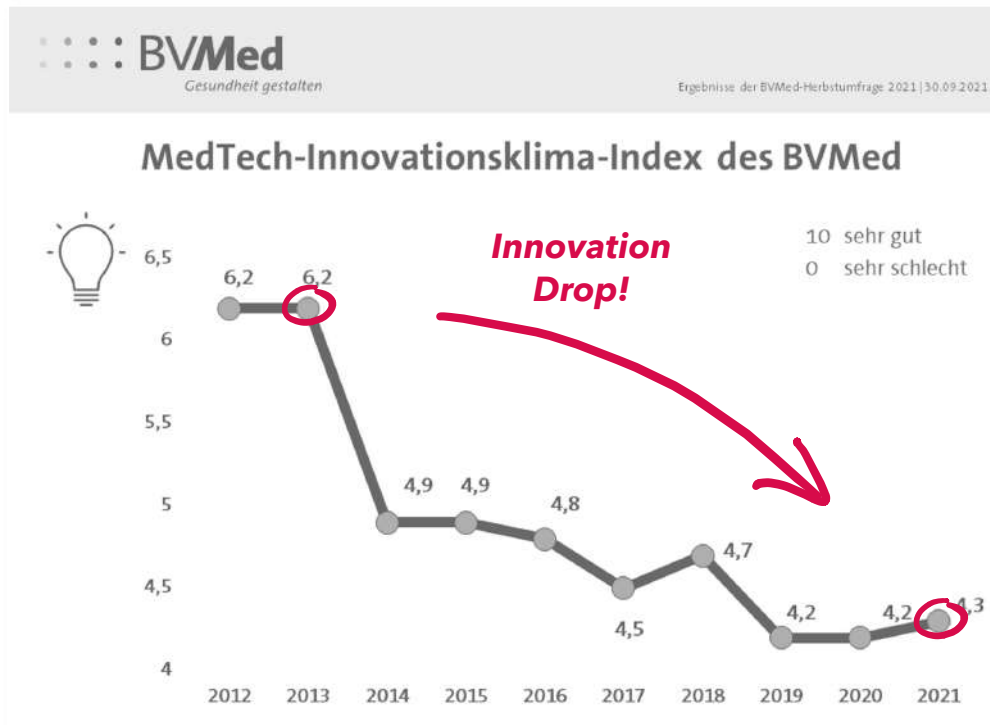
Agenda



- Key Challenges in the Medical Technology Industry
- Overview of inspiring solutions for the Medtech Industry



MEDTECH Industry today



**Less and less innovation
in Medtech in Europe**



**Patients do not receive
the care they need**



**Competition & lead from
companies from other countries
is increasing!**



Barriers to Innovation



Example Germany:

BV Med MedTech-Marktpräsentation
27.07.2023 Seite 25

Aktuelle Herausforderungen

- Unsichere Lieferketten
- Gestiegene Kosten für Energie, Rohstoffe und Logistik
- Inflation und steigende Löhne

Hausgemachten Probleme

- • Kompliziertes regulatorisches System für Medizinprodukte (MDR)
- Überbordende Bürokratisierung und Regulierungswut
- • Schleppende Digitalisierung und mangelnde Datennutzung
- Unzureichende Unterstützung des Mittelstandes

Survey results from German industry association BVMed: Current challenges of the industry, key problems:

- **Too complex regulatory system** for medical devices (**MDR/IVDR**)
- **Digitalization** is far **too slow** and **lack of data usage**

DIGITALISATION supports management & implementation of complex regulatory requirements for:

- 1. PROCESSES**
- 2. TECHNICAL DOCUMENTATION**



Key Challenges

Problems with regard to information in regulatory processes & technical documentation (TD):

1. Consistent regulatory language
2. Reuse & consistency
3. Dependency of Information
4. Completeness of required information

Through
Digitalization



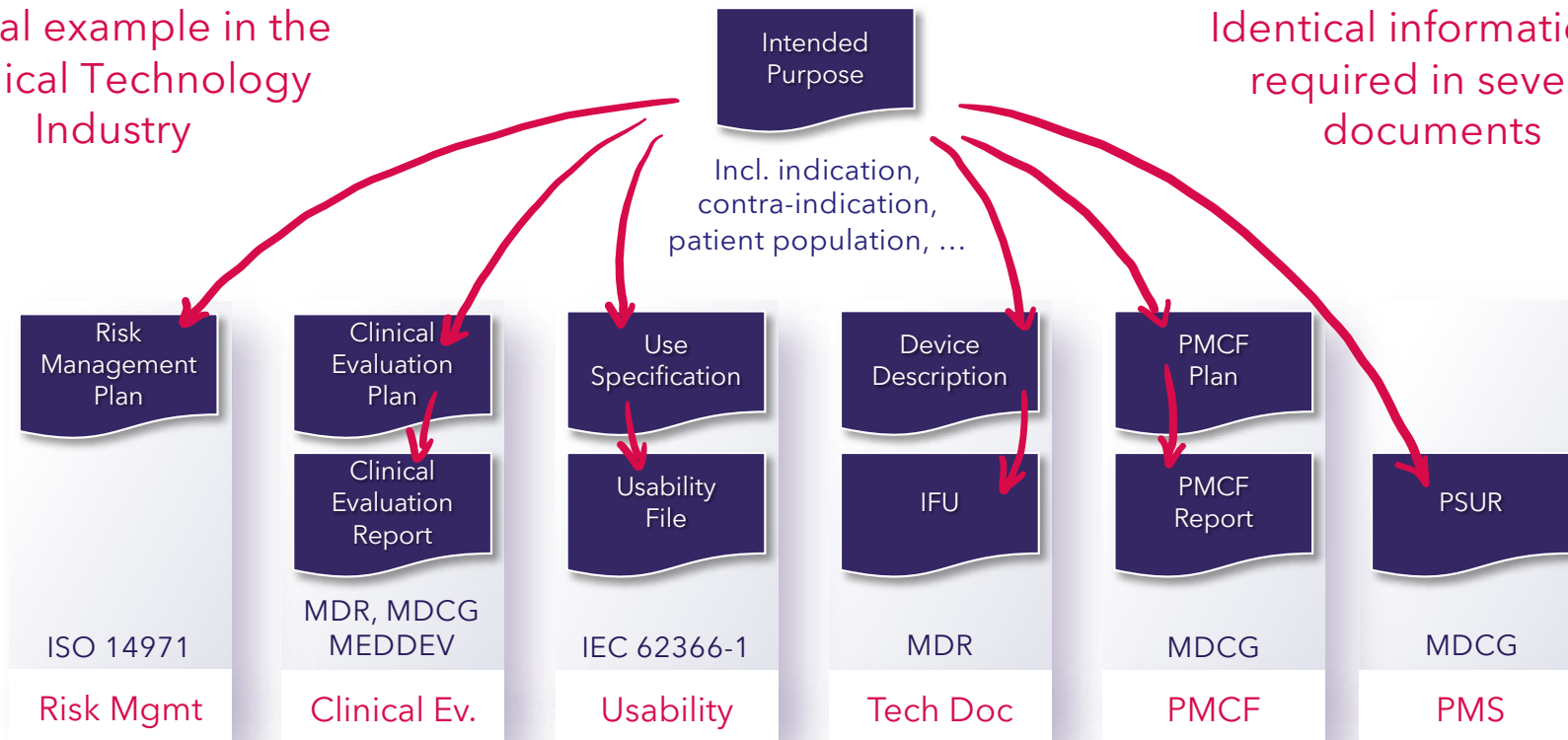
Industry Challenge 2

Reuse of Information for Regulatory Compliance



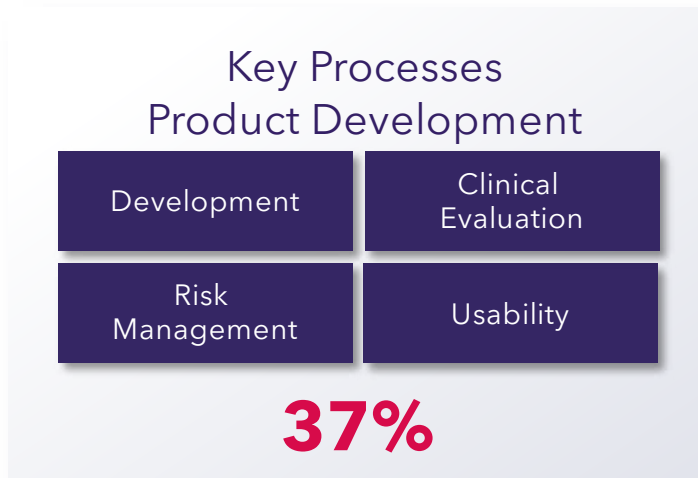
Typical example in the Medical Technology Industry

Identical information is required in several documents



Industry Challenge 2

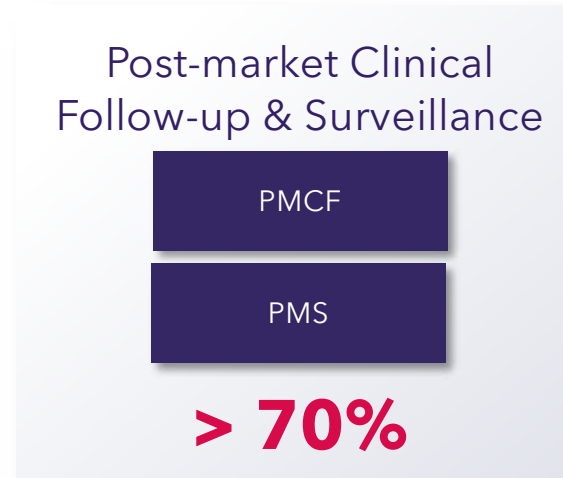
Reuse of Information: Potential of Digitalization



Source: avasis

**„MDR als Chance zur digitalen Transformation:
Wechsel von Dokumenten zu Informationseinheiten“**

World Café Workshop, 15.05.2019, Zürich
World Café Workshop, 24.09.2019, Munich



Source: avasis

**Analysis of content required in PMS/PMCF
documents acc. to related MDCG guidances**

For details see avasis Webinar „PMS & PMCF“

+ Reuse for Variations!



Technical Solution 3

Transformation from Documents to Knowledge



2 Intended Purpose

2.1 Medical Purpose

PDT-9396 - The PRODUCT system is an imaging tool used to detect and visualize and acoustic properties similar to breast tissue or tissue of regions as defined by

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 optical properties over several centimeters.

PDT-9430 - The PRODUCT system is indicated for measurement of the MSOT values for the established diagnosis of inflammatory bowel disease (IBD), specifically Crohn's Disease. The MSOT values provided may be used as an aid to the assessment of inflammatory bowel disease.

2.1.1 Indications

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

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



Technical Solution 3

Manage Information with Work Items



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 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 several centimeters.

Intended Purpose, Medical Purpose

PDT-9430 - The PRODUCT system is indicated for measurement of the MSOT values in the bowel wall of patients with established diagnosis of inflammatory bowel disease (IBD), specifically Crohn's Disease (CD) and Ulcerative Colitis (UC). MSOT values provided may be used as an aid to the assessment of inflammatory disease activity in the bowel wall.

Intended Purpose, [Knowledge Unit Sub]

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, 1.0

PDT-9398 - Application of the PRODUCT system is indicated for:

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

Intended Purpose, Indication, 1.0

Work Item Properties

ID: PDT-9396 **Unique ID**

*Status: Draft **Lifecycle**

Version: 2.0

Last Approval: 2019-09-22 14:23

Links

Edit Links

has parent

- MSOT-9263 - Medical Purpose **Source**

Documents

This Work Item is contained in Intended Purpose (this document) and referenced in:

- Risiko Management Plan Example **Reuse**



Industry Challenge 3

Visualization of Dependencies between Processes



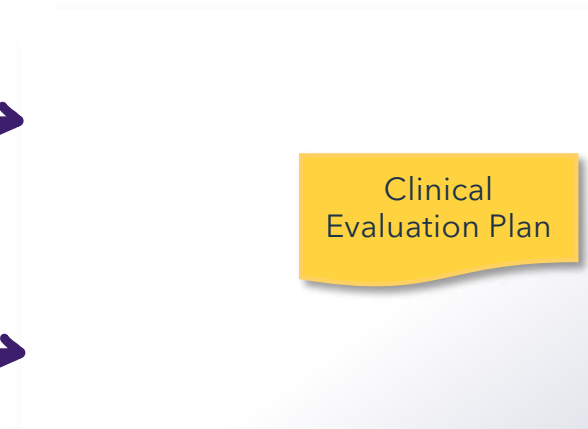
Risk Management Process



Development Process



Clinical Evaluation Process



- Interdependency of processes and related documents
- Connection of documents in form of references



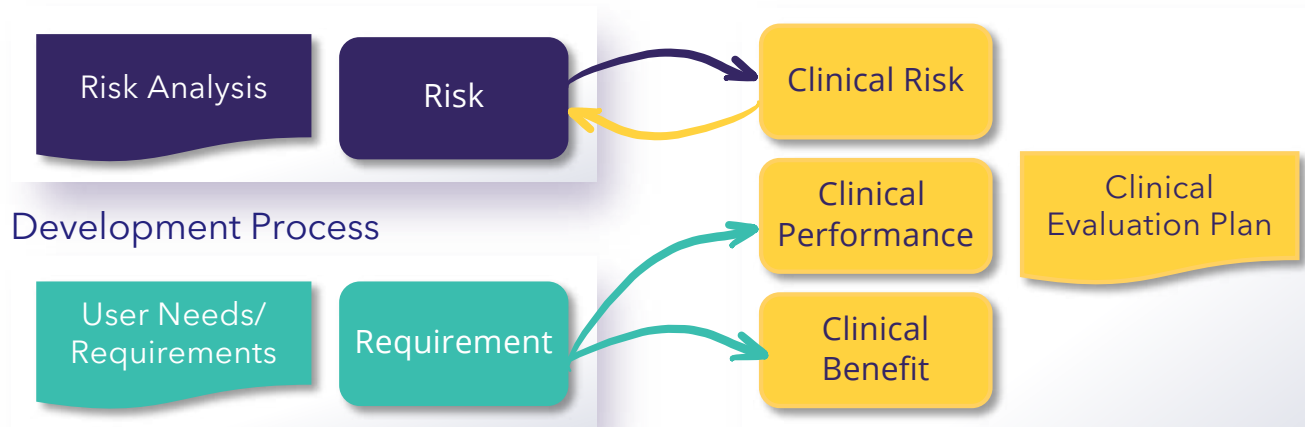
Technical Solution 3

Visualization of Dependencies

Risk Management Process



Clinical Evaluation Process



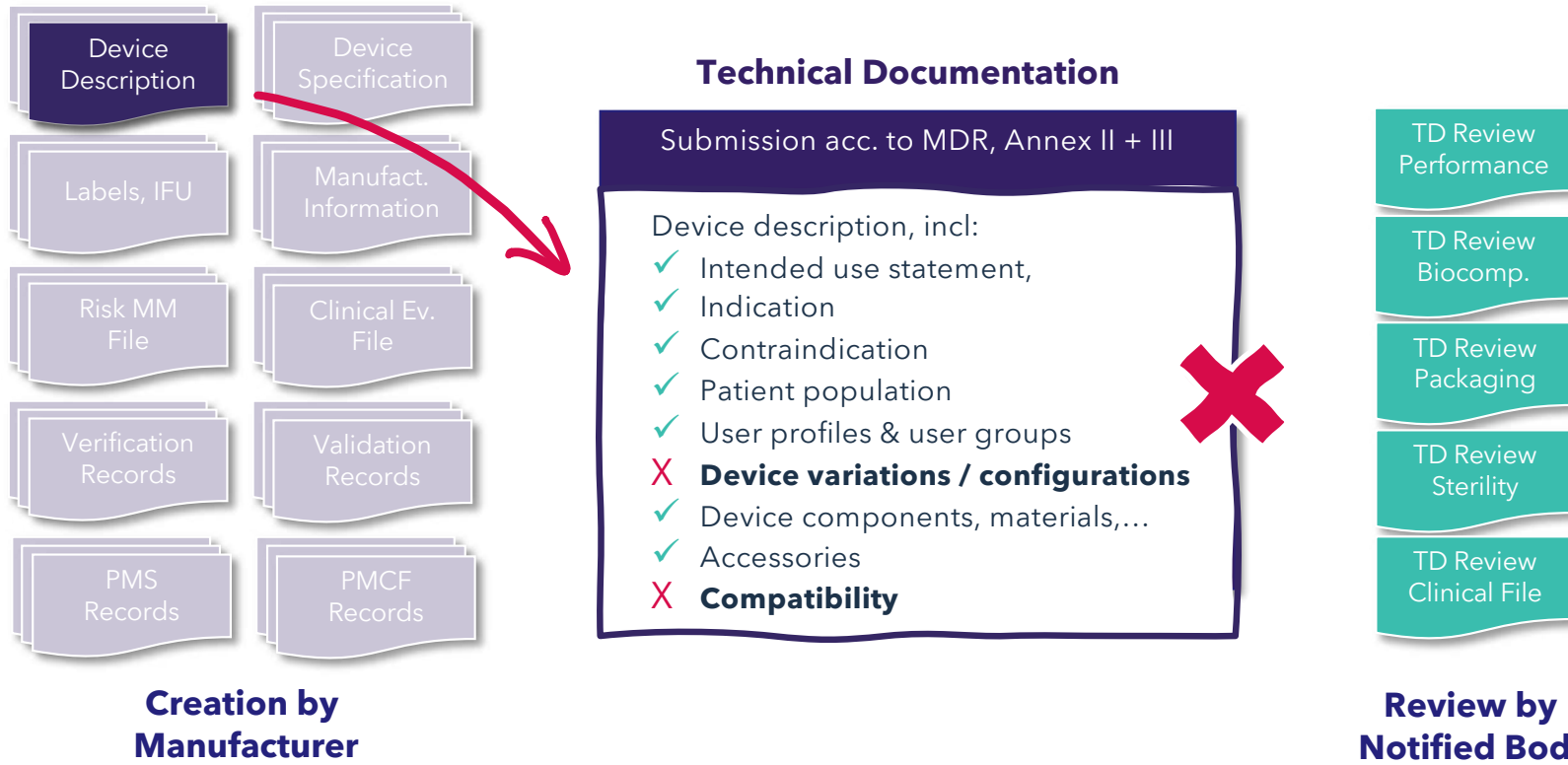
Development Process



- Interdependency of processes and related data in documents
- Connection of single input and output data
- **Connection on data level and not only document level required!**

Industry Challenge 4

Ensuring Completeness of Information



Technical Solution 4

Automated Completeness Checks



Compliance	Regulatory Requirements	Applicable	Requirements	Verification	Execution Status	Test Record(s)
Item	Item	Item	Linked Item(s)/ Rationale	Test Case(s)	Item	Item
- 23. Label and instructions for use						
Valid	PDT22-4321 - Label and instructions for use	Header	Header only	-	-	-
Invalid	PDT22-4322 - Each device shall be accompanied by the information needed to identify the devic...	yes	PDT22-3710 - Label - Device Name (in System Requirements Specification)	PDT22-3741 - Review of label - device name (in System Verification Specification)	Invalid	20220316-1701 - System Verification A.1 Result: Failed Tester: Lukas Vogler Date: 2022-03-16 17:11 UUTs:
			PDT22-3711 - Label - Manufacturer Name (in System Requirements Specification)	PDT22-3742 - Review of label - manufacturer name (in System Verification Specification)	Valid	20220214-2020 - System Test Run #1 - Labeling Result: Failed Tester: Lukas Vogler Date: 2022-03-16 13:43 UUTs:
						20220316-1701 - System Verification A.1

Automated Check (indicated by a red arrow pointing to the 'Invalid' status)

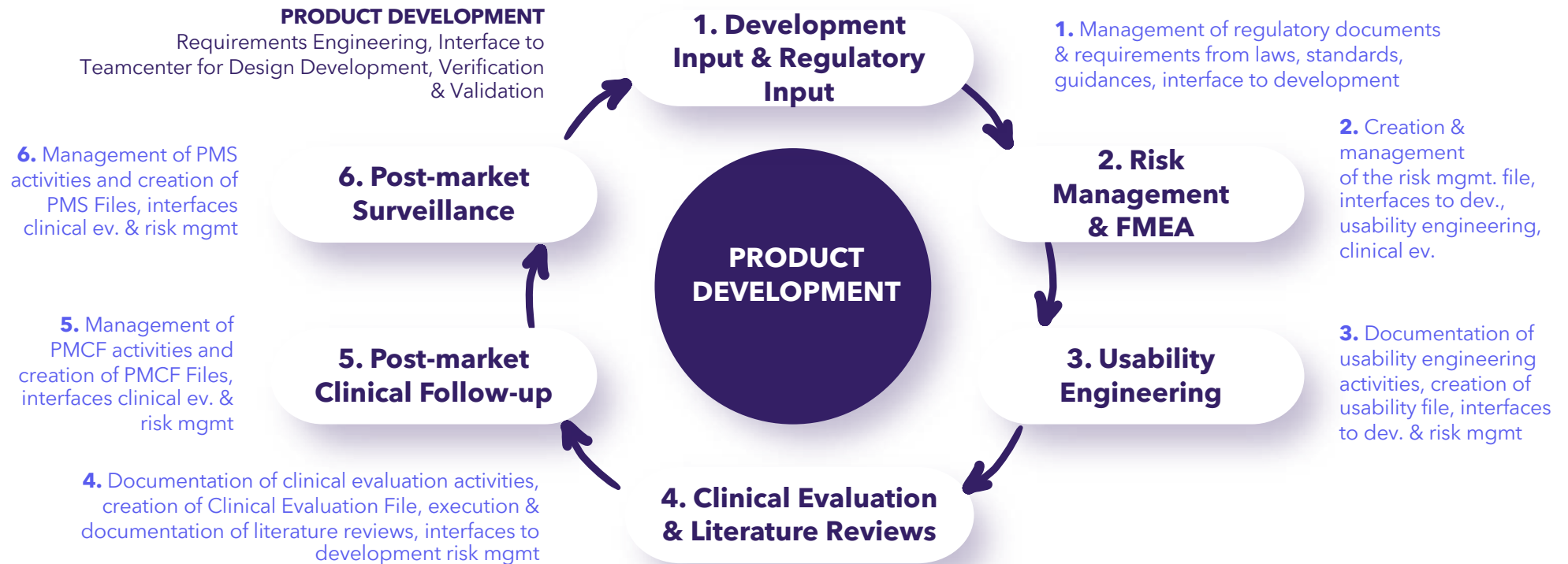
Automated visualization of linked requirements, test cases and test execution status

Regulatory Requirement → **Design Input Requirement** → **Verification Test Case** → **Verification Test Result**



Overview

Solutions for Medical Device Lifecycle Processes



Benefits of presented Solutions

Speeds up processes & Document Creation



Completeness and easy reuse of information in different processes and documents:

- **Save up to 30% of time*** for creation of regulatory documents
- Ensure completeness and consistency of information in different documents
- Visualize the source document of an information unit and documents in which it is reused
- Decide, if changes of information in the source document shall be automatically implemented in other documents as well

Visualize dependencies between single data sets instead of references to documents:

- Fulfill regulatory requirements for traceability between processes and documents
- Analyze automatically the impact of changes across different processes and documents

* Estimated by avasis customers based on calculation of time for „copy & paste“ / „review of consistency“ - Contact provided on request



References



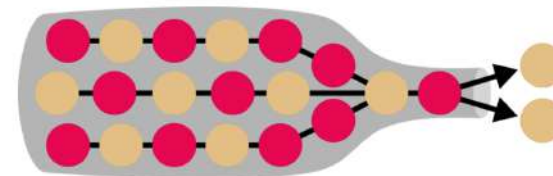
More information
check this website:
<https://mdku.digital/>



Situation in the MedTech Industry

The medical technology sector is one of the most innovative industries in the world, but the innovative strength of manufacturers is constantly being slowed down by ever-increasing regulatory requirements. Proof of the regulatory compliance of a medical device is provided on the basis of the technical documentation, which is the result of the product development process and various interface processes. If regulatory requirements are not fulfilled, manufacturers cannot sell products and therefore cannot operate successfully in economic terms.

Development of
innovative diagnostic or
therapeutic devices



Devices that reach
market access in Europe



Questions?

Expert
Partner

Digital Industries Software

SIEMENS

MEDISCHE ELEKTRONICA
Ontwikkelingen, normen en toepassingen
6 februari 2024 | Van der Valk Vianen



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