

A collage of several photographs showing different views of a modern, multi-story building with a light grey facade and dark window frames. The building has a flat roof with several air conditioning units and a balcony with a red railing. The background shows a clear sky and some distant buildings.

seleon GmbH

Medtech Consulting, Product Development and Production

30th testXpo – International Expo for Materials Testing, Ulm



Digitalization of the development process including testing

Peter Hartung
Head of Business Unit Consulting
seleon gmbh, Heilbronn

High-Class Medical Technology – First-Class Service



- Engineering of medical devices
- Regulatory & Clinical Consulting
- Medical Production



www.seleon.com

Support over the entire product life cycle

customer's core tasks

seleon's network

General Management	Risk Management (Business-related)	Legal Affairs & Insurances	Compliance Management	Product Portfolio Management	Infrastructure & IT
Sales	Installation, Service	User Training	Personnel management (HR services)	Finances, Accounting, Taxes, ERP System	Market analysis/ observation
Marketing	Funding	Intellectual Property (IP) Management	Innovation Management	Product Management	Reimbursement Management
Business Processes & Quality Management	Product Development	Risk Management (Product-/ process-related)	Usability Engineering	Purchasing	Stock, Logistics, Shipping
Production	Quality Assurance	Prod. Maintenance & Sustaining Engineering	Regulatory Affairs	Clinical Affairs	Complaint Handling & Vigilance

seleon's core competences

fundamental activities in case seleon is the legal manufacturer

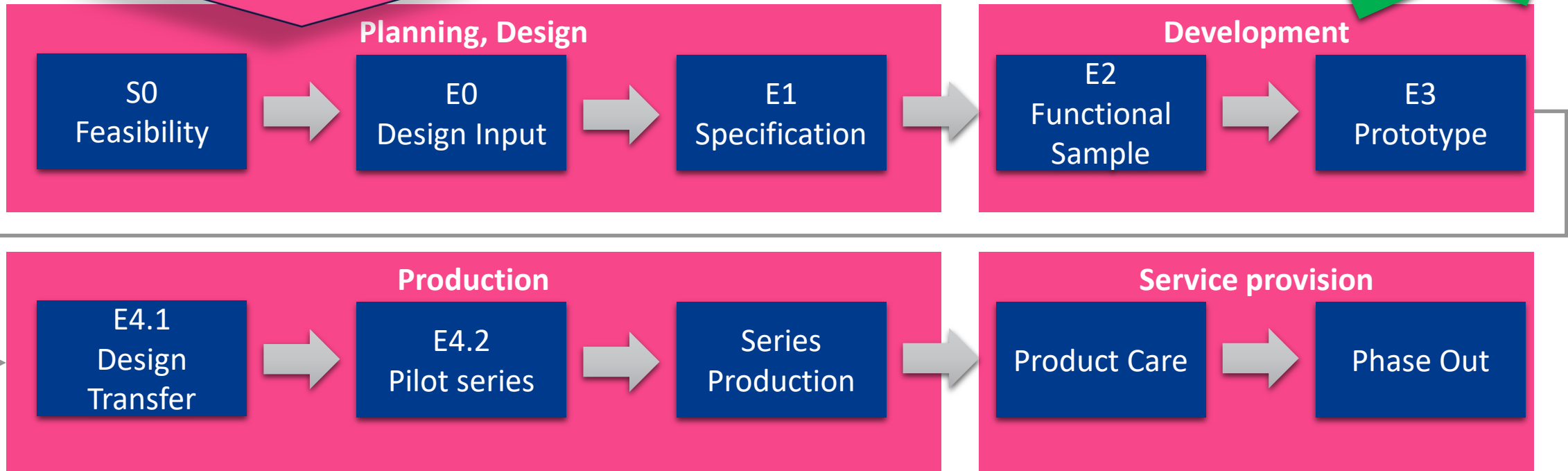
Product Lifecycle Process for medical or other devices

PLM Perspective

Digitalization of process workflows necessary

Product realisation / System development

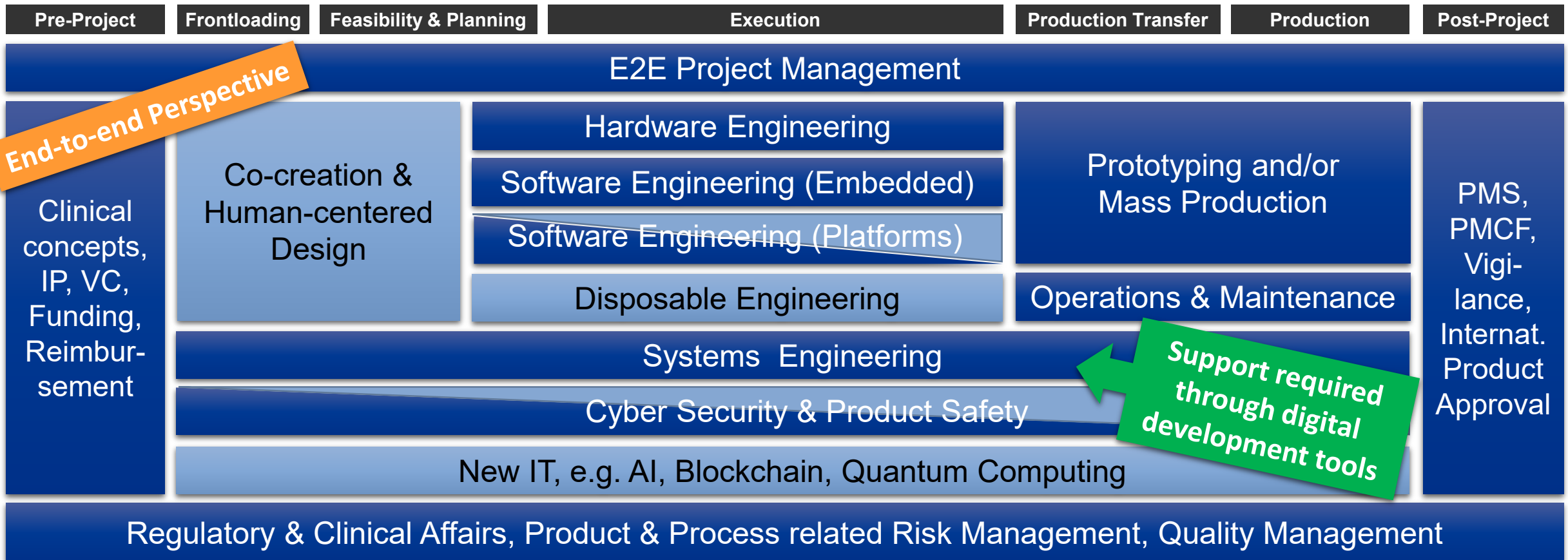
Regulatory Input



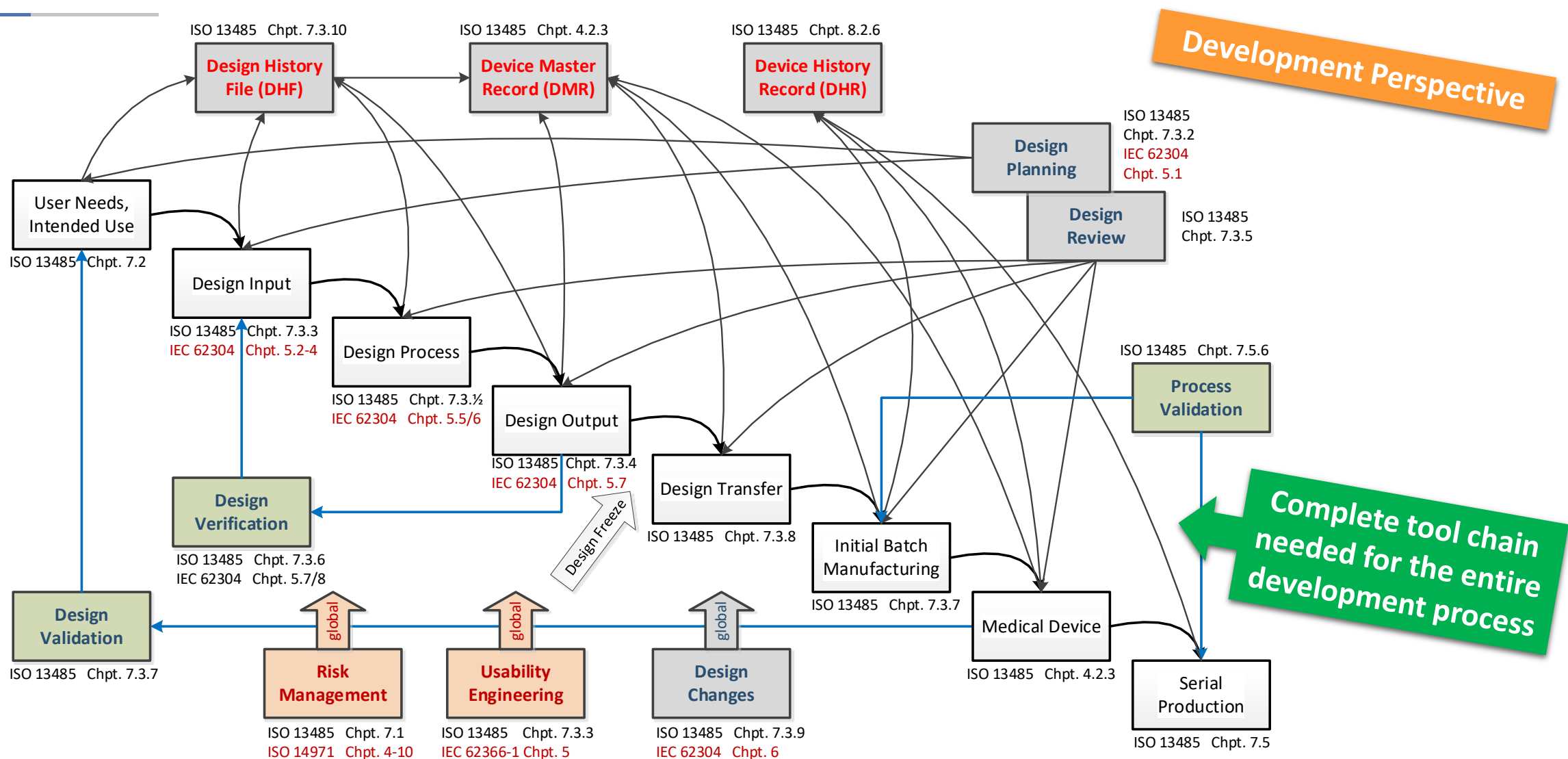
Project Management, Risk Management, Usability Engineering, Quality Management, Regulatory Affairs

Product Lifecycle Process for medical or other devices

Design & development, regulatory approval and production of medical device systems

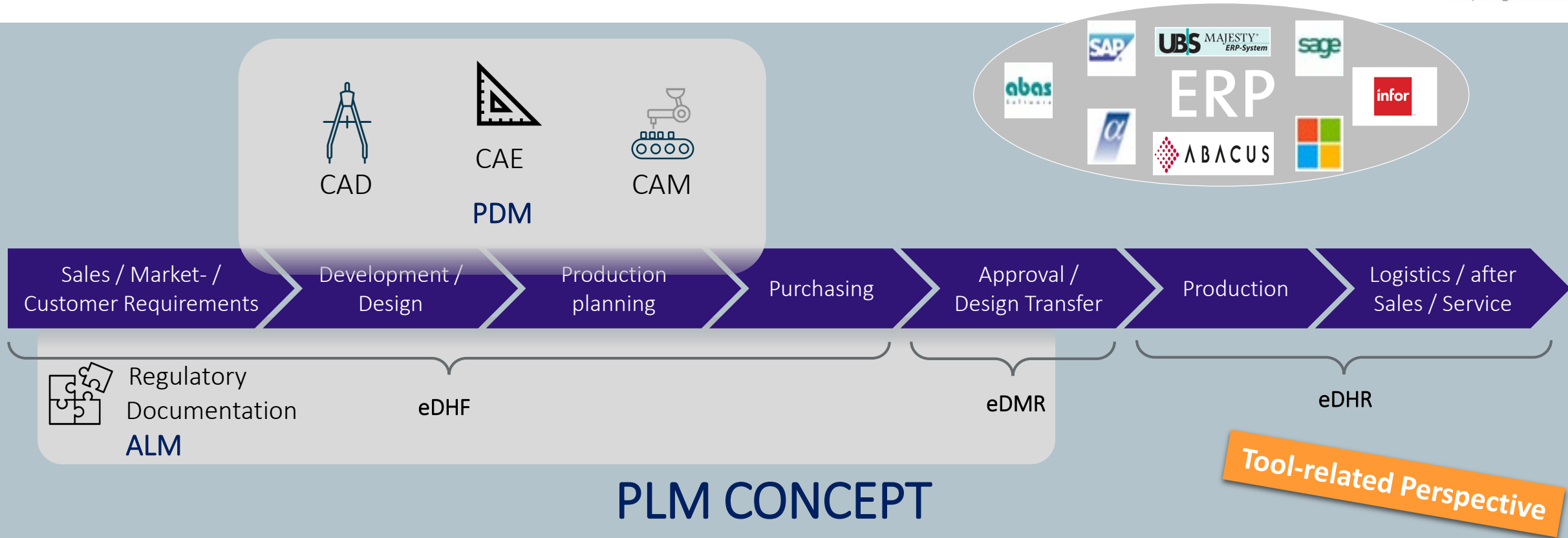


Product Lifecycle Process for medical or other devices



Design & Development Process from FDA's and ISO 13485:2016 perspective – © by seleon gmbh

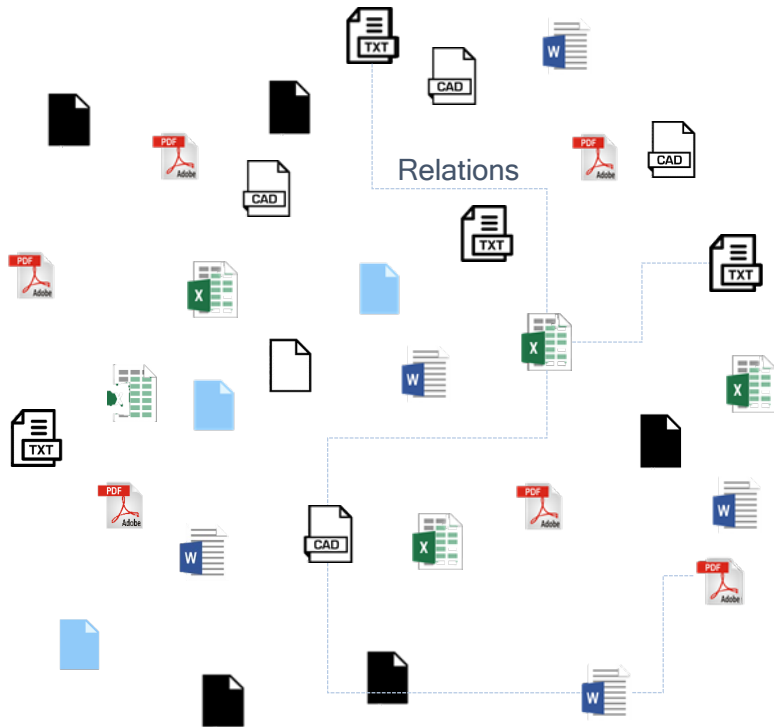
Product Lifecycle Process for medical or other devices



Digitalization of the development process using TEAMCENTER

Daily questions and the answers

TEAMCENTER

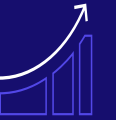


Project



How do I get information about the project and its progress?

Efficiency



What effects do my changes have on the documentation / approval / project?

Quality



How do I ensure complete registration documentation?

Speed



Are all my tasks created and is the documentation complete?

Flexible



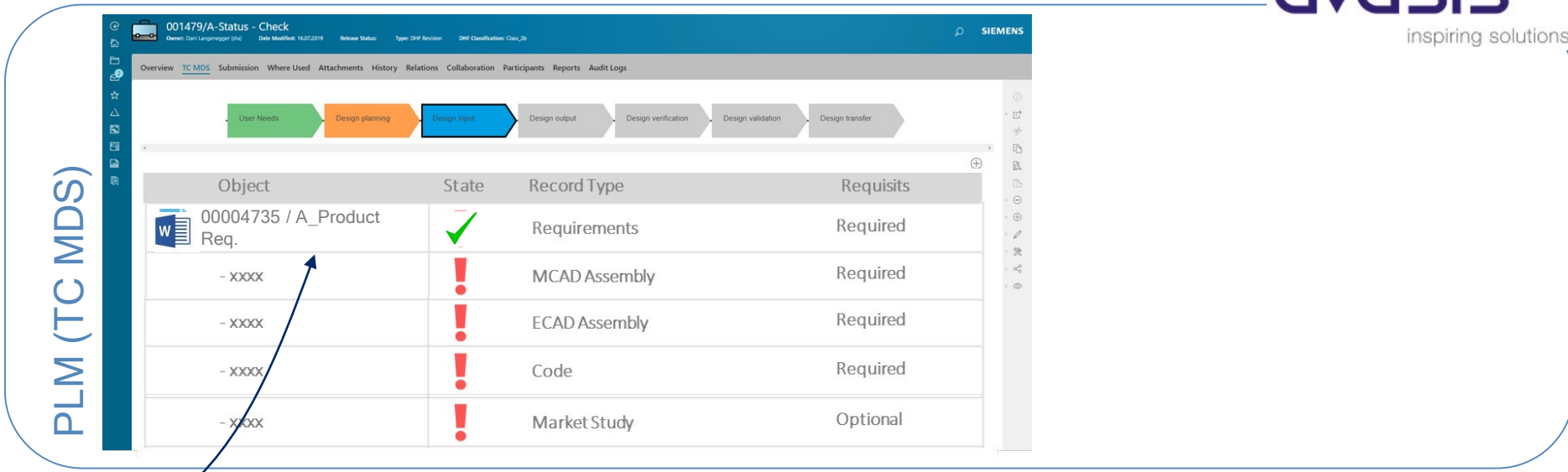
Digitalization of the development process using TEAMCENTER

Word Requirements

00004735

- Product Requirement
- Introduction
- Purpose
- Software Req.
- Reference
- Design Req.
 - Weight
 - Dimension

PLM (TC MDS)



001479/A-Status - Check
Owner: Dori Langmeyer (dli) Date Modified: 16.07.2019 Release Status: Type: DfP Revision DfP Classification: Clst_2b SIEMENS


Overview TC MDS Submission Where Used Attachments History Relations Collaboration Participants Reports Audit Logs

User Needs → Design planning → Design input → Design output → Design verification → Design validation → Design transfer


Object	State	Record Type	Requisites
00004735 / A_Product Req.	✓	Requirements	Required
- xxxx	! !	MCAD Assembly	Required
- xxxx	! !	ECAD Assembly	Required
- xxxx	! !	Code	Required
- xxxx	! !	Market Study	Optional

Authoring tools


Digital TD
(Req., Risk, etc.)




Writing tools




MCAD



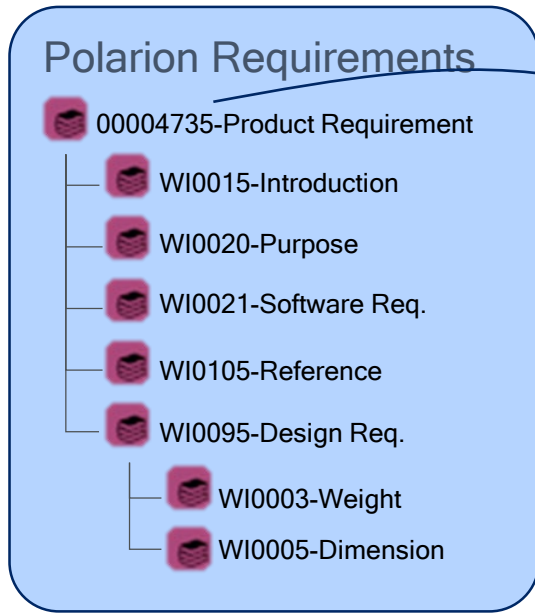
ECAD



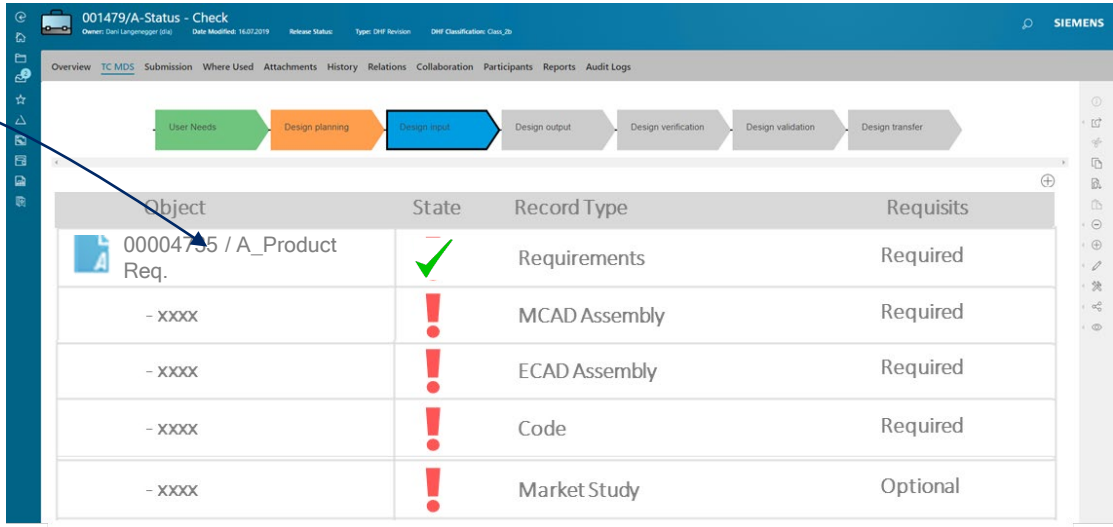
Other



Digitalization of the development process using TEAMCENTER

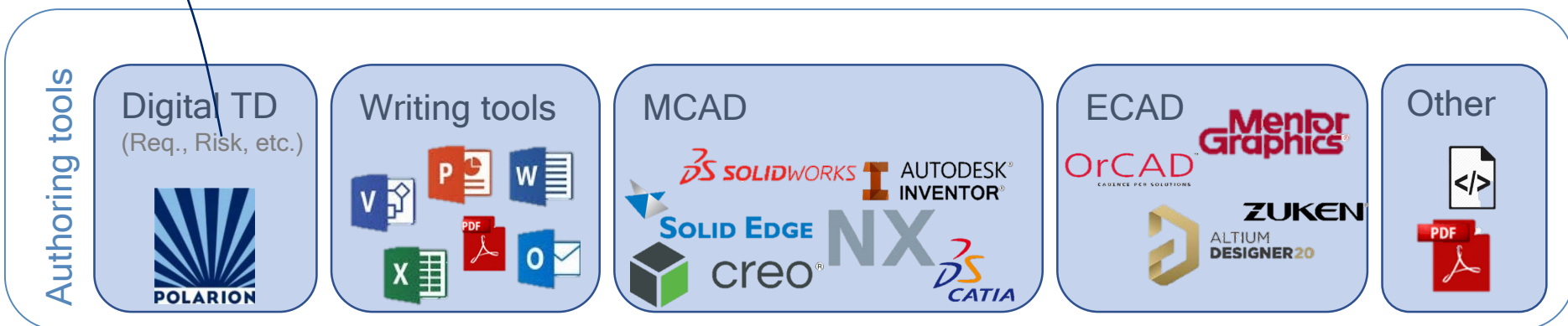


PLM (TC MDS)

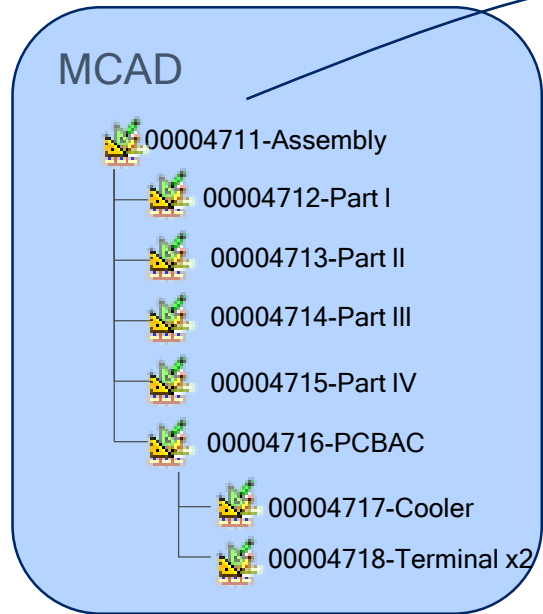


Object	State	Record Type	Requisites
00004735 / A_Product Req.	✓	Requirements	Required
- xxxx	!	MCAD Assembly	Required
- xxxx	!	ECAD Assembly	Required
- xxxx	!	Code	Required
- xxxx	!	Market Study	Optional

- Polarion**
- Req. Mgmt.
 - Risk Mgmt.
 - V & V
 - Digitalize other doc.

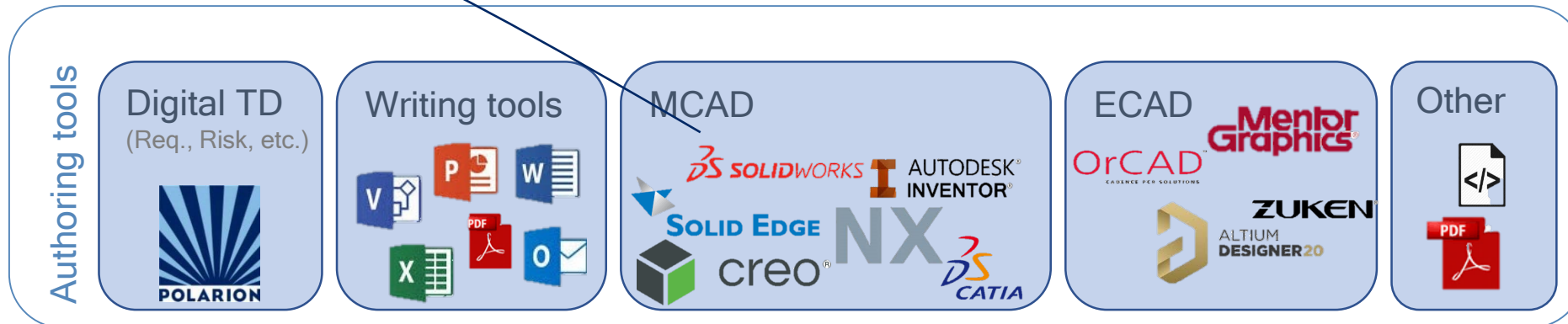


Digitalization of the development process using TEAMCENTER

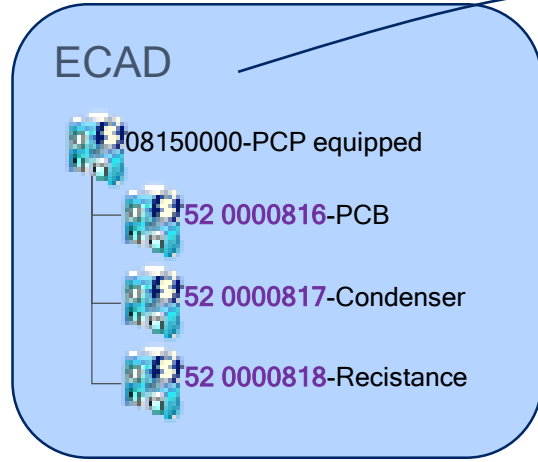


PLM (TC MDS)

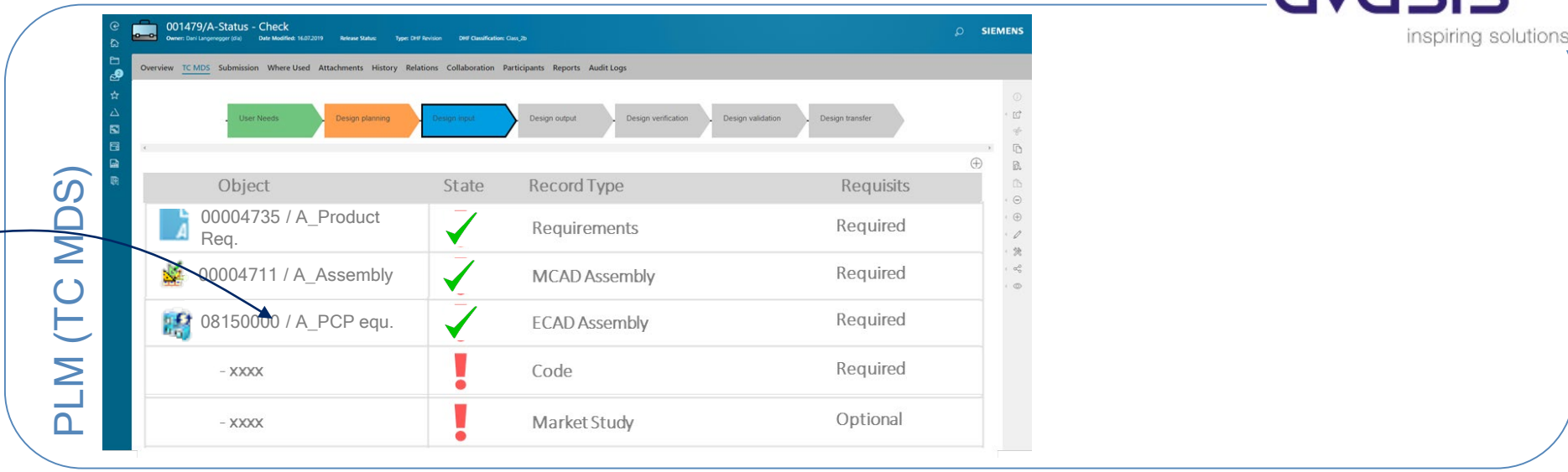
Object	State	Record Type	Requisits
00004735 / A_Product Req.	✓	Requirements	Required
00004711 / A_Assembly	✓	MCAD Assembly	Required
- xxxx	!	ECAD Assembly	Required
- xxxx	!	Code	Required
- xxxx	!	Market Study	Optional



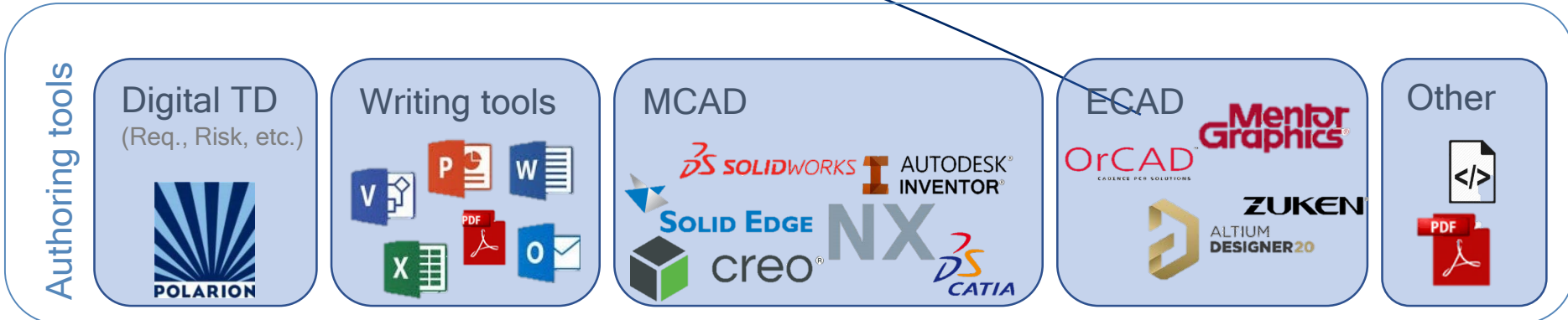
Digitalization of the development process using TEAMCENTER



PLM (TC MDS)




Object	State	Record Type	Requisits
00004735 / A_Product Req.	✓	Requirements	Required
00004711 / A_Assembly	✓	MCAD Assembly	Required
08150000 / A_PCP equ.	✓	ECAD Assembly	Required
- xxxx	!	Code	Required
- xxxx	!	Market Study	Optional



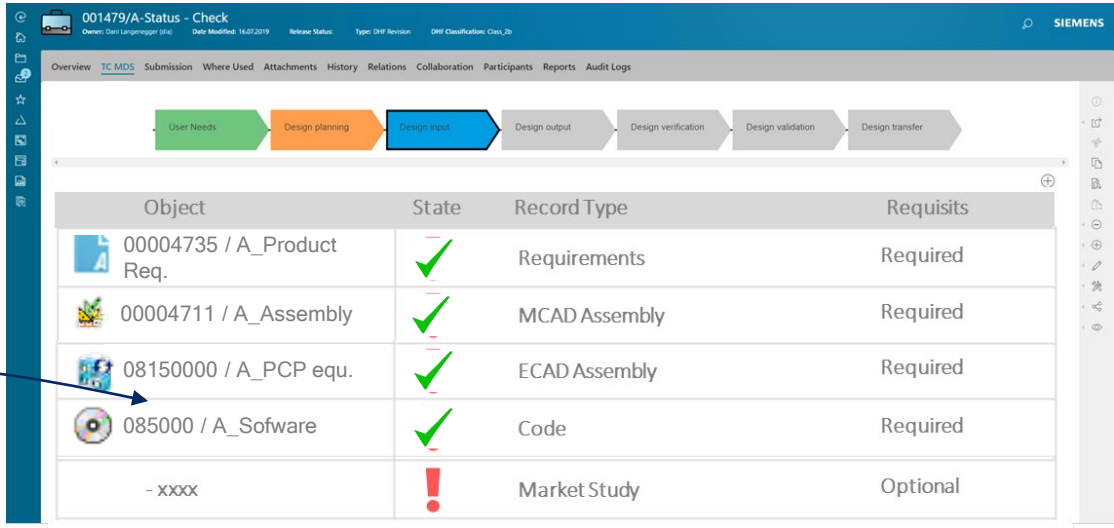
Digitalization of the development process using TEAMCENTER

Software



085000 Software


PLM (TC MDS)



Object	State	Record Type	Requisites
00004735 / A_Product Req.	✓	Requirements	Required
00004711 / A_Assembly	✓	MCAD Assembly	Required
08150000 / A_PCP equ.	✓	ECAD Assembly	Required
085000 / A_Software	✓	Code	Required
- xxxx	!	Market Study	Optional


Authoring tools

Digital TD
(Req., Risk, etc.)




POLARION


Writing tools




MCAD



ECAD



Other



Digitalization of the development process using TEAMCENTER

001479/A-Status - Check
Owner: Dani Langmeyer (da) Date Modified: 16.07.2019 Release Status: Type: DfP Revision DfP Classification: Class_2b SIEMENS


Overview TC MDS Submission Where Used Attachments History Relations Collaboration Participants Reports Audit Logs

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PLM (TC MDS)

Object	State	Record Type	Requisites
00004735 / A_Product Req.	✓	Requirements	Required
00004711 / A_Assembly	✓	MCAD Assembly	Required
08150000 / A_PCP equ.	✓	ECAD Assembly	Required
085000 / A_Software	✓	Code	Required
00005010 / A_Market Study	✓	Market Study	Optional

Writing tools



Market Study.pdf

Authoring tools

- Digital TD (Req., Risk, etc.)**
POLARION
- Writing tools**
V, P, W, X, PDF, O
- MCAD**
SOLIDWORKS, AUTODESK INVENTOR, SOLID EDGE, NX, CATIA, creo
- ECAD**
OrCAD, Mentor Graphics, ZUKEN, ALTIUM DESIGNER20
- Other**
PDF

Digitalization of the development process using TEAMCENTER

Transfer to ERP

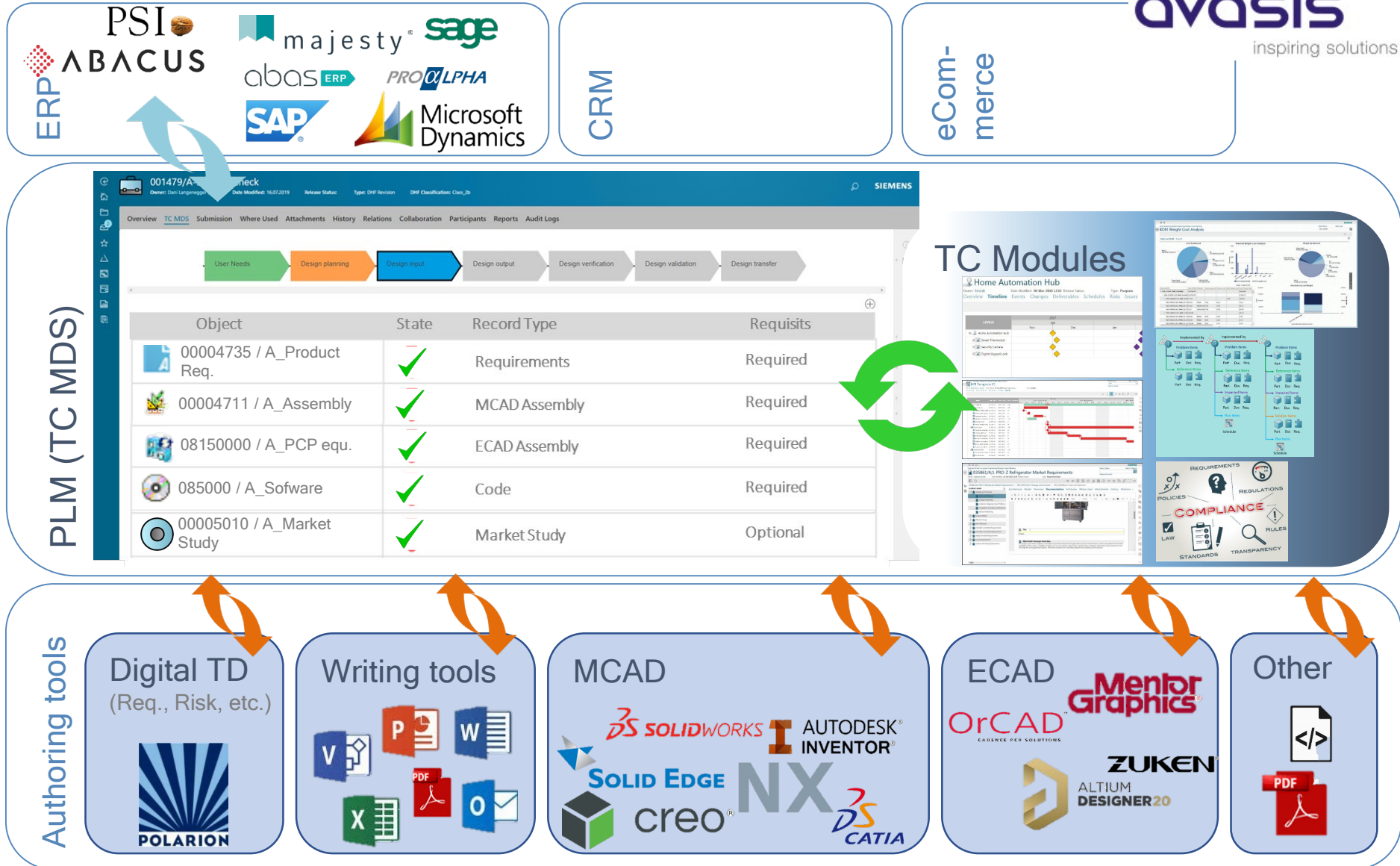
Examples:

- BOM information
- Neutral-Format (for Purchasing, AVOR etc.)

Transfer to PLM

Examples:

- Stock information
- Cost / Price informationen



Digitalization of the development process using TEAMCENTER

Transfer to CRM

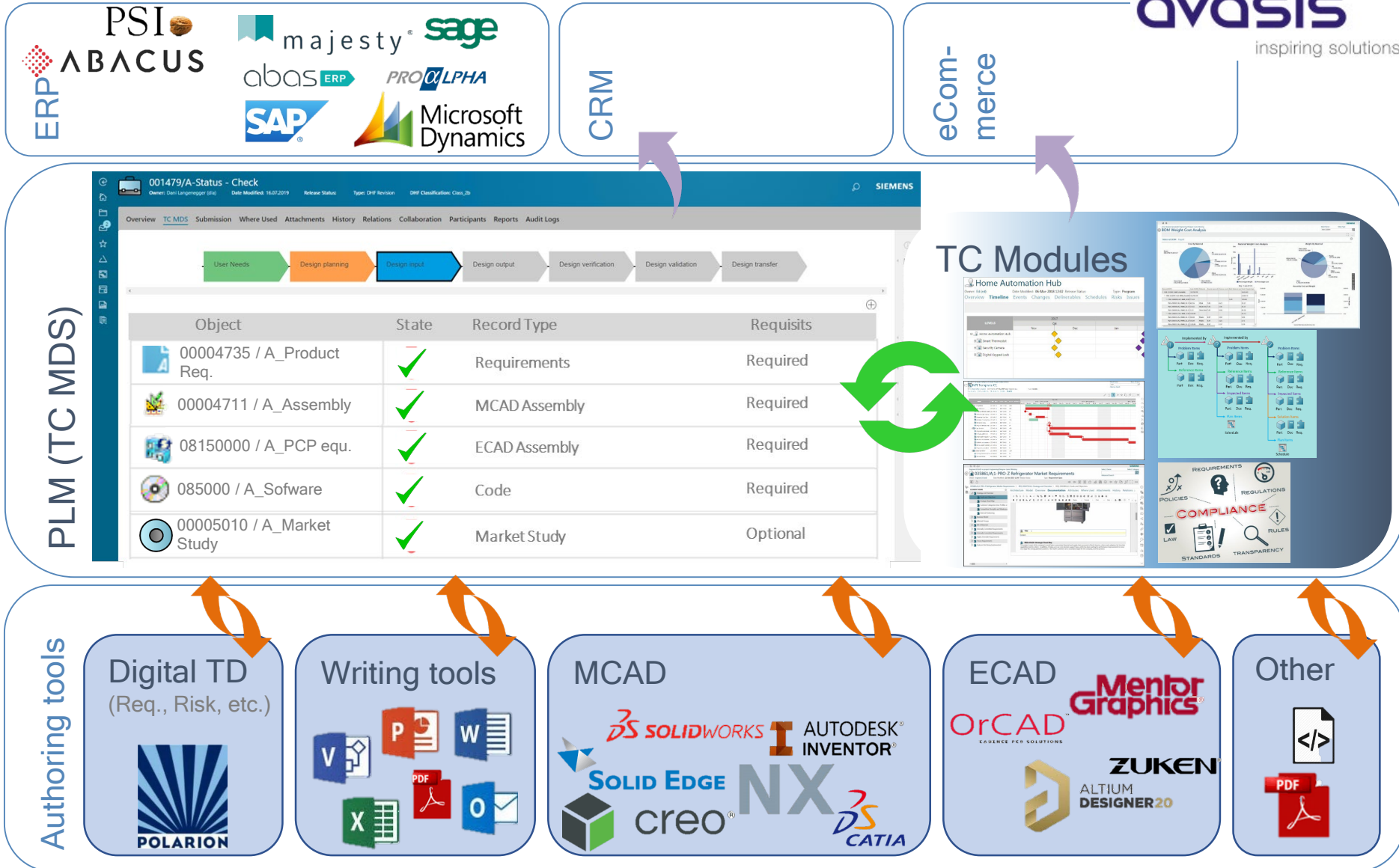
Examples:

- Vendor information
- RFQ Datas

Transfer to eCommerce

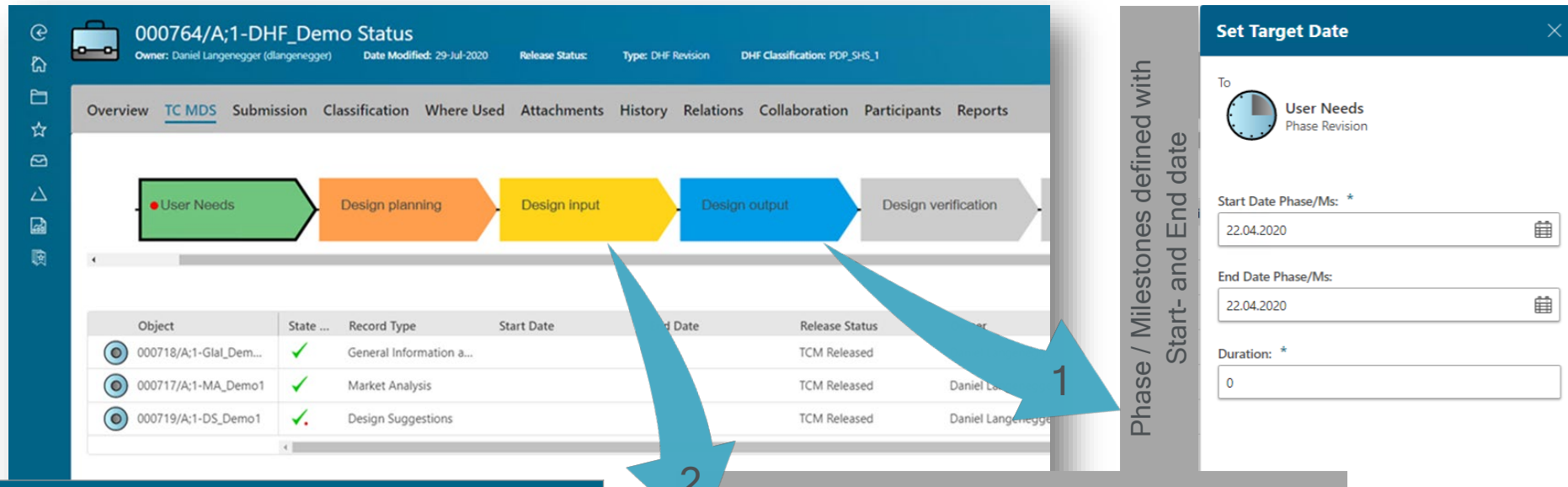
Examples:

- Data sheets
- 3D Datas (dummy)



Digitalization of the development process using TEAMCENTER

Planning of Product Development Process (PDP) including Technical Documentation (TD)



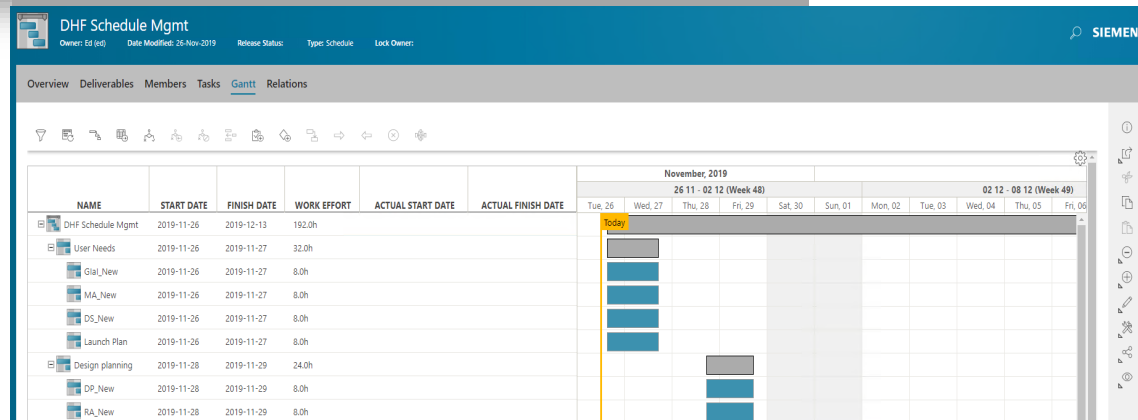
The screenshot shows the '000764/A;1-DHF_Demo Status' page. The process flow includes: User Needs (green), Design planning (orange), Design input (yellow), Design output (blue), and Design verification (grey). Below the flow is a table of objects:

Object	State	Record Type	Start Date	End Date	Release Status	Owner
000718/A;1-Gla_Dem...	✓	General Information a...			TCM Released	
000717/A;1-MA_Demo1	✓	Market Analysis			TCM Released	Daniel Langenegger
000719/A;1-DS_Demo1	✓	Design Suggestions			TCM Released	Daniel Langenegger

A 'Set Target Date' dialog box is open, showing 'User Needs' with a start and end date of 22.04.2020 and a duration of 0. A vertical label 'Phase / Milestones defined with Start- and End date' is positioned next to the dialog. Arrows labeled '1' and '2' point from the dialog and the process flow respectively to the 'Planning with Schedule Management integration' section.

Icon	Colour	State
✓	Green arrow	Released
✓ with red dot	Green arrow	current object not newest
⚙️	Blue arrow	Working
⌚	Yellow arrow	Less then 3 days until due
⌚	Orange arrow	Past due
!	Red arrow	Missing or obsolete

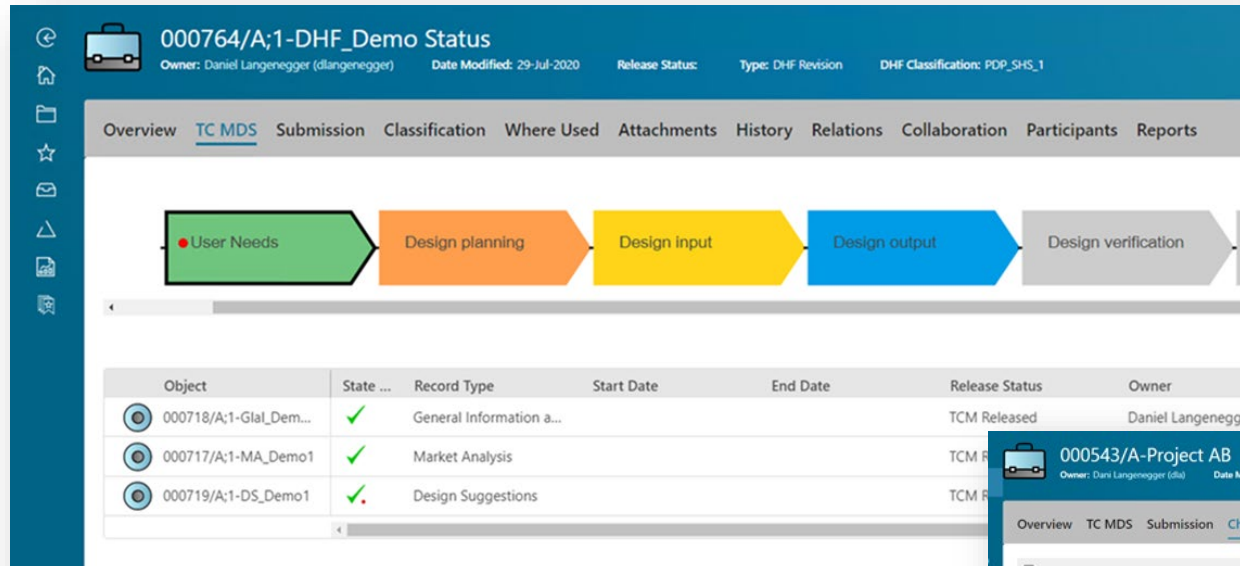
Planning with Schedule Management integration



The screenshot shows the 'DHF Schedule Mgmt' interface with a Gantt chart for November 2019. The chart displays tasks such as 'User Needs', 'Gla_New', 'MA_New', 'DS_New', 'Launch Plan', 'Design planning', 'DP_New', and 'RA_New' with their respective start and finish dates and work effort.

Digitalization of the development process using TEAMCENTER

Monitoring of project progress

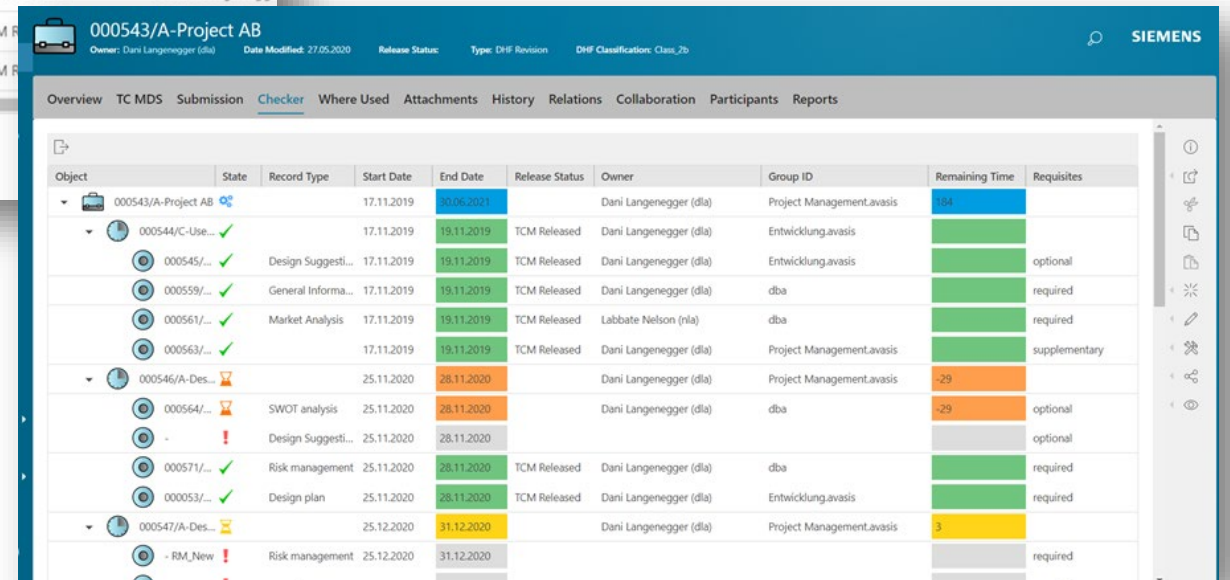


000764/A;1-DHF_Demo Status
Owner: Daniel Langenegger (dlangenegger) Date Modified: 29-Jul-2020 Release Status: Type: DHF Revision DHF Classification: PDP_SHS_1

Overview **TC MDS** Submission Classification Where Used Attachments History Relations Collaboration Participants Reports

User Needs Design planning Design input Design output Design verification

Object	State ...	Record Type	Start Date	End Date	Release Status	Owner
000718/A;1-Gla_Dem...	✓	General Information a...			TCM Released	Daniel Langenegger
000717/A;1-MA_Demo1	✓	Market Analysis			TCM Released	Daniel Langenegger
000719/A;1-DS_Demo1	✓	Design Suggestions			TCM Released	Daniel Langenegger



000543/A-Project AB
Owner: Dani Langenegger (dia) Date Modified: 27.05.2020 Release Status: Type: DHF Revision DHF Classification: Class_7b

Overview TC MDS Submission **Checker** Where Used Attachments History Relations Collaboration Participants Reports

Object	State	Record Type	Start Date	End Date	Release Status	Owner	Group ID	Remaining Time	Requisites
000543/A-Project AB	🕒		17.11.2019	30.06.2021		Dani Langenegger (dia)	Project Management.avasis	34	
000544/C-Use...	✓		17.11.2019	19.11.2019	TCM Released	Dani Langenegger (dia)	Entwicklung.avasis		
000545/...	✓	Design Suggesti...	17.11.2019	19.11.2019	TCM Released	Dani Langenegger (dia)	Entwicklung.avasis		optional
000559/...	✓	General Informa...	17.11.2019	19.11.2019	TCM Released	Dani Langenegger (dia)	dba		required
000561/...	✓	Market Analysis	17.11.2019	19.11.2019	TCM Released	Labbate Nelson (nla)	dba		required
000563/...	✓		17.11.2019	19.11.2019	TCM Released	Dani Langenegger (dia)	Project Management.avasis		supplementary
000546/A-Des...	🕒		25.11.2020	28.11.2020		Dani Langenegger (dia)	Project Management.avasis	-29	
000564/...	🕒	SWOT analysis	25.11.2020	28.11.2020		Dani Langenegger (dia)	dba	-29	optional
-	!	Design Suggesti...	25.11.2020	28.11.2020					optional
000571/...	✓	Risk management	25.11.2020	28.11.2020	TCM Released	Dani Langenegger (dia)	dba		required
000053/...	✓	Design plan	25.11.2020	28.11.2020	TCM Released	Dani Langenegger (dia)	Entwicklung.avasis		required
000547/A-Des...	🕒		25.12.2020	31.12.2020		Dani Langenegger (dia)	Project Management.avasis	3	
- RM_New	!	Risk management	25.12.2020	31.12.2020					required

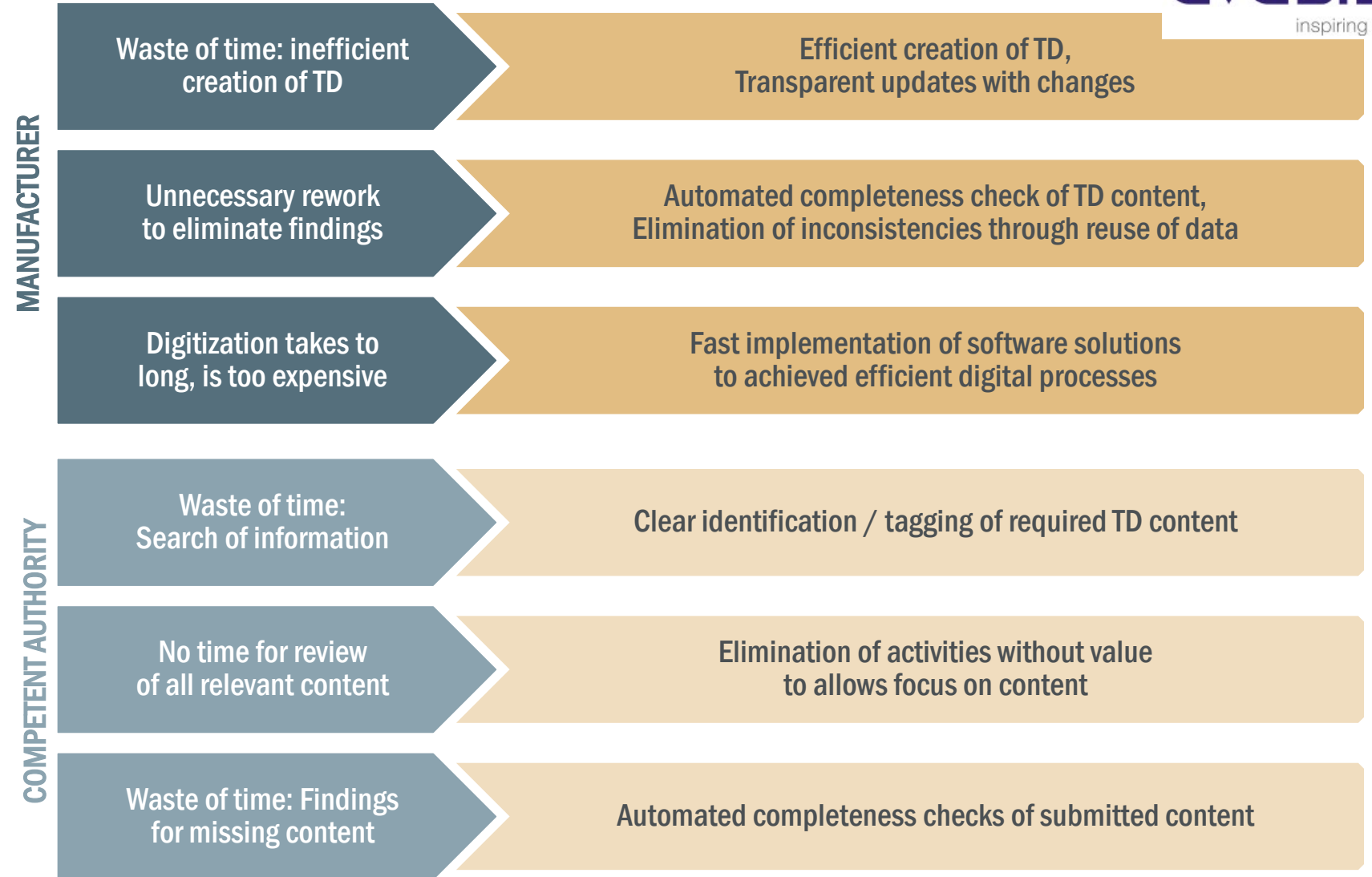
Icon	Colour	State
✓	Green arrow	Released
✓ with red dot	Green arrow with red dot	current object not newest
⚙️	Blue arrow	Working
🕒	Yellow arrow	Less then 3 days until due
🕒	Orange arrow	Past due
!	Red arrow	Missing or obsolete

Challenge: Most of the effort goes into the Technical Documentation

- ✓ **FASTER**
- ✓ **CHEAPER**
- ✓ **LESS RESOURCES**



- ✓ **REDUCED COSTS**
- ✓ **FAST MARKET APPROVAL**
- ✓ **MORE INNOVATION**
- ✓ **IMPROVED PATIENT CARE**

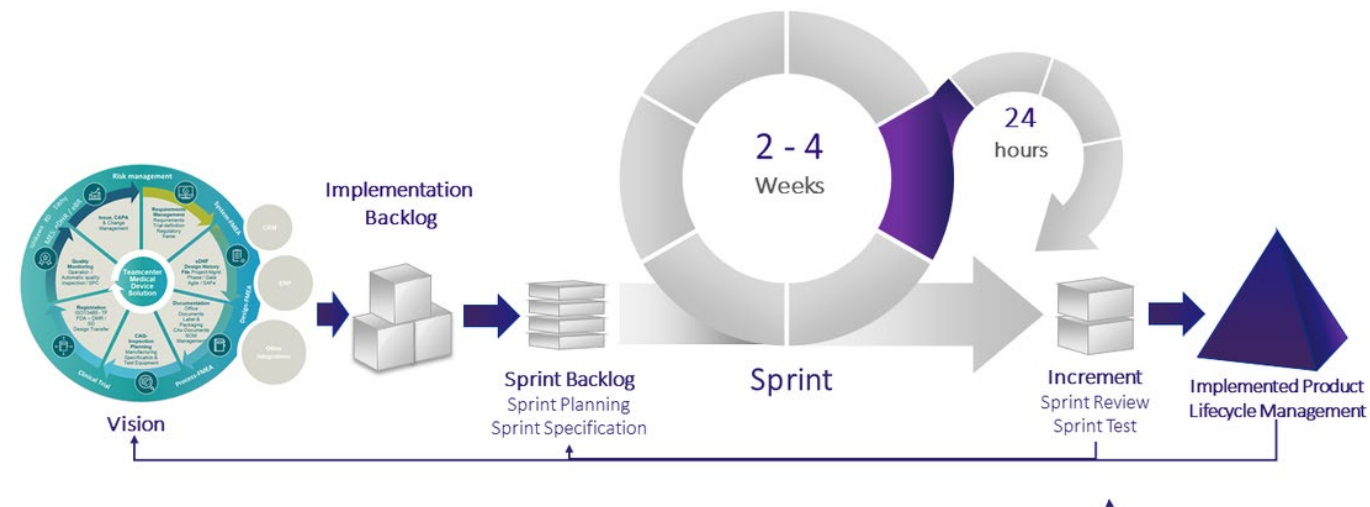


Solution: Application Lifecycle Management (ALM)

Digitalization of the development process

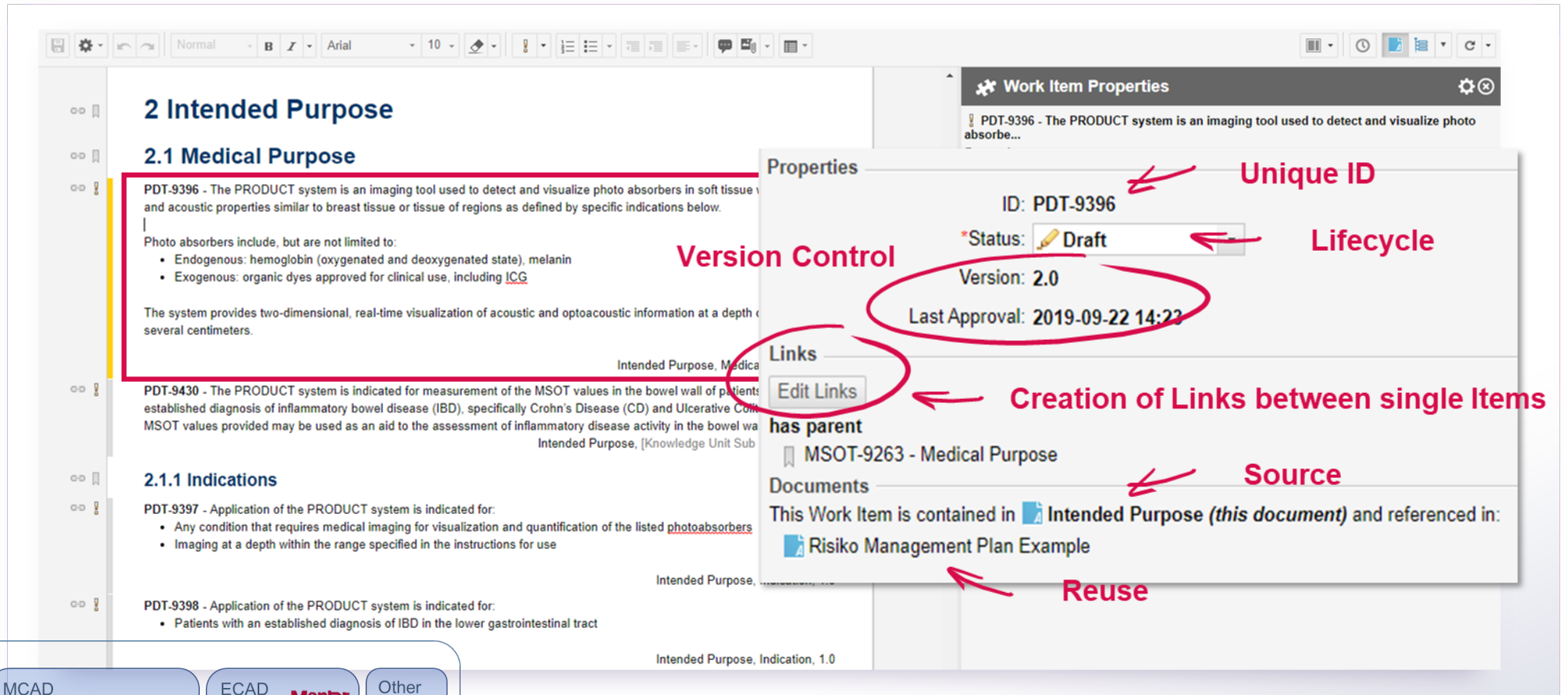


- Browser-based **Application Lifecycle Management (ALM)** software from **Siemens** based on linked **Work Items**
- Simple creation of work items in **LiveDoc** documents
- **Requirements and Test Management** as well as ensuring **Complete Test Coverage** (standard functional scope)
- **Digital documentation** of development, risk management, usability engineering, clinical evaluation (avasis modules)
- **Electronic review and approval processes** for work items and documents
- Visualization and analysis of dependencies between information through **Traceability Reports**
- Tracking of changes through complete **Audit Trail**



Solution: Application Lifecycle Management (ALM)

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.

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

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

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

Work Item Properties

! PDT-9396 - The PRODUCT system is an imaging tool used to detect and visualize photo absorbe...

Properties

ID: PDT-9396

*Status: Draft

Version: 2.0

Last Approval: 2019-09-22 14:22

Links

Edit Links

has parent

MSOT-9263 - Medical Purpose

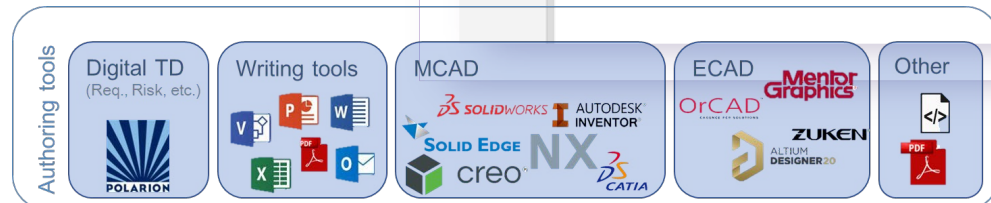
Documents

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

Risiko Management Plan Example

Annotations:

- Unique ID (points to ID: PDT-9396)
- Lifecycle (points to Status: Draft)
- Version Control (points to Version: 2.0)
- Creation of Links between single Items (points to Edit Links)
- Source (points to MSOT-9263 - Medical Purpose)
- Reuse (points to Risiko Management Plan Example)

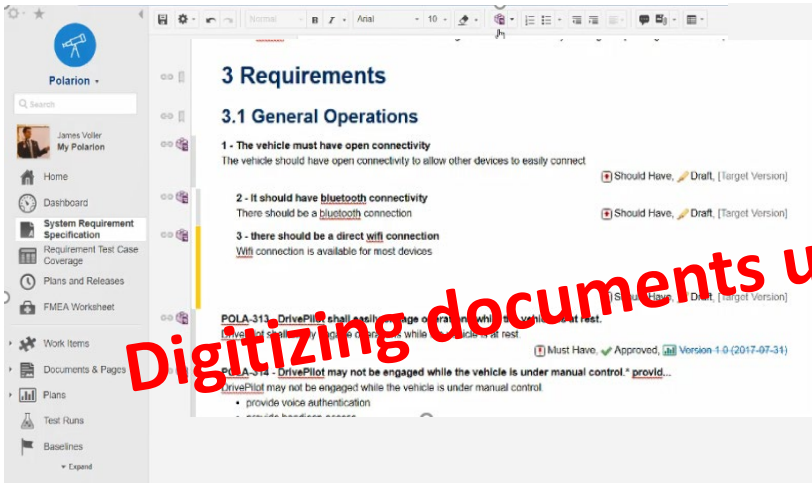


Authoring tools

- Digital TD (Req., Risk, etc.)
- Writing tools
- MCAD: SOLIDWORKS, AUTODESK INVENTOR, SOLID EDGE, NX, CATIA, CREO
- ECAD: Mentor Graphics, OrCAD, ZUKEN, ALTUM DESIGNER 20
- Other

Solution: Application Lifecycle Management (ALM)

Requirements Management



3 Requirements

3.1 General Operations

- 1 - The vehicle must have open connectivity
The vehicle should have open connectivity to allow other devices to easily connect
- 2 - It should have bluetooth connectivity
There should be a bluetooth connection
- 3 - there should be a direct wifi connection
Wifi connection is available for most devices

POLA-313 - DrivePilot shall maintain charge of battery while the vehicle is at rest.
DrivePilot may not be engaged while the vehicle is under manual control. provide voice authentication

Risk Management

1 Risikomanagement Plan

1.1 Risikomanagement Policy
1.2 Definition Schweregrad
1.3 Definition Auftretenswahrscheinlichkeit
1.4 Funktionale Analyse

1.1 Risikomanagement Policy

Auftrittswahrscheinlich	Schweregrad				
	s1	s2	s3	s4	s5
w1	akzeptabel	akzeptabel	akzeptabel	akzeptabel	nicht akzeptabel
w2	akzeptabel	akzeptabel	akzeptabel	nicht akzeptabel	nicht akzeptabel
w3	akzeptabel	akzeptabel	nicht akzeptabel	nicht akzeptabel	nicht akzeptabel
w4	akzeptabel	nicht akzeptabel	nicht akzeptabel	nicht akzeptabel	nicht akzeptabel
w5	nicht akzeptabel	nicht akzeptabel	nicht akzeptabel	nicht akzeptabel	nicht akzeptabel

Risk	Description
akzeptabel	vertretbares Risiko, keine weiteren Maßnahmen notwendig
nicht akzeptabel	nicht vertretbares Risiko, Risikokontrollmaßnahmen notwendig

1.2 Definition Schweregrad

Verification & Validation

Traceability Report

Source Document: 01 User Needs and Stakeholder Requirements, Stakeholder Requirements

Source Document

Space	Document	Release	Version	Status / Last Change	Items Traceability
01 User Needs and Stakeholder Requirements	Stakeholder Requirements		1.0	Approved 2020-01-29 14:27	Total: 3 Valid Traceability: 3 Missing Traceability: 0 Invalid Documentation Status: 0

Linked Documents

Space	Document	Release	Version	Status	Last Change
02 System Requirements	System Requirements Specification		2.2	In Review	2020-01-29 12:02

Traceability

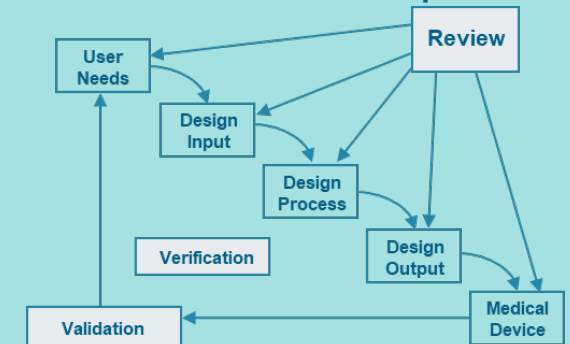
Traceability	Item	Linked Items	Document	Documentation Status
✓	1.1 - Management and Marketing	PLT-623 - Sys Req 1	System Requirements Specification	Valid
✓	PLT-607 - Der Titel der Anforderung	PLT-622 - Sys Req 2	System Requirements Specification	Valid
✓	PLT-609 - Eine weitere Anforderung	PLT-636 - ganz neues Req	System Requirements Specification	Valid
✓	PLT-608 - Das dritte Requirement	PLT-629 - neues Req	System Requirements Specification	Valid

Digitizing documents using object-oriented working methods in Polarion

- Simple & fast documentation of requirements
- Centralized documentation
- Artefact-based documentation for increased reuse, live cycle management etc.
- Traceability with one click to each test case and Polarion element

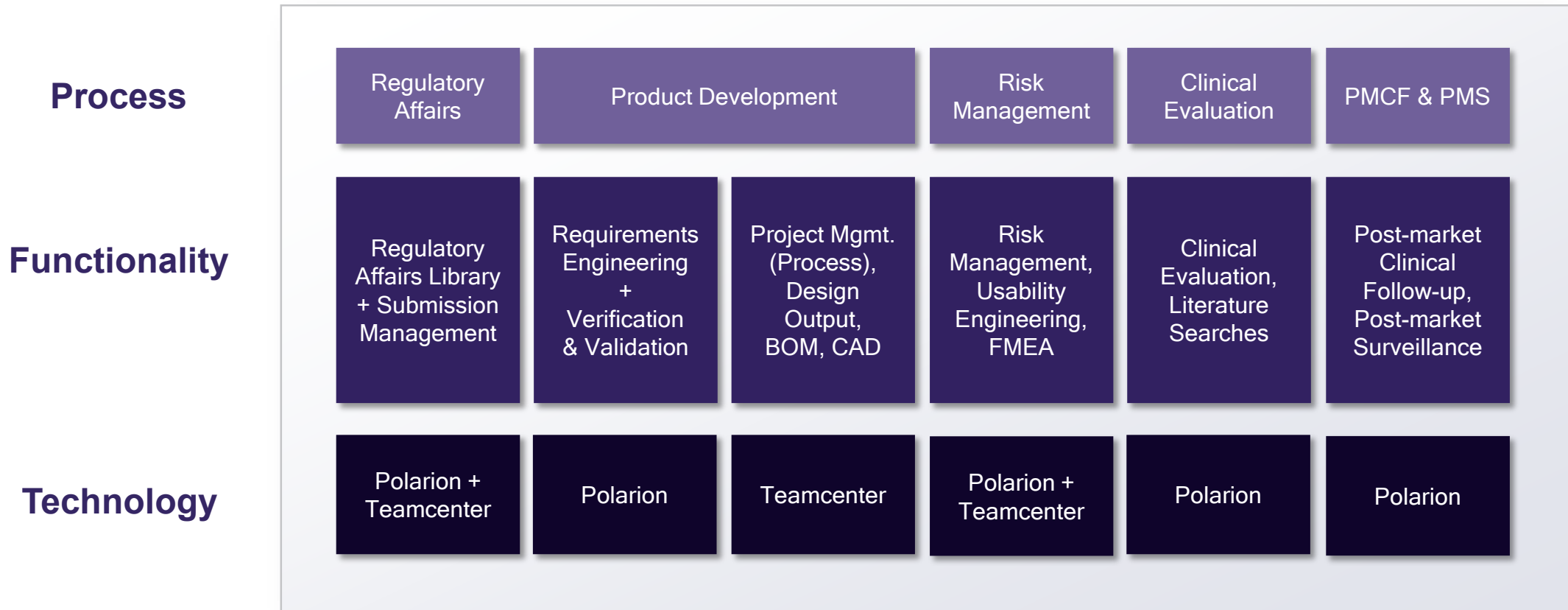
- Smart user interfaces for users & risk managers
- Document templates for risk management plan, report and analysis
- Integration of product architecture into risk analysis
- Traceability overview of risk control measures to requirements and tests
- Support of common assessment procedures (PHA, FMEA)
- Functional Safety Analysis

- Traceability Report: From the requirement to the test definition to the test report



Digitalization of the development process including testing

Key Take Aways



Partners in Digitalization

Who does what?

avasis

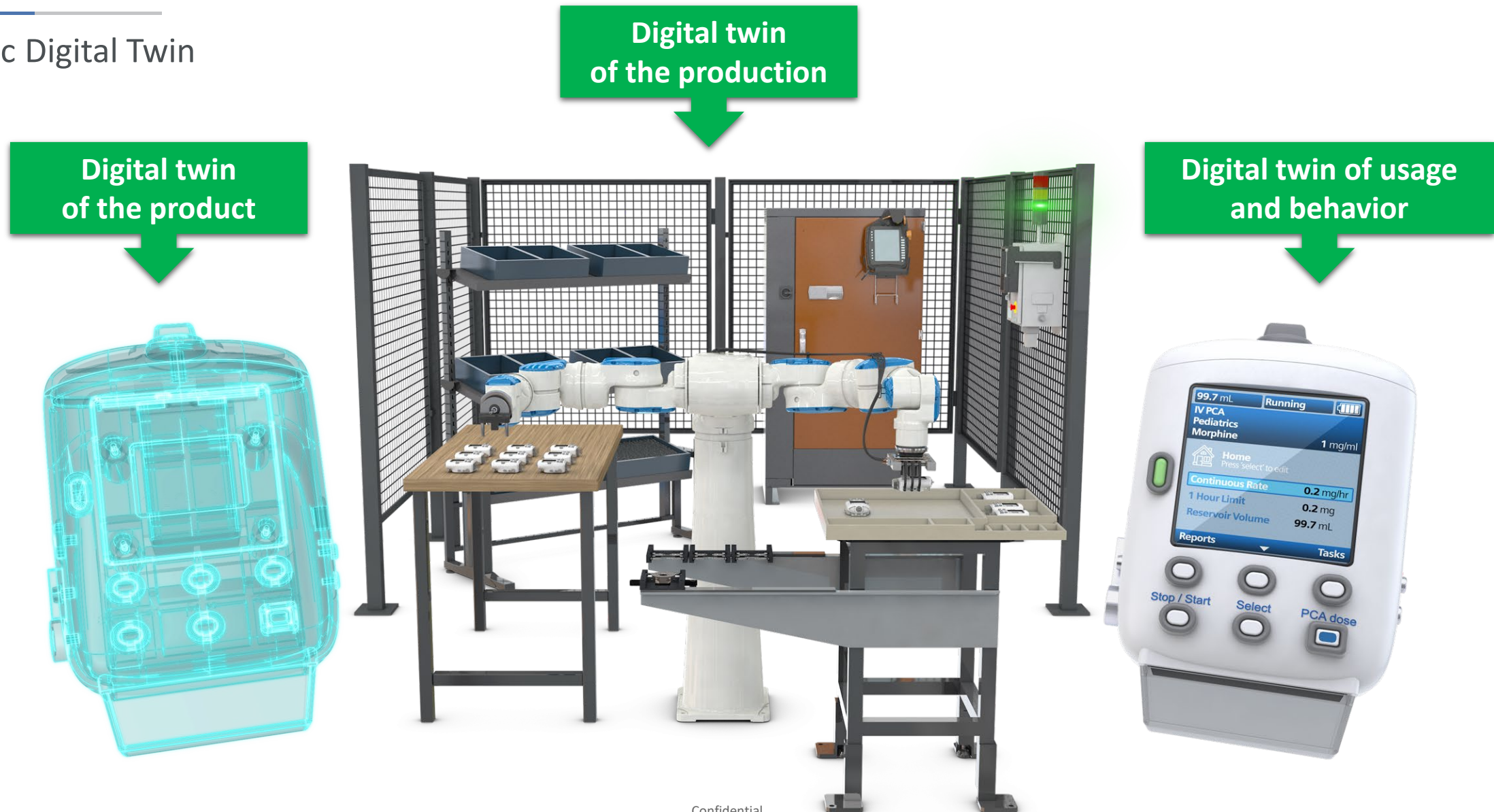
- Design and implementation of TEAMCENTER and/or POLARION

seleon

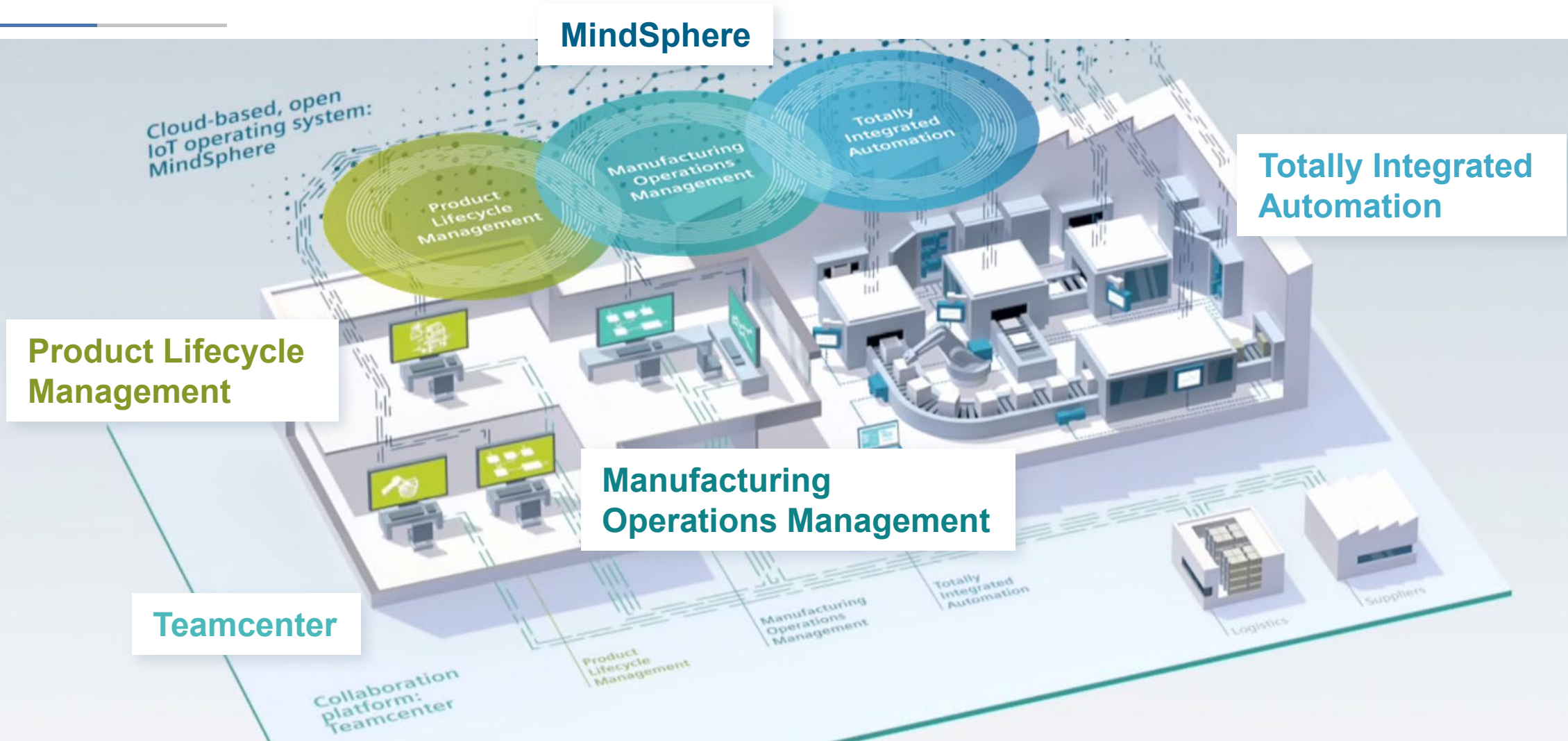
- Process Optimization with regard to the relevant tools (the process should follow the tool – not vice versa)
- Development of set-up and transfer concepts
- Support in setting up and/or transferring the QM system into the digital systems
- Support in setting up and/or transferring the Technical Documentation(s) into the digital systems
- Support with all implementation issues

A look into the future...

Holistic Digital Twin



A look into the future...



Digital Enterprise Suite - Platform for digital transformation



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Germany

Why seleon? We advise & implement. Targeted & hands-on.

- Many years of **experience in introducing** new regulations and implementing new regulatory requirements for **products and processes**
- Use of the **know how of experienced experts** in our interdisciplinary team (natural scientists, engineers, doctors, auditors, ...)
- High **planning reliability** in terms of **times, budget and quality** through a project realization as planned with our experienced project managers
- **Training** your employees on site **so they can do it themselves**
- **Broad range of services:**
Adaptation of processes, QM system & Technical documentation, preparation of clinical/performance evaluations & management of clinical/performance investigations/studies, support in process optimization as well as internal, certification, MDSAP and supplier audits, approval of medical apps/DiGA & health software, assumption of regulatory roles, etc.





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