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

Confidential

High-Class Medical Technology – First-Class Service

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

CONSULTING

HAMBURG

DESSAU

ENGINEERING

PRODUCTION

LEIPZIG

ENGINEERING

CONSULTING

ADMINISTRATION

HEILBRONN

ENGINEERING/
SOFTWARE

www.seleon.com

seleon GmbH| Im Zukunftspark 9 | 74076 Heilbronn, Germany

Confidential

Support over the entire product life cycle

customer's core tasks

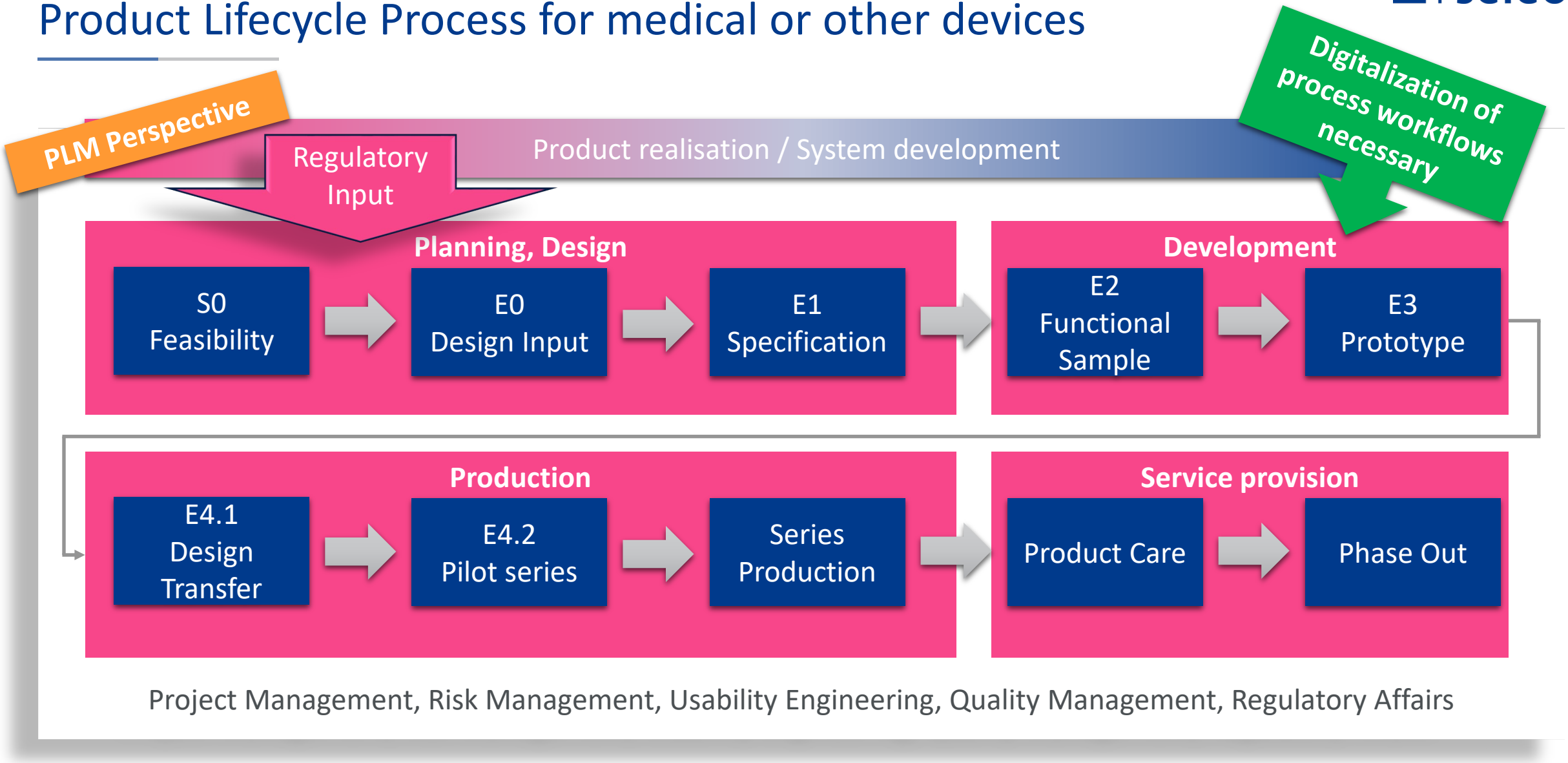
seleon's network

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 Pro-cesses & 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



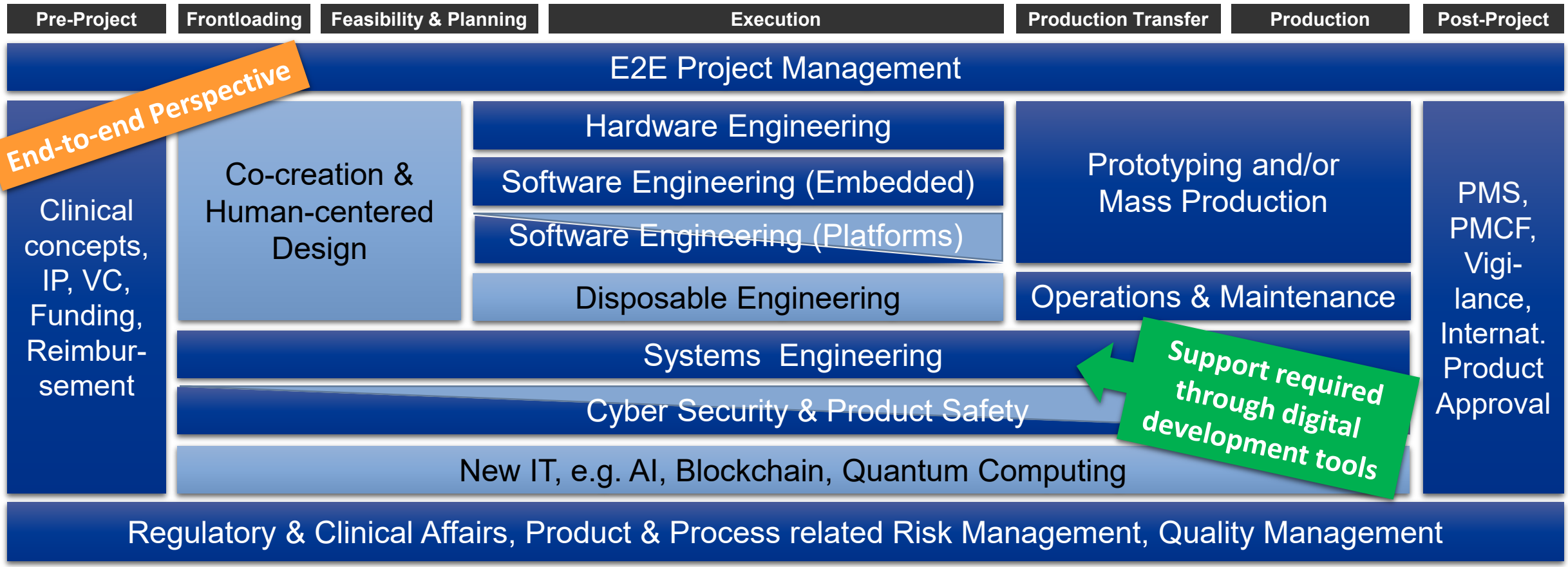
Product Lifecycle Process for medical or other devices

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

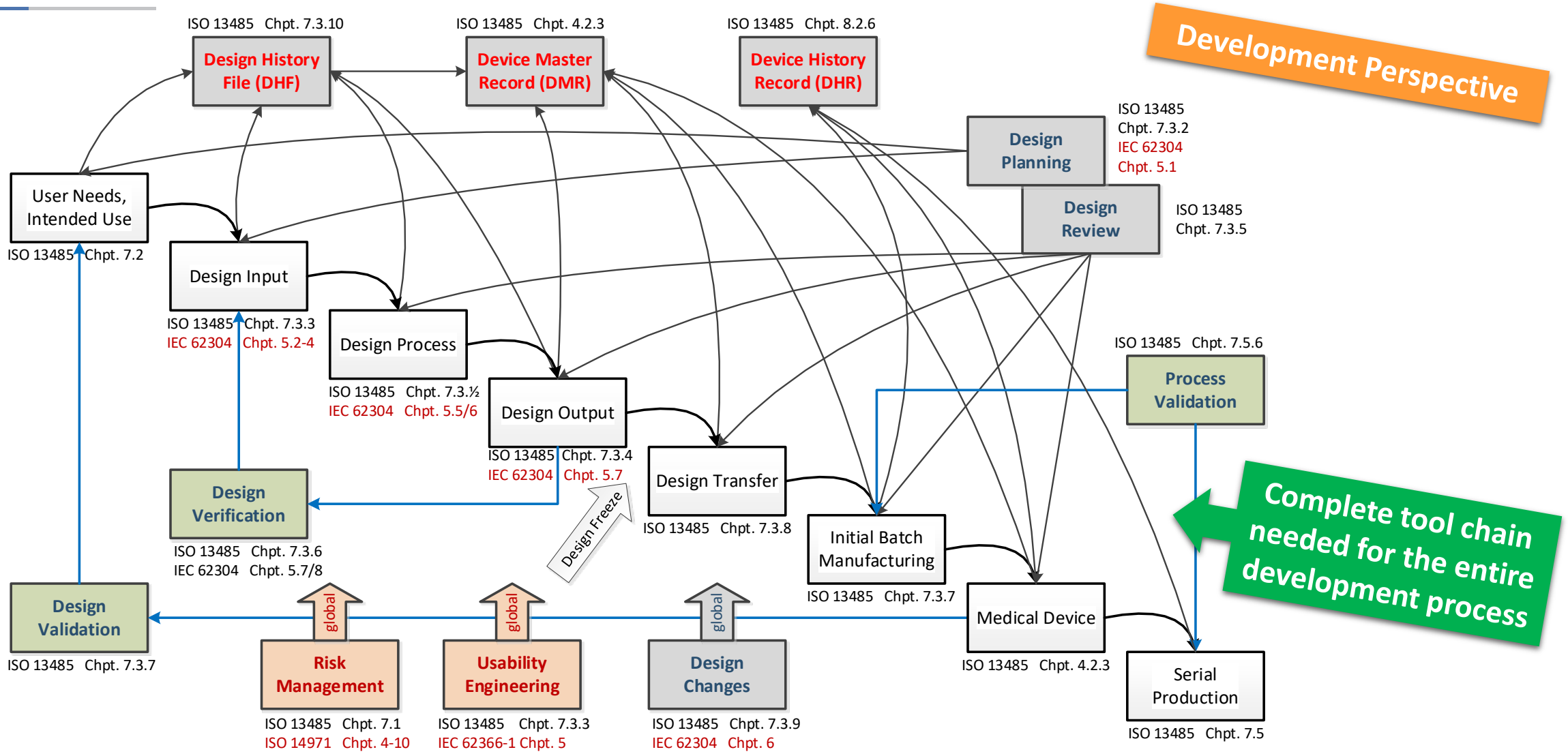
seleon

seleon

Partner

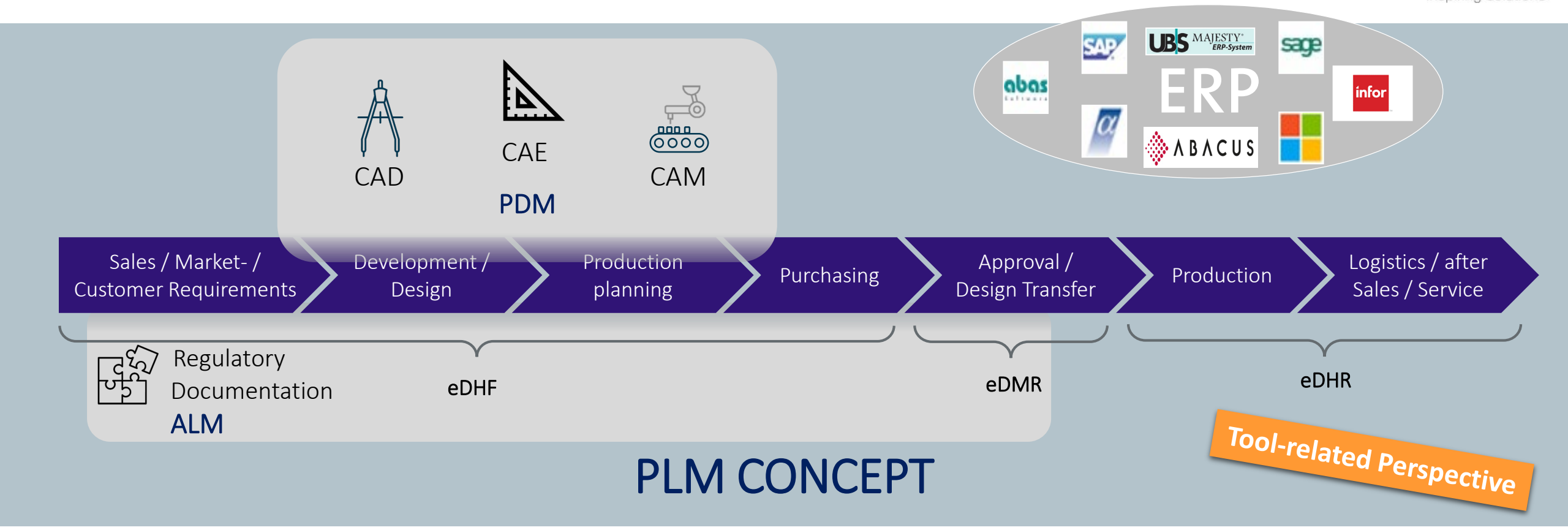


Product Lifecycle Process for medical or other devices



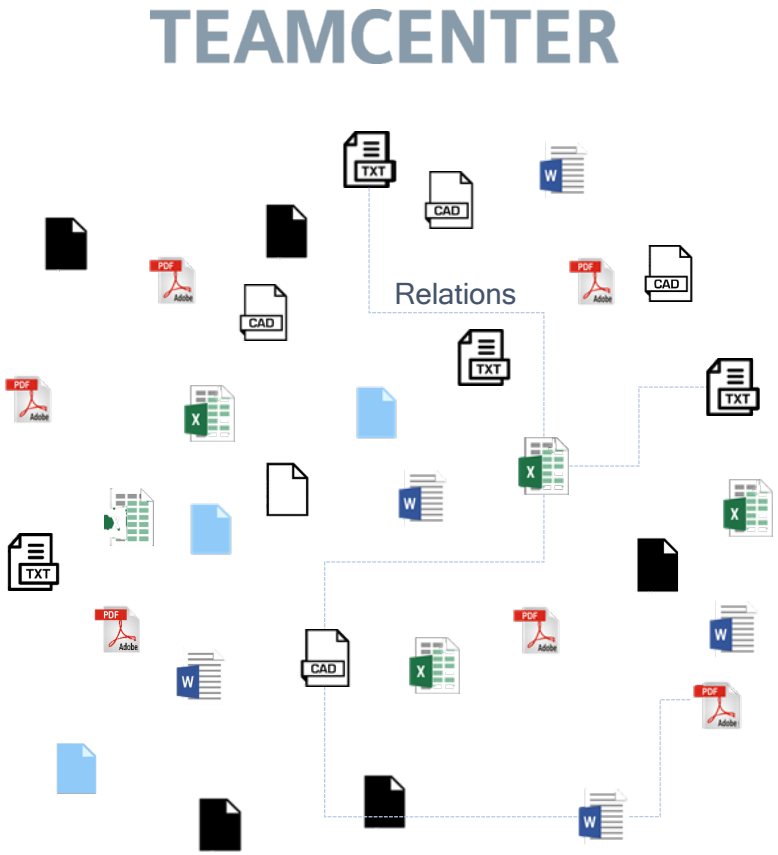
Design & Development Process from FDA's and ISO 13485:2016 perspective – © by seleon gmbh

Product Lifecycle Process for medical or other devices



Digitalization of the development process using TEAMCENTER

Daily questions and the answers



Project

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

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

How do I ensure complete registration documentation?

Are all my tasks created and is the documentation complete?

Efficiency

Quality

Speed

Flexible

Digitalization of the development process using TEAMCENTER

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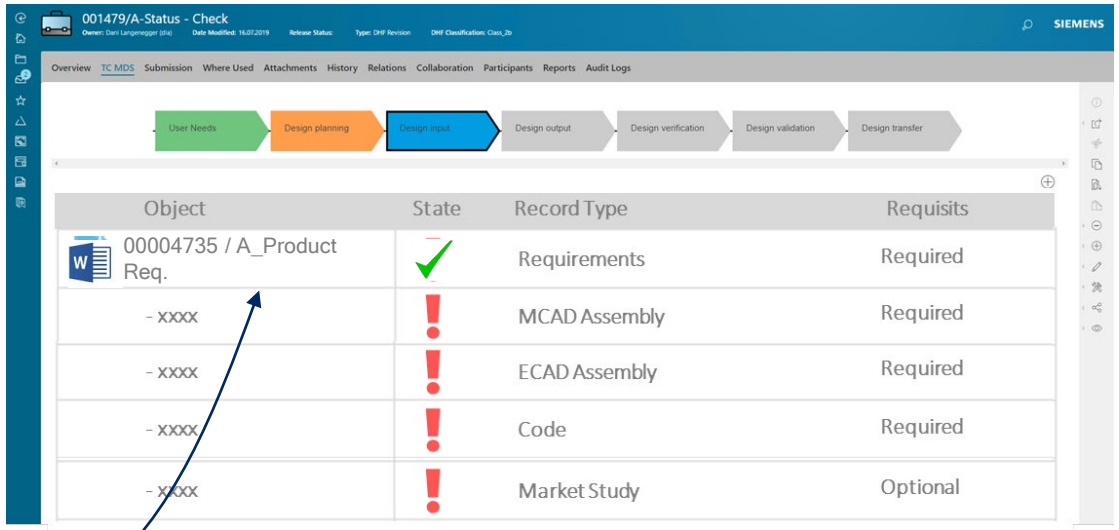
inspiring solutions

PLM (TC MDS)



Word Requirements

00004735

Product Requirement

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

Authoring tools

Digital TD
(Req., Risk, etc.)

POLARION

Writing tools

MCAD

SOLIDWORKS
AUTODESK INVENTOR
SOLID EDGE
NX
creo
CATIA

ECAD

Mentor Graphics
OrCAD
ZUKEN
ALTIUM DESIGNER20

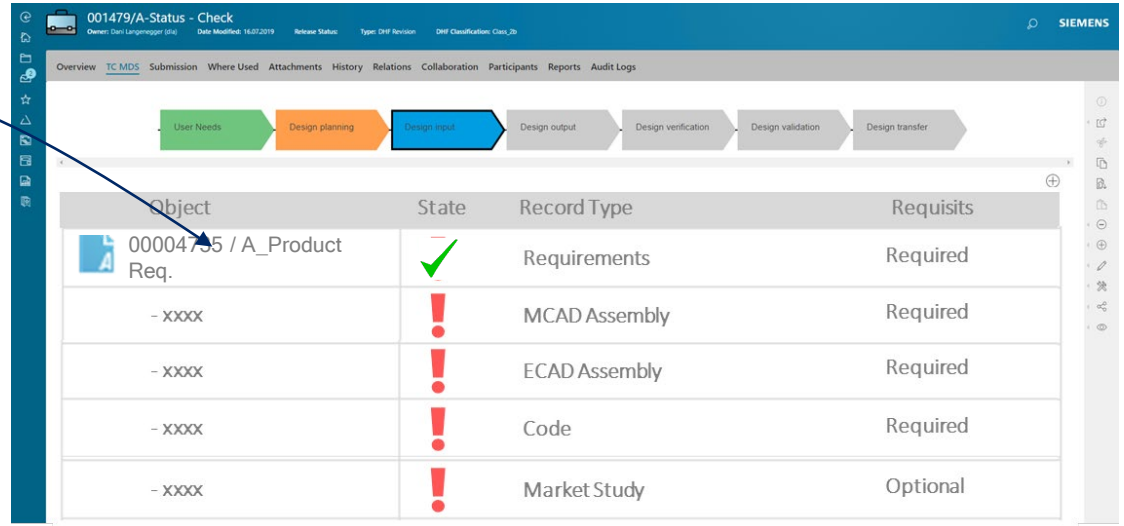
Other

Digitalization of the development process using TEAMCENTER

Polarion Requirements

- 00004735-Product Requirement
  - WI0015-Introduction
  - WI0020-Purpose
  - WI0021-Software Req.
  - WI0105-Reference
  - WI0095-Design Req.
    - WI0003-Weight
    - WI0005-Dimension

PLM (TC MDS)



Object	State	Record Type	Requisits
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.

Authoring tools

Digital TD
(Req., Risk, etc.)

POLARION

Writing tools

MCAD

SOLIDWORKS, AUTODESK INVENTOR, SOLID EDGE, NX, creo, CATIA

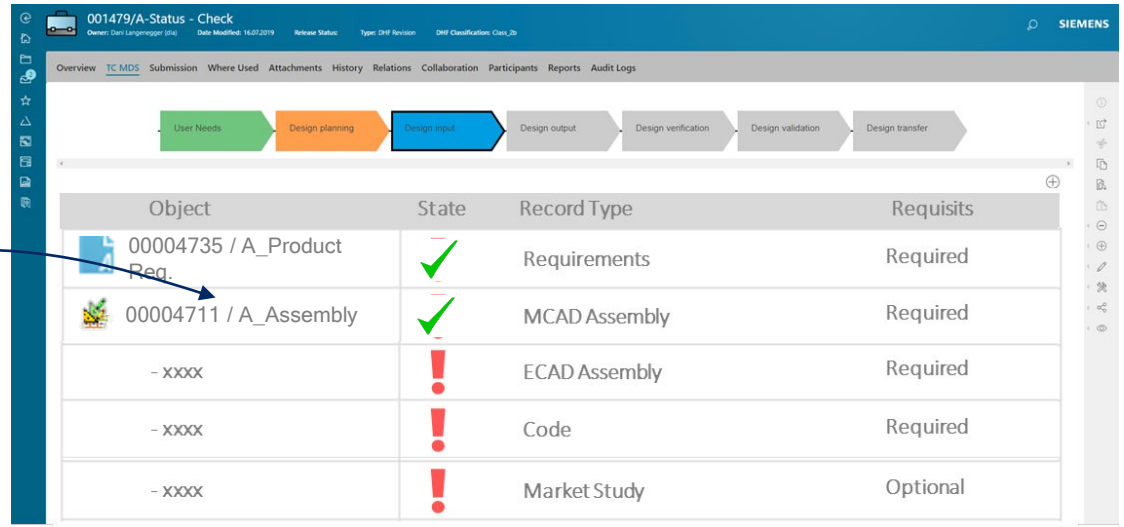
ECAD

Mentor Graphics, OrCAD, ZUKEN, ALTIUM DESIGNER 20

Other

Digitalization of the development process using TEAMCENTER

PLM (TC MDS)



MCAD

- 00004711-Assembly
  - 00004712-Part I
  - 00004713-Part II
  - 00004714-Part III
  - 00004715-Part IV
  - 00004716-PCBAC
    - 00004717-Cooler
    - 00004718-Terminal x2

Authoring tools

Digital TD
(Req., Risk, etc.)

POLARION

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Other

Digitalization of the development process using TEAMCENTER

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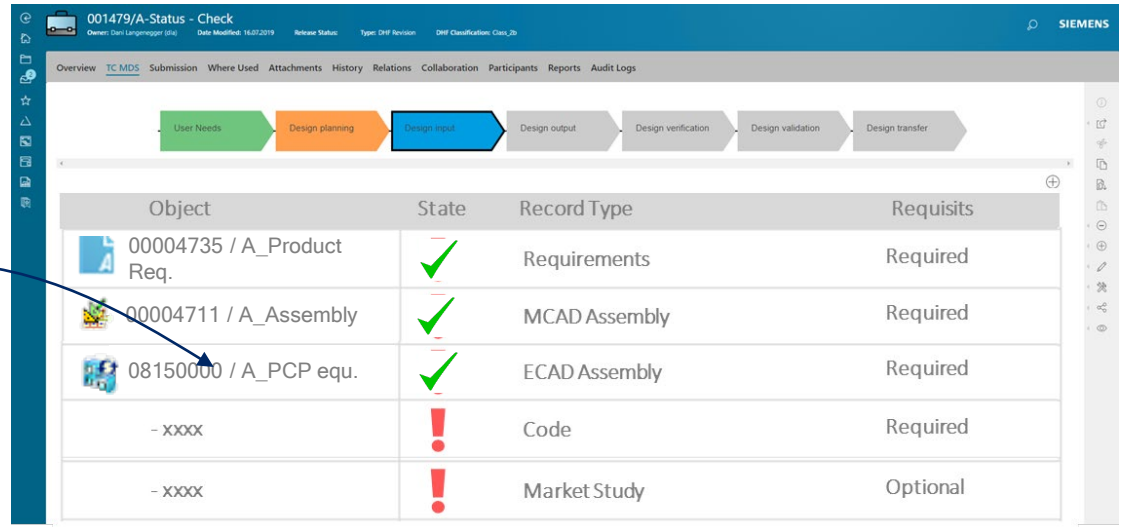
avasis
inspiring solutions

PLM (TC MDS)



ECAD

08150000-PCP equipped

52 0000816-PCB

52 0000817-Condenser

52 0000818-Recistance

Authoring tools

Digital TD
(Req., Risk, etc.)

POLARION

Writing tools

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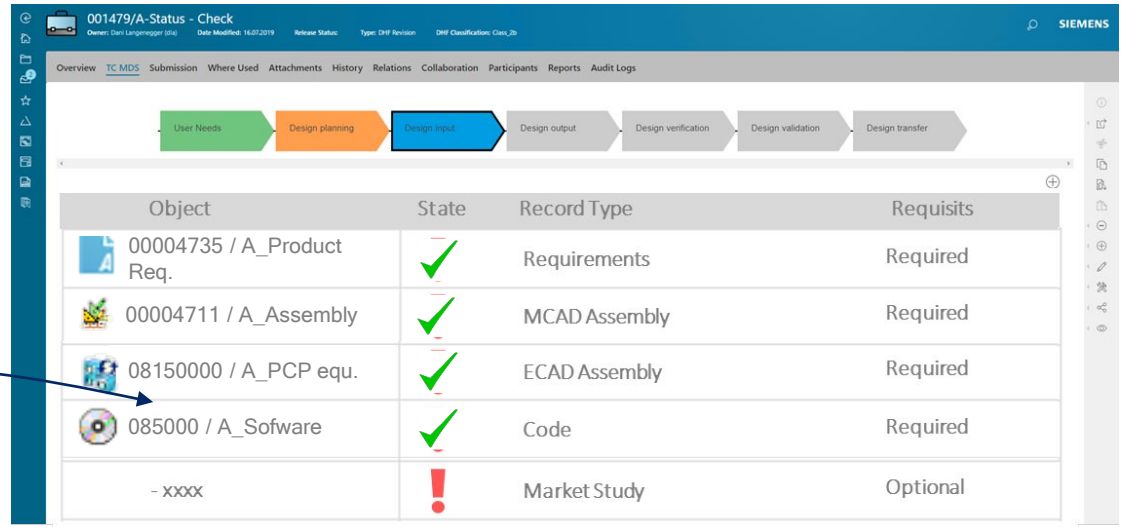
PLM (TC MDS)



Software

085000 Software

Authoring tools

Digital TD
(Req., Risk, etc.)

POLARION

Writing tools

MCAD

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NX
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CATIA

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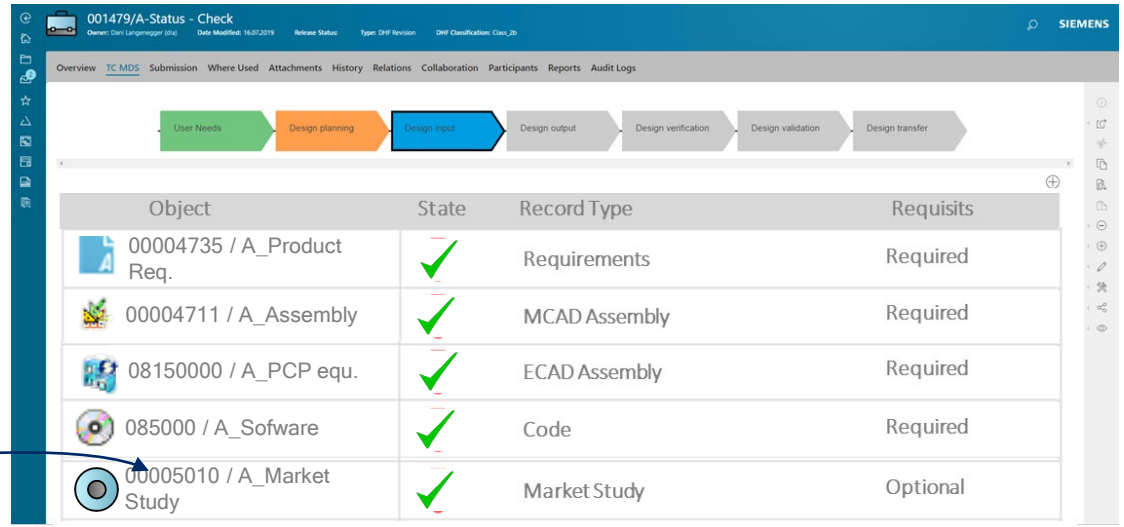
Other

Digitalization of the development process using TEAMCENTER

PLM (TC MDS)



Writing tools

PDF

Market Study.pdf

Authoring tools

Digital TD
(Req., Risk, etc.)

POLARION

Writing tools

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SOLIDWORKS
AUTODESK INVENTOR
SOLID EDGE
NX
creo
CATIA

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Mentor Graphics
OrCAD
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

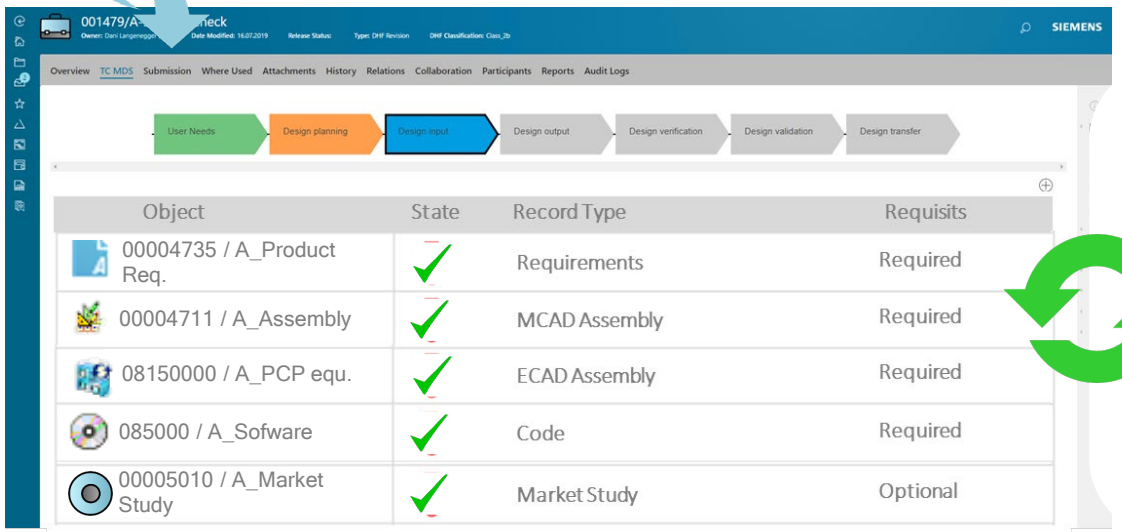
Examples:
- Stock information
- Cost / Price informationen

ERP: PSI ABACUS, majesty, sage, abas ERP, PROALPHA, SAP, Microsoft Dynamics

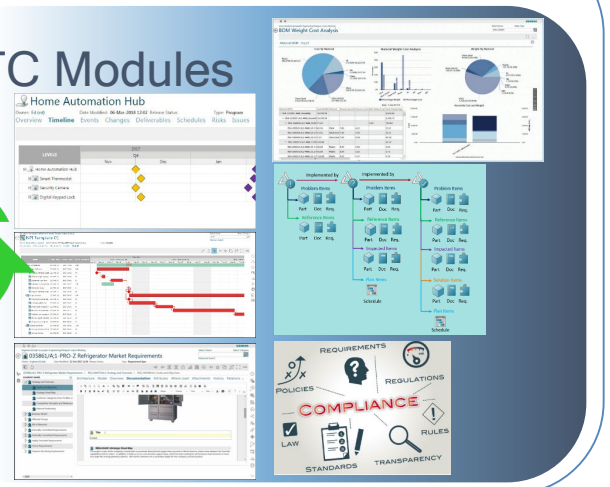
CRM

eCom-merce

PLM (TC MDS)



TC Modules



Authoring tools

Digital TD (Req., Risk, etc.)
POLARION

Writing tools

MCAD: SOLIDWORKS, AUTODESK INVENTOR, SOLID EDGE, NX, creo, CATIA

ECAD: Mentor Graphics, OrCAD, ZUKEN, ALTIUM DESIGNER

Other

Digitalization of the development process using TEAMCENTER

Transfer to CRM

Examples:
- Vendor information
- RFQ Datas

Transfer to eCommerce

Examples:
- Data sheets
- 3D Datas (dummy)

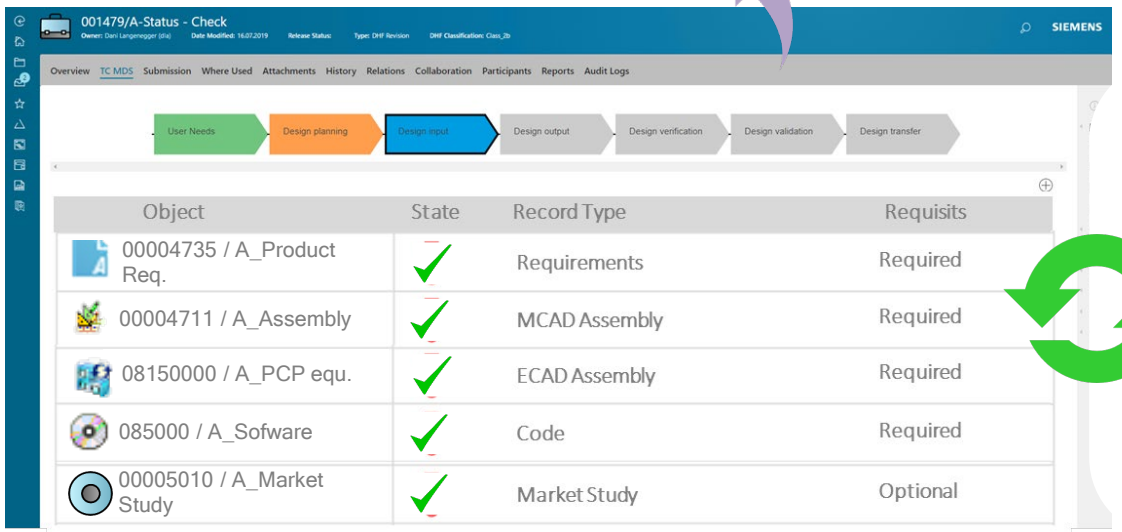
ERP

PSI ABACUS majesty sage abas ERP PROALPHA SAP Microsoft Dynamics

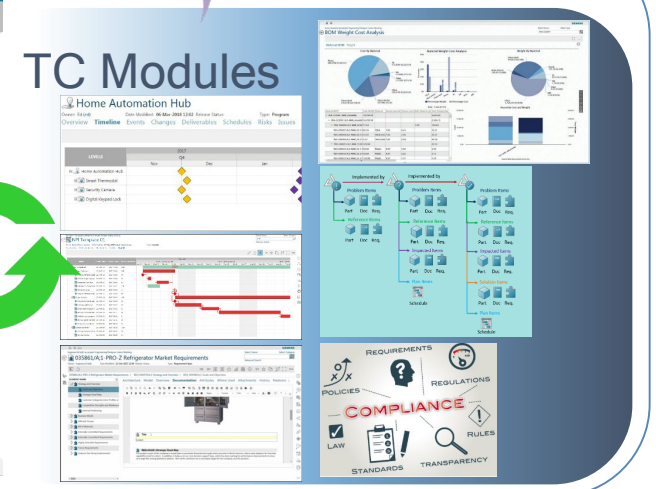
CRM

eCom-merce

PLM (TC MDS)



TC Modules



Authoring tools

Digital TD
(Req., Risk, etc.)

POLARION

Writing tools

MCAD

SOLIDWORKS AUTODESK INVENTOR SOLID EDGE NX creo CATIA

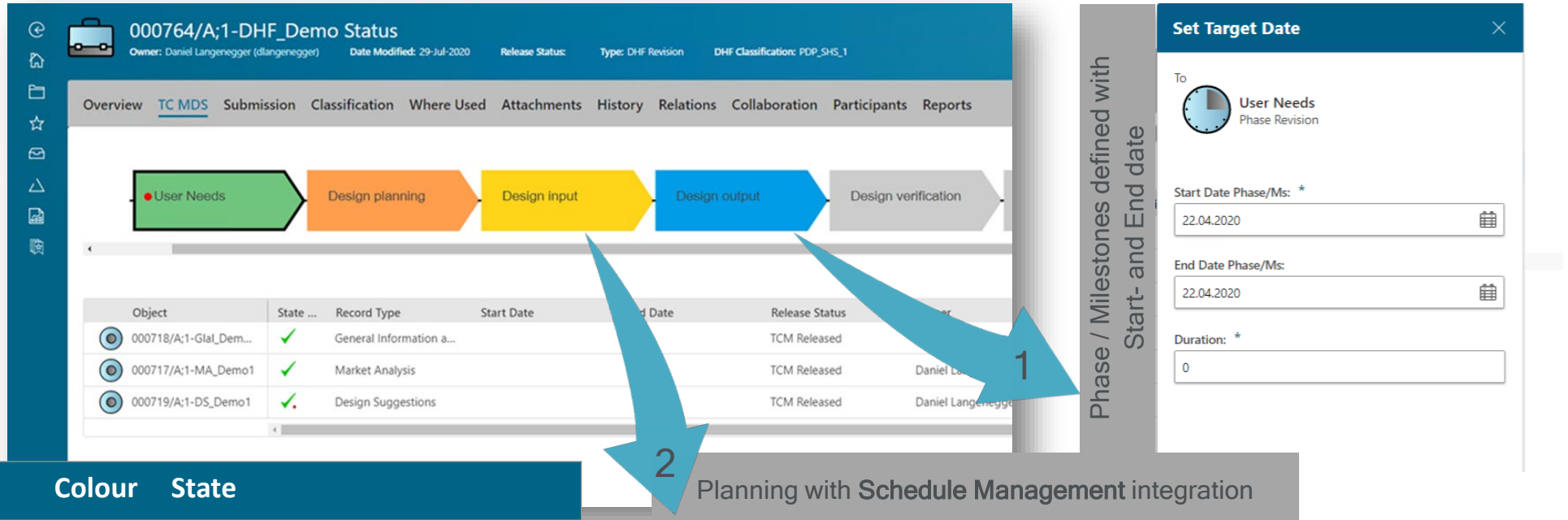
ECAD

Mentor Graphics OrCAD ZUKEN ALTIUM DESIGNER20

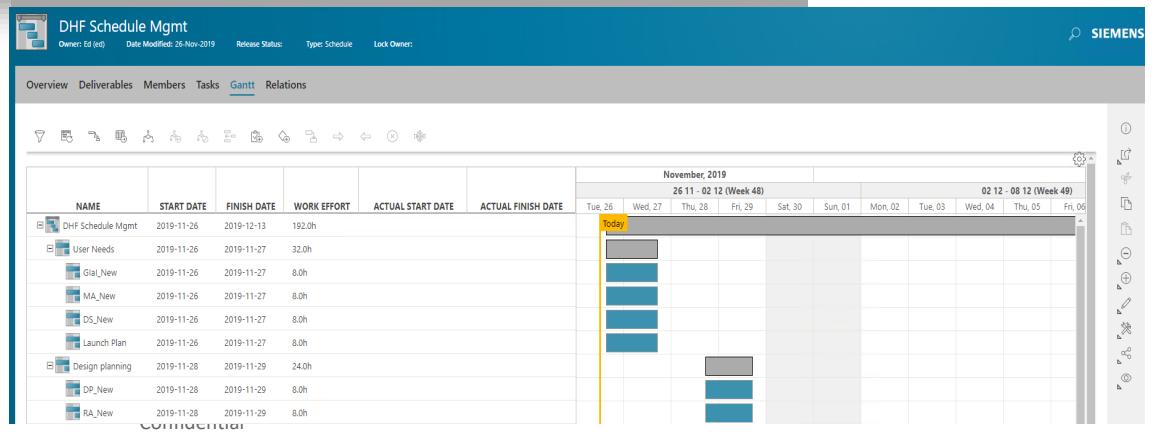
Other

Digitalization of the development process using TEAMCENTER

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

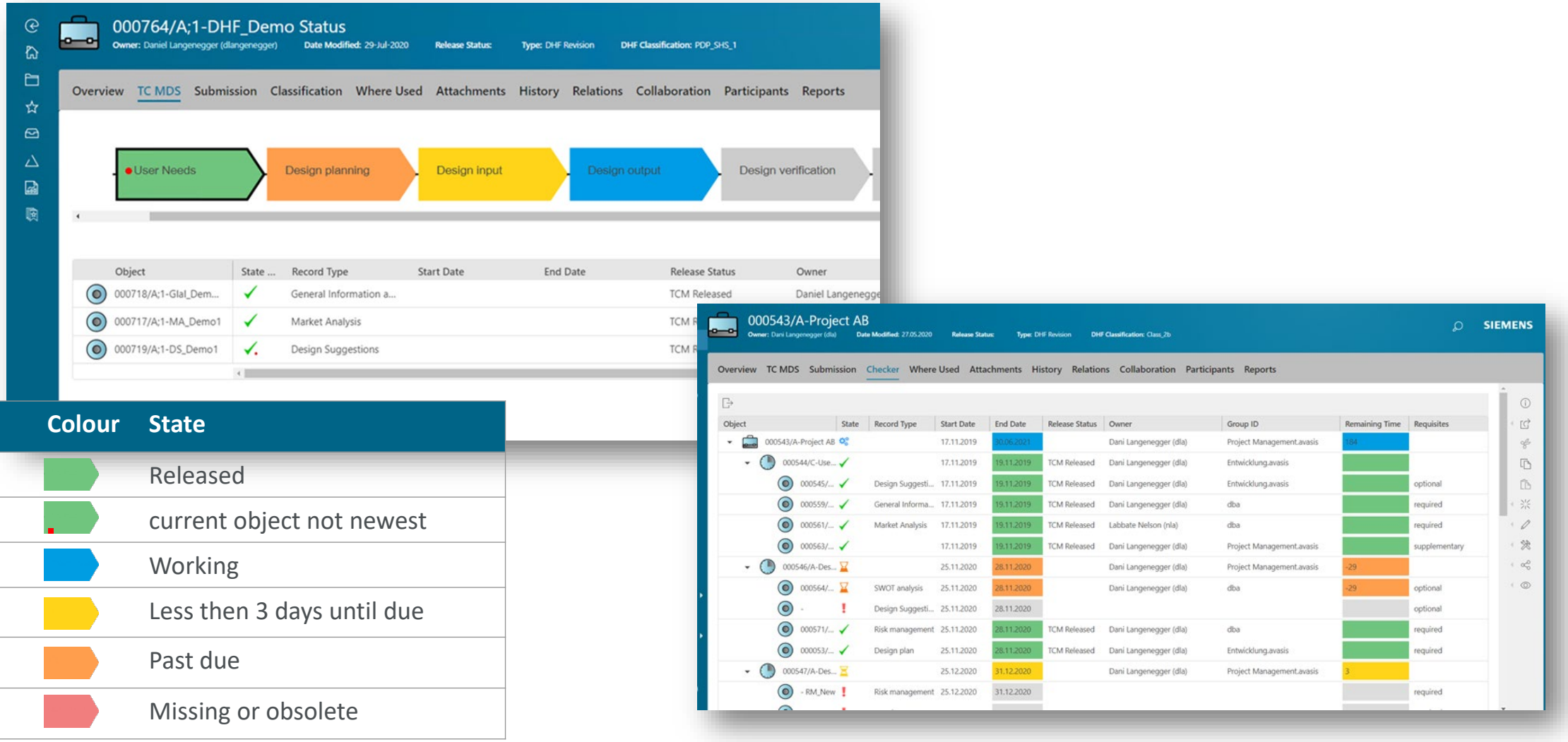


Icon	Colour	State
✓		Released
✓		current object not newest
⚙		Working
⧗		Less then 3 days until due
⧗		Past due
!		Missing or obsolete



Digitalization of the development process using TEAMCENTER

Monitoring of project progress



Icon	Colour	State
✓		Released
✓.		current object not newest
⚙		Working
⧗		Less then 3 days until due
⧗		Past due
!		Missing or obsolete

Challenge: Most of the effort goes into the Technical Documentation

- ✓ FASTER
- ✓ CHEAPER
- ✓ LESS RESOURCES

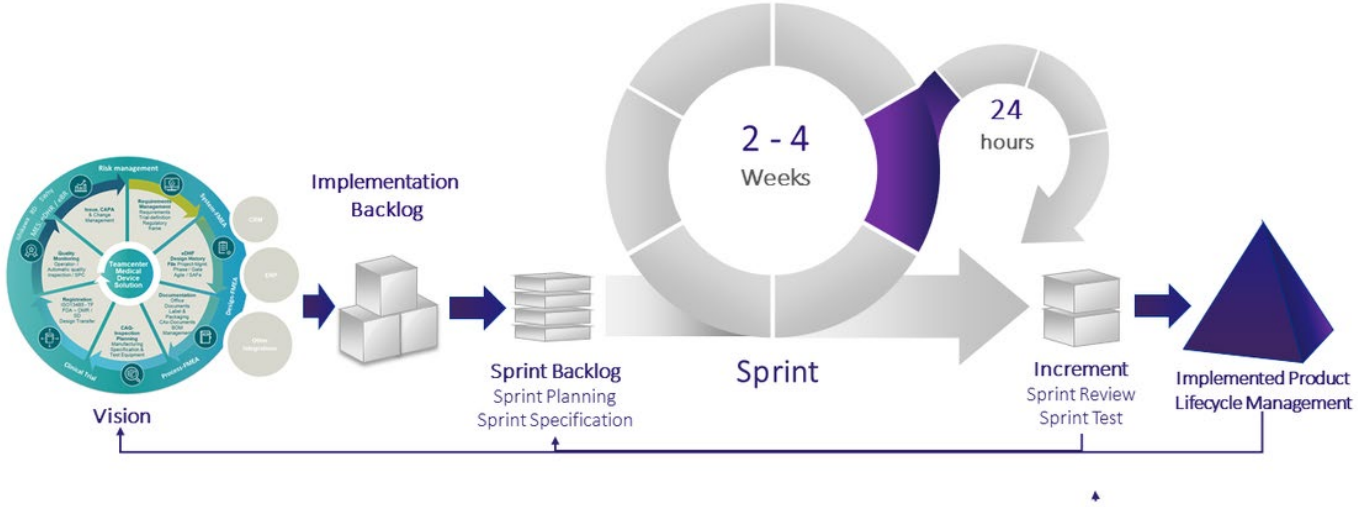
- ✓ REDUCED COSTS
- ✓ FAST MARKET APPROVAL
- ✓ MORE INNOVATION
- ✓ IMPROVED PATIENT CARE

MANUFACTURER	Waste of time: inefficient creation of TD	Efficient creation of TD, Transparent updates with changes
	Unnecessary rework to eliminate findings	Automated completeness check of TD content, Elimination of inconsistencies through reuse of data
	Digitization takes to long, is too expensive	Fast implementation of software solutions to achieved efficient digital processes
COMPETENT AUTHORITY	Waste of time: Search of information	Clear identification / tagging of required TD content
	No time for review of all relevant content	Elimination of activities without value to allows focus on content
	Waste of time: Findings for missing content	Automated completeness checks of submitted content

Solution: Application Lifecycle Management (ALM)

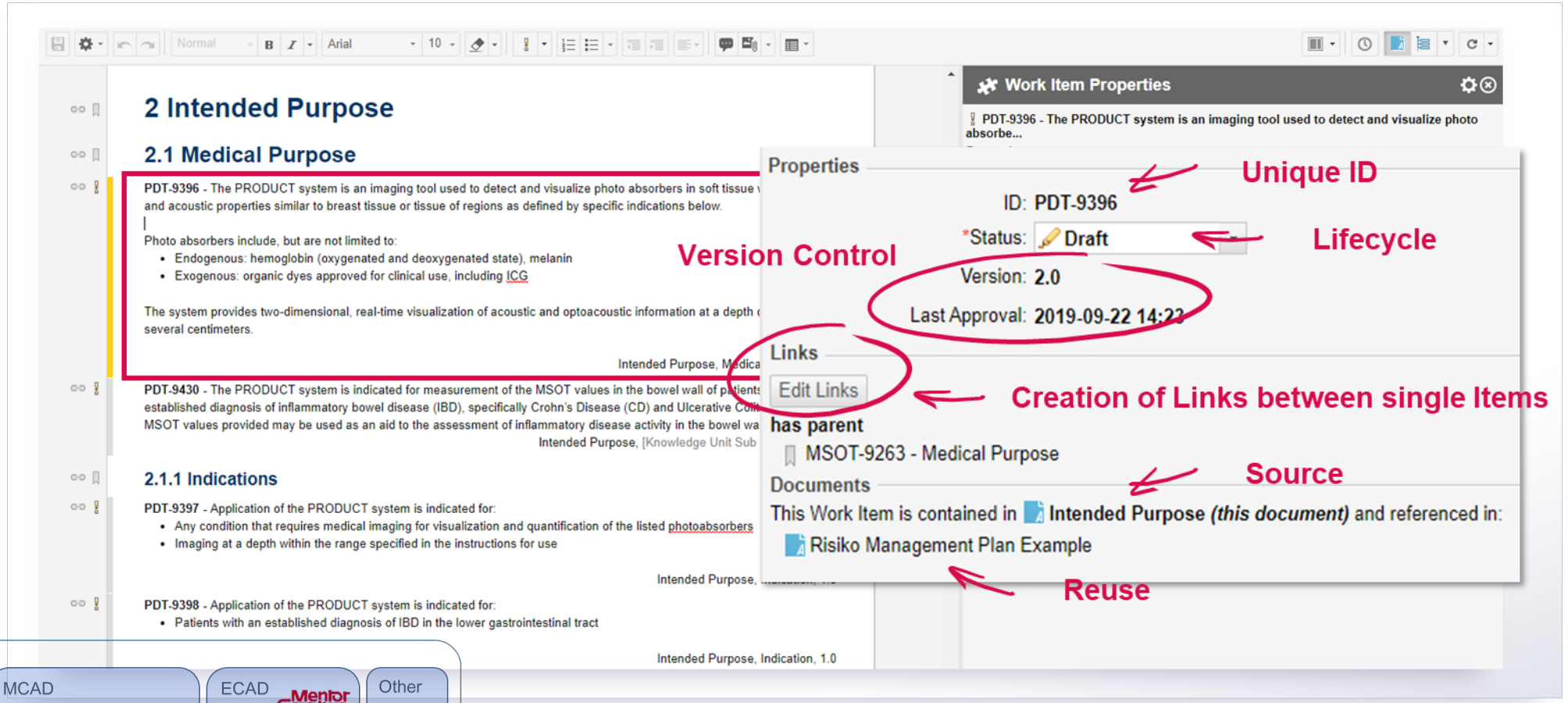
Digitalization of the development process

- Browser-based A**pplication 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



Solution: Application Lifecycle Management (ALM)

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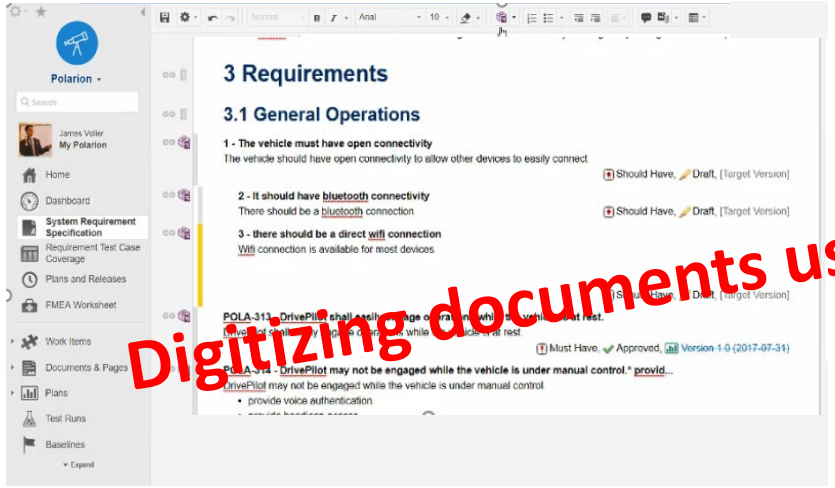
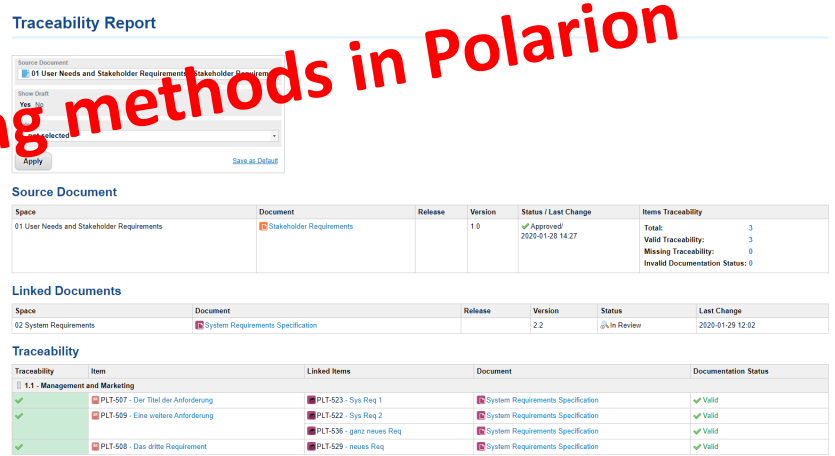
avasis
inspiring solutions

Requirements Management	Risk Management	Verification & Validation



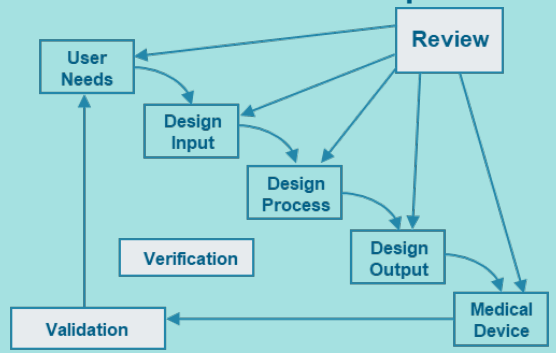


Digitizing documents using object-oriented working methods in Polarion

- 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

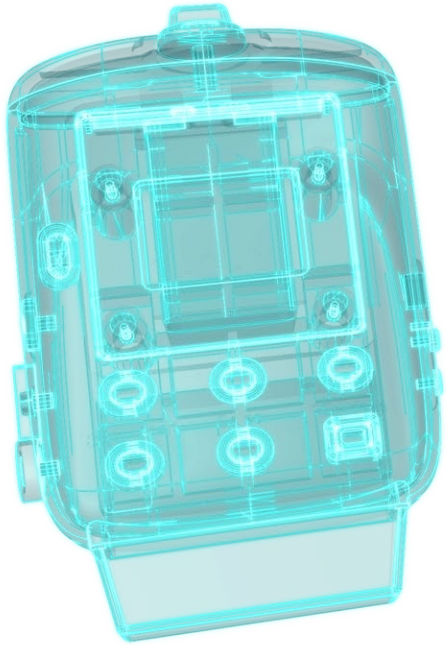
- Process Optimization with regard to the relevant tools (the process should follow the tool – not vice versa)
- Development of set-up and transfer concepts
- Support in setting up and/or transferring the QM system into the digital systems
- Support in setting up and/or transferring the Technical Documentation(s)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

A look into the future…

Holistic Digital Twin

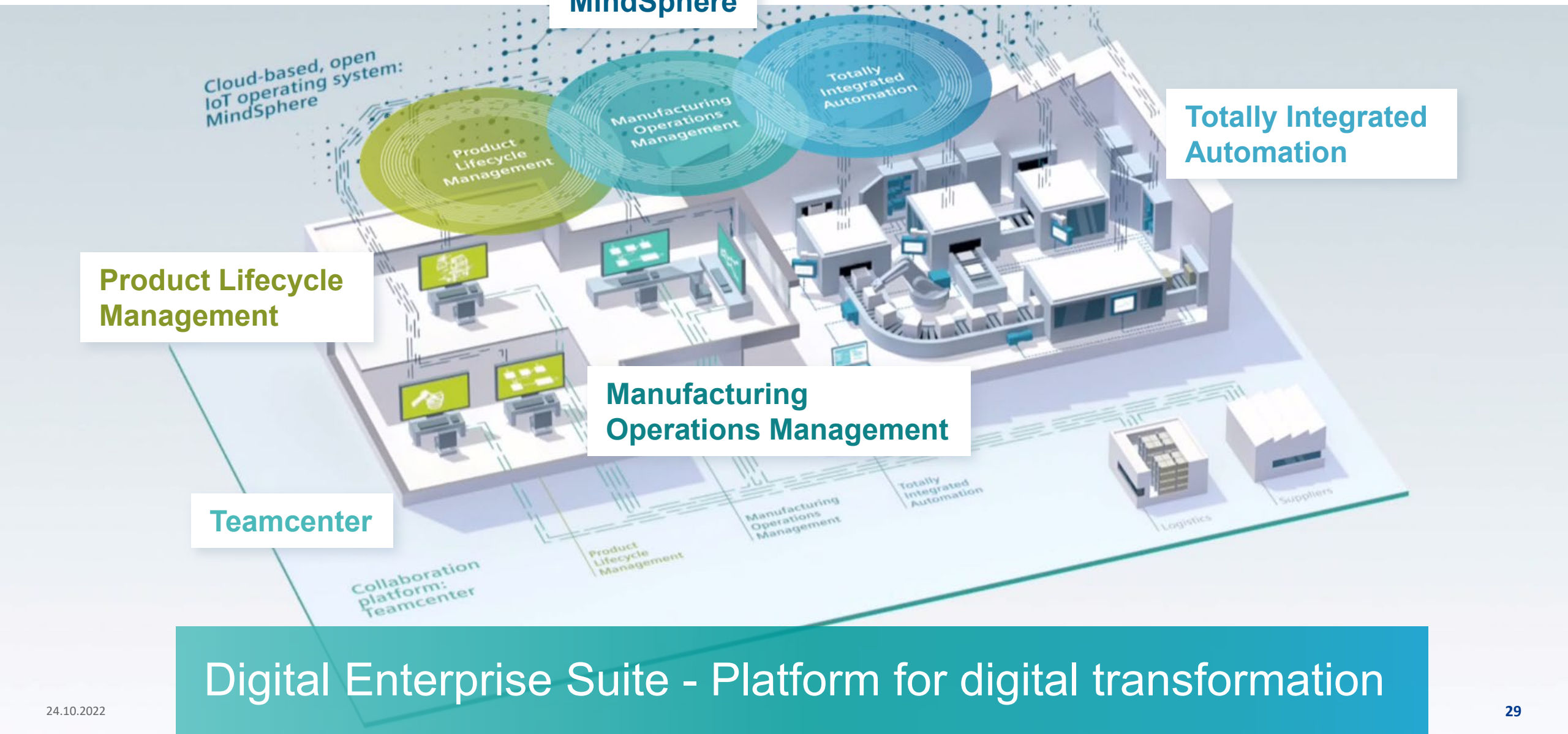
Digital twin of the production

Digital twin of the product



Digital twin of usage and behavior

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.

Contact

Tel.: 07131 / 2774 - 0

Fax: 07131 / 2774 - 100

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