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**Digitalisierung von 0 auf 100
– Traum oder Wirklichkeit?**



Hosts



SHL Medical AG

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2021 -	Business Owner PLM
2018 – 2021	PLM Introduction Program Lead
2013 – 2017	Head of CAx Methodology
2013	MBA Medical Devices and Healthcare Mangement
2005 - 2012	Entwicklungsingenieur spinal implants and instruments
2005	Dipl.-Ing. (FH) Maschinenbau

2021 -	Gesellschafter-Geschäftsführer
2012 - 2021	Geschäftsführer MRT PLM Deutschland GmbH
2005 - 2012	PLM Solution Architect & Lead Development MRT Information Management GmbH
2005	Werkmeister der Elektrotechnik



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 - Wo suchen wir noch nach Lösungen?
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Hinweise

- Workshop
- Interaktiv
- Einfach fragen
- Bremsen, wenn es zu technisch wird

- **Wir werden weniger zeigen, wie unsere Prozesse aussehen. Sondern was wir getan haben, um uns darauf konzentrieren zu können**
- Der erste Teil wird eher theoretisch sein, im zweiten Teil zeigen wir wie es tatsächlich funktioniert
- Wir zeigen den Inhalt an unseren live Systemen – Fehler können passieren



SHL Medical



What we do

We design, develop, and manufacture advanced drug delivery devices such as **autoinjectors, pen injectors, and innovative specialty delivery systems** for large-volume and high-viscosity formulations.

We also provide **design-to-build and contract manufacturing services** for products like laboratory handling equipment, neurosurgical instruments, and industrial equipment for the integrated circuit and semiconductor industry.

By equipping our experienced development teams and skilled workforce with **efficient manufacturing**, we have developed a business model that works for everyone. It allows us to deliver comprehensive solutions for even the industry's most demanding projects and to offer **experience, excellence, and vision** to customers and partners all over the world.





Facts and figures



Top 25

majority of pharma/biotech companies in partnership with SHL



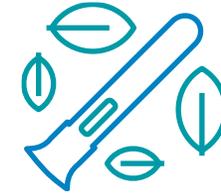
+34%

compound annual shipment growth rate (CAGR) 2019-2023



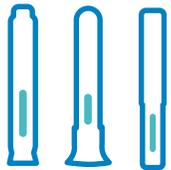
> 5,700

employees worldwide



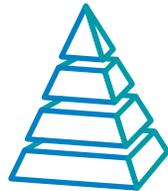
-40%

energy usage per sold device since 2020



Over 50

combination products launched*



30 years

of pioneering the drug delivery industry



~60

employee nationalities



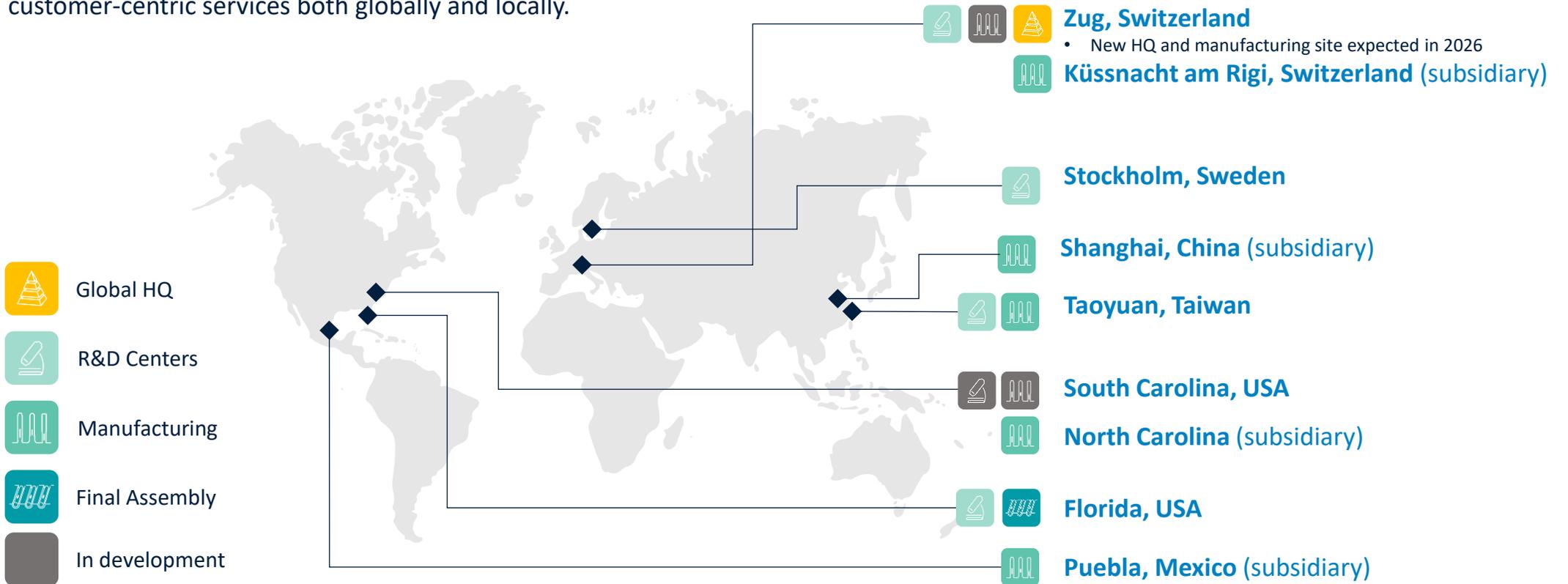
>86 M

SHL autoinjectors reached patients worldwide between Q3 2022 to Q2 2023*



We operate across the globe

Our global teams provide support **across multiple time zones with streamlined project management skills** to deliver excellent customer-centric services both globally and locally.

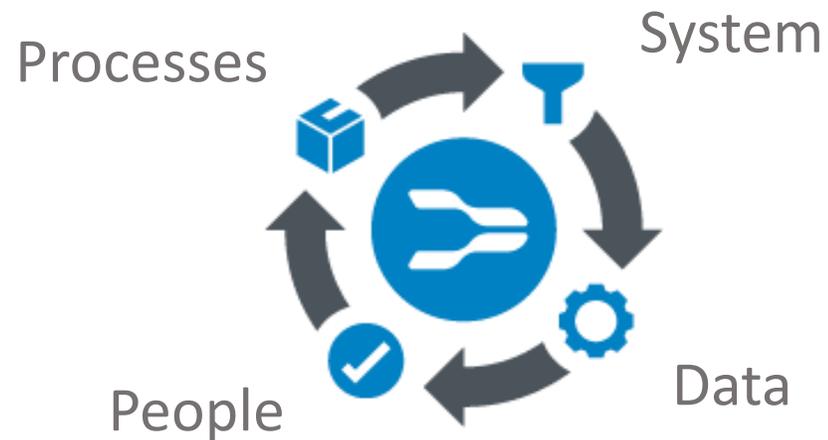




Digital Vision



4 Dimensions



People

Org **structure** and skill level needs to fit -> OCM

Processes

Processes need to be adapted and **optimized** for digitalisation -> BPM

System

Out-of-the-Box and **best practise** approach from the system needs to be paired with **custom-process** needs -> agile and robust implementation with fast improvements

Data

Data-centric mindset instead of thinking in documents -> Data Backbone and Architecture

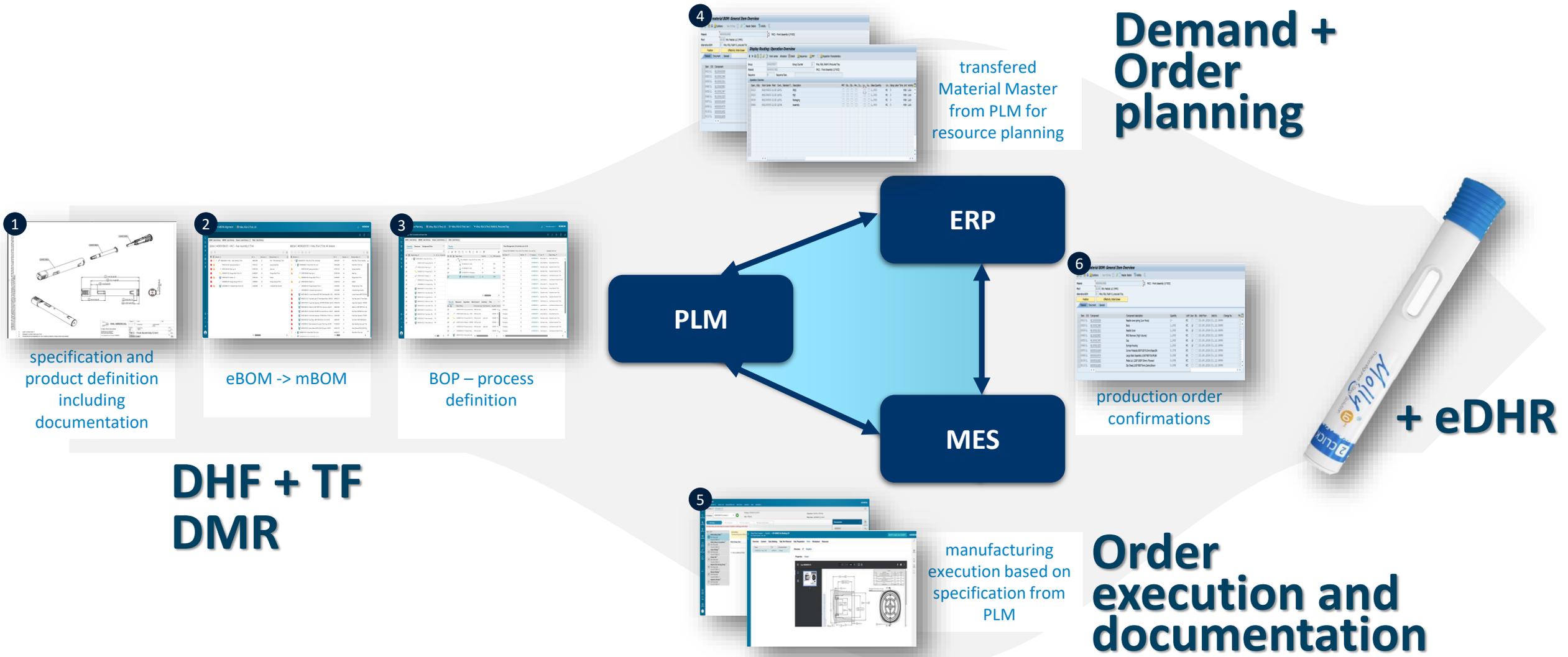


Principles for PLM Governance

-  • **One harmonized SHL Framework**
 - Same methodology and thinking for all users – harmonized main process and derived process variants e.g. Design Process with variants for mechanical and electro-mechanical product or Change Management with variants for design, document, project and equipment
-  • **Seamless End-to-End**
 - Process design overarching several domains comprising a core process
-  • **Single Source of Truth**
 - One defined (leading/master) platform for each data set. The other platforms “only” use or link
-  • **Out of the Box functionality / best practice approach**
 - Base the process design on best practice and out of the box functionality – only customization or enhancements where it is really needed.
-  • **Process-centric approach with data**
 - No department, functional and document driven focus! Focus on our core processes according TOM



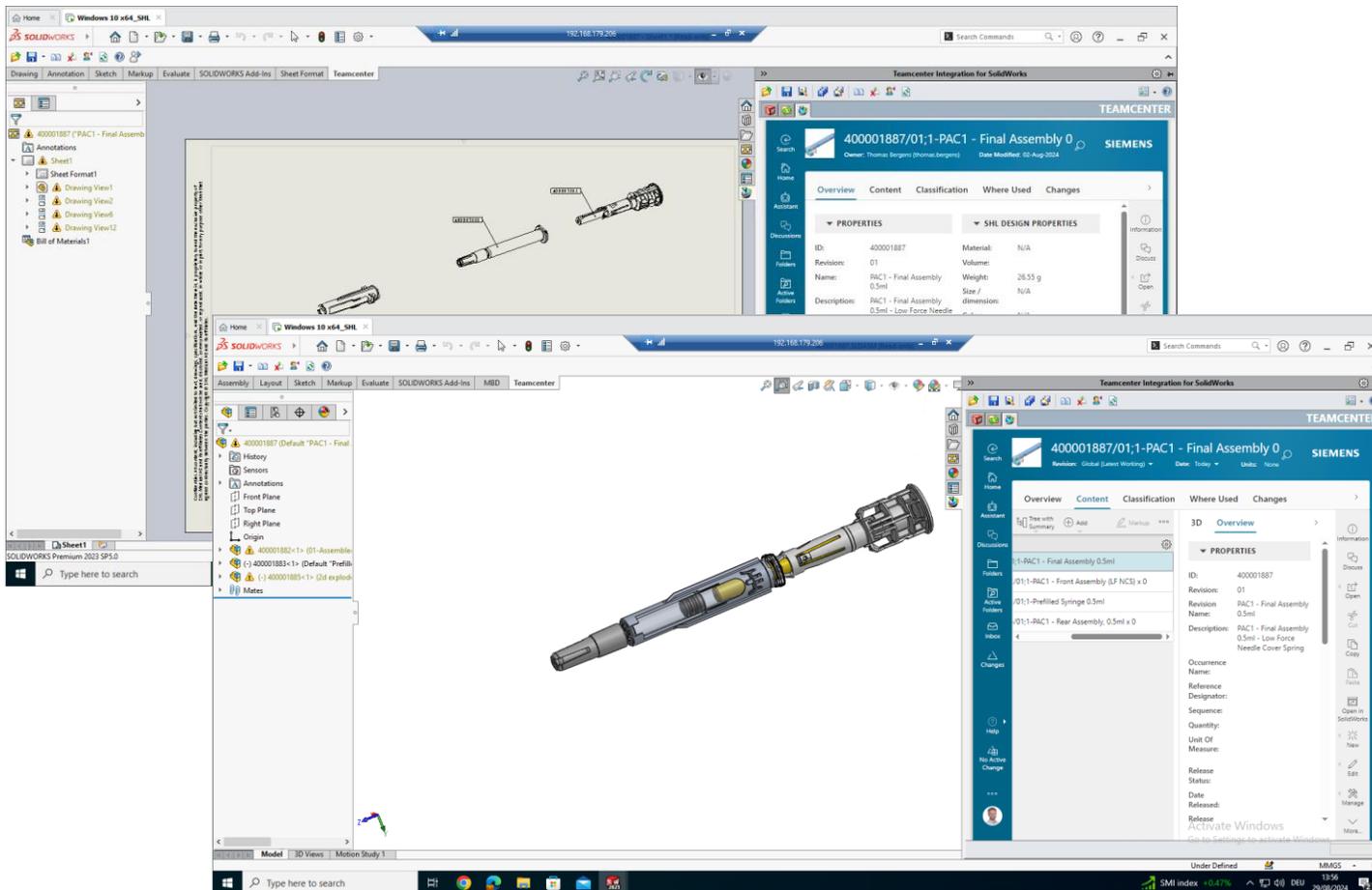
The "Magic Triangle"





Cx Integration into PLM

SolidWorks-Teamcenter integration



Comments:

- CAD tools SolidWorks and NX interfaced to Teamcenter
- 3D models / drawing created and maintained in Teamcenter
- Workflows could be started directly out of CAD
- PLM users are able to view drawing and models without CAD access
- eBOM automatically created based on the 3D model



Requirements Engineering and Risk Management integrated

SHL Document Library > ...emplates > 1. Product Development > DIR Template for D1 Device

7 FUNCTIONAL REQUIREMENTS

Ensure Trace Information include Customer Input Document(s), or other input document, as well as document and item number(s).

7.1 Functional requirements with specification limit

This section defines functional requirements for the medical device. All Primary Functions shall be well as after preconditioning.
This section additionally defines the applicable parts of ISO 11608-5 for D1
Be careful to not specify specification limits with higher accuracy (e.g. CL 95% / p 95%) than by test equipment/systems.

RL-89 - Dose Accuracy
The device shall be able to deliver the entire labelled volume from

Specification Limit	≥ [insert LSL] mL
Requirement Type	Functional
Verification Method	Instrumental Test
DV Acceptance Criteria	CL 95%/ p [insert]
	ISO 11608-1:2022 require acceptance cr Free fall where CL 95%/ p 95% can be us
SHL End User Severity of Harm	N/A
Rationale	N/A
Assumption	N/A
Remark	Primary Function nor [Add reference to it

Document Properties: DIR Template for D1 Device (Rename)
Location: 1_Design > DIR Requirements Template for D1 Device
Type: Design Input Requirements (DIR) (Change)
Updated: 1 month ago by Mohamed Shehata on 2024-09-11 08:35 (V)
Fields: *Status: Approved or Relea

12 Risk Management File

The following figure [Figure 1] depicts the content of the Risk Management File (RMF) and provides a general flow of risk management activities at SHL Medical. Risk management activities at SHL Medical are integrated into the device development and product lifecycle management processes.

Document Properties: Risk Management Plan Template (1)
Location: 3_RiskManagement > RiskManagement
Type: Risk Management Plan (RMP) (Change)
Updated: 4 months ago by AVA.Dennis Todoric on
Fields: *Status: Approved or Releaz
Chinese Title:
Document Author: Florian Meisgen
Reviewer(s): --
Document ID:
Document Version:
Change Description:
N/A
Template ID: 00000788
Template Version: 01
Medical Harm List: ..

Comments:

- Requirements authored in Polarion
- Risks collected and evaluated
- Results transferred to PDP / TF



PLM a single source for product data

The screenshot displays the Siemens Teamcenter PLM interface for project A-000407/01-Molly_AID_TC. The top navigation bar includes tabs for Overview, TC MDS, Collections, Checker, Classification, Where Used, Attachments, History, Relations, Participants, Reports, and Audit Logs. A progress bar shows the project phases: Intake, Planning, Design, Engineering (highlighted), and Validation. Below the progress bar, the start and end dates for the phase are listed as 31.10.2022. A table of deliverables is shown with columns for Object, State, Deliverable Type, Name, Requisites, Owner, Group ID, R..., and End date. An inset window shows a 'DHF Master List' with columns for Object, State, Record Type, Start date, End date, Release, Owner, Group ID, Remaining Time, and Requit. Another inset window shows a 'Checker' view with columns for Object, State, Record Type, Start date, End date, Release, Owner, Group ID, Remaining Time, and Requit.

Comments:

- PDP contains all data around the product
- All deliverables in one place
- Collections represent DHF or DMR
- Quick overview for Project Managers via checker



Enriching eBOM to full qualified mBOM

Example eBOM and mBOM

EBOM 400001886/01;1-PAC1 - Rear Assembly 0.75ml				MBOM 400002687/01;1-Mira, RSA 0.75ml, All Variants			
Part Number	Quantity	Revision	Description	Part Number	Quantity	Revision	Description
400001886/01;1-PAC1	01	01	Rear Assembly 0.75ml	400002687/01;1-Mira, RSA 0.75ml, All Variants	01	01	Mira, RSA 0.75ml, All Variants
410001323/03;1-Spring Guide Rod x 0	03	03	Spring Guide Rod	400002688/01;1-Mira, RSA 0.75ml, Var.1	01	01	Mira, RSA 0.75ml, Var.1
410001326/03;1-Rear Cap x 0	03	03	Rear Cap	410001323/04;1-Spring Guide Rod x 1	04	04	Spring Guide Rod
410002837/02;1-Plunger Rod 0.75 mL x 0	02	02	Plunger Rod 0.75 mL	410001326/04;1-Rear Cap x 1	04	04	Rear Cap
410001324/01;1-Rotator x 0	01	01	Rotator	410002837/02;1-Plunger Rod 0.75 mL x 1	02	02	Plunger Rod 0.75 mL
410002852/03;1-Plunger Spring 0.75mL x 0	03	03	Plunger Spring 0.75mL	410001324/02;1-Rotator x 1	02	02	Rotator
410002898/01;1-U-Bracket (High Volume) x 0	01	01	U-Bracket (High Volume)	410002852/03;1-Plunger Spring 0.75mL x 1	03	03	Plunger Spring 0.75mL

Comments:

- The eBOM is created in Teamcenter automatically based on the device design
- The mBOM is created based on eBOM by adding non-design parts / manufacturing items such as:
 - Raw materials
 - Packaging materials
- Multiple mBOM can be created based on the same eBOM depending on the variations in the manufacturing process



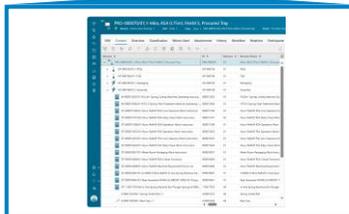
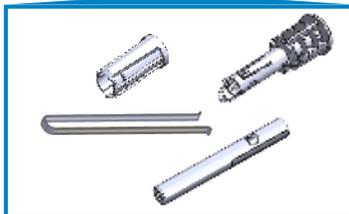
Definition of the manufacturing process in the BOP

Example BOP

The screenshot displays the SAP S/4HANA Process Planning interface. The main window shows a list of manufacturing operations for process PRO-000068/01:1-Mira, RSA 0.75ml, FAAM 4. The operations include IPQC, FQC, and various assembly steps. A 'Time Management' window is open, showing a detailed view of the operations with columns for Rev Name, Find No., Assigned, Line, and Object String. The total duration is 66.43 minutes. Below the operations list, there are sections for 'Parts (8)', 'Resources', 'Inspection', 'Work Area (1)', and 'Summary'.

Comments:

- The manufacturing process is defined in the Bill of Processes (BOP) by its manufacturing operations
- Each operations is described by:
 - **Where** the operation is executed – the **work center and resource**
 - **What** is consumed in the operation – the **materials** (design, packaging, raw material...)
 - **How** the operations shall be executed – specifying **DMR and QMS documents**
- Additionally, the manufacturing process cycle times are input to the BOP
- The content of the BOP is transferred to SAP as BOM/routing
- Document information is transferred to MES for operator access and documentation in the eDHR



Work center / resources

Design / packaging materials

DMR / QMS documents



ERP side for planning

Example transfer of mBOM & BOP to ERP BOM & routing

400002649/02:1-Mira, FSA, Var.3

Element #	Type #	Description #
400002649/02:1-Mira, FSA, Var.3	SHL MBOM Ass.	Mira, FSA, FAAM 5, procured Tray
41000038/03:1-Needle Cover Spring (Low Force) x 1	SolidWorks Des.	Needle Cover Spring (Low Force) for Molly 1.0 mL
41000148/01:1-Body x 1	SolidWorks Des.	Migrated - Body - Selma
41000132/03:1-Needle Cover x 1	SolidWorks Des.	Needle Cover component for Molly 1.0 mL plg
410002947/01:1-RNS Remover (High Volume) x 1	SolidWorks Des.	Migrated - RNS Remover from progressive s
41000147/01:1-Cap x 1	SolidWorks Des.	Migrated - Cap - Selma
410001325/03:1-Syringe Housing x 1	SolidWorks Des.	Syringe Housing component for Molly 1.0 mL
400001469/01:1-Corner Protector/900*180*5mm,Paper,BN	SolidWorks Des.	Corner Protector/900*180*5mm,Paper,BN
400001478/01:1-Large Stack Separator,1180*800*26,PR,BN	SolidWorks Des.	Large Stack Separator,1180*800*26,PR,BN
400001482/01:1-Pallet Lid,1200*1000*15mm,Plywood x 8...	SolidWorks Des.	
400001485/01:1-Slip Sheet,1180*900*3mm,Carbon,Brown x...	SolidWorks Des.	
400001486/01:1-Small Stack Separator,370*800*25mm, P...	SolidWorks Des.	Small Stack Separator,370*800*25mm, P...
400001487/01:1-Top Sheet,1600*1450*0.04mm, PE x 9.5e...	SolidWorks Des.	Top Sheet,1600*1450*0.04mm, PE
400001475/01:1-Wire,0.70mm,SUS302,BR,NC,Spool x 0.0014	SHL Raw Part R...	
410002917/01:1-FAAM Label,DC-121160 x 0.000473	SolidWorks Des.	Migrated - FAAM Label DC-121160GAP3000
400001033/01:1-Tray,40001033,589*389*22,74*11,2,RET...	SolidWorks Des.	A-000147 Front Assembly Tray (gray)

PLM

0060/02:1-Mira, FSA, FAAM 5 Procured Tray

Element #	ID #	Revision #	Revision Name #
PRO-000000/02:1-Mira, FSA, FAAM 5 Procured Tray	PRO-000000	02	Mira, FSA, FAAM 5 Procured Tray
OP-000161/01:1-FQC	OP-000161	01	FQC
OP-000162/01:1-FQC	OP-000162	01	FQC
OP-000163/01:1-Packaging	OP-000163	01	Packaging
OP-000164/01:1-Assembly	OP-000164	01	Assembly
W-000013203/01:1-FIL26 - Spring Coiling Machine Operating Instructi...	000013203	01	FIL26 - Spring Coiling Machine Op
W-000013204/01:1-HTU12 Spring Heat Treatment Machine Operating I...	000013204	01	HTU12 Spring Heat Treatment Machi
ZF-000015060/01:1-Nowo FAAMS FSA Line Clearance Work Instruction	000015060	01	Nowo FAAMS FSA Line Clearance H
ZF-000015070/01:1-Nowo FAAMS FSA Daily Check Work Instruction	000015070	02	Nowo FAAMS FSA Daily Check Work
ZF-000015080/01:1-Nowo FAAMS FSA Operation Work Instruction	000015080	01	Nowo FAAMS FSA Operation Work I
ZF-000015432/01:1-Nowo FAAMS FSA Operation Work Instruction	000015432	01	Nowo FAAMS FSA Operation Work I
ZF-000015433/01:1-Nowo FAAMS FSA Line Clearance Work Instruction	000015433	01	Nowo FAAMS FSA Line Clearance W
ZF-000015434/01:1-Nowo FAAMS FSA Daily Check Work Instruction	000015434	01	Nowo FAAMS FSA Daily Check Work
ZF-000016075/01:1-Metal Room Packaging Work Instruction	000016075	01	Metal Room Packaging Work Instru
ZF-000016405/01:1-Nowo FAAMS FSA Critical Functions	000016405	01	Nowo FAAMS FSA Critical Functions
ZF-000016406/01:1-Nowo FAAMS FSA Machine/Equipment List	000016406	01	Nowo FAAMS Machine/Equipment
ZF-000016447/01:1-A-000414 Mira FAAMS In-Line Spring Machine No...	000016447	01	A-000414 Mira FAAMS In-Line Sprn
41000038/04:1-Needle Cover Spring (Low Force) x 1	41000038	04	Needle Cover Spring (Low Force)
41000148/02:1-Body x 1	41000148	02	Body
41000132/04:1-Needle Cover x 1	41000132	04	Needle Cover
410002947/02:1-RNS Remover (High Volume) x 1	410002947	02	RNS Remover (High Volume)

Display material BOM: General Item Overview

Material: 400001882 PAC1 - Front Assembly (LF NCS)

Plant: 2102 SHL Medical LLC (MFG)

Alternative BOM: 3 Mira, FSA, FAAM 5, procured Tray

Item	ICt	Component	Component description	Quantity	UoM	Asm	SIs	Valid From	Valid to
0010	L	410003038	Needled cover spring (Low Force)	1	-	PC	<input type="checkbox"/>	23.08.2024	31.12.9999
0020	L	410001348	Body	1,000	PC	<input checked="" type="checkbox"/>	<input type="checkbox"/>	23.08.2024	31.12.9999
0030	L	410001321	Needle Cover	1,000	PC	<input checked="" type="checkbox"/>	<input type="checkbox"/>	23.08.2024	31.12.9999
0040	L	410002947	RNS Remover (High Volume)	1,000	PC	<input type="checkbox"/>	<input type="checkbox"/>	23.08.2024	31.12.9999
0050	L	410001347	Cap	1,000	PC	<input checked="" type="checkbox"/>	<input type="checkbox"/>	23.08.2024	31.12.9999
0060	L	410001325	Syringe Housing	1,000	PC	<input checked="" type="checkbox"/>	<input type="checkbox"/>	23.08.2024	31.12.9999
0070	L	400001469	Corner Protector,900*180*5mm,Paper,BN	0.379	PC	<input type="checkbox"/>	<input type="checkbox"/>	23.08.2024	31.12.9999
0090	L	400001478	Large Stack Separator,1180*800*26,PR,BN	0.095	PC	<input type="checkbox"/>	<input type="checkbox"/>	23.08.2024	31.12.9999
0100	L	400001482	Pallet Lid,1200*1000*15mm, Plywood	0.095	PC	<input type="checkbox"/>	<input type="checkbox"/>	23.08.2024	31.12.9999
0110	L	400001485	Slip Sheet,1180*900*3mm,Carbon,Brown	0.095	PC	<input type="checkbox"/>	<input type="checkbox"/>	23.08.2024	31.12.9999

SAP

Display Routing: Operation Overview

Group: 50020527 Group Counter: 1 Mira, FSA, FAAM 5 Procured Tray

Material: 400001882 PAC1 - Front Assembly (LF NCS)

Sequence: 0 Sequence Desc.

Oper...	Sop	Work Center	Plant	Cont...	Standard T...	Description	PRT	Cl...	Ob...	Per...	Cu...	Lo...	Su...	Base Quantity	Un...	Setup Labc
0010		US100603	2102	ZP01		IPQC	<input type="checkbox"/>	1,000	PC	0						
0020		US100603	2102	ZP01		FQC	<input type="checkbox"/>	1,000	PC	0						
0030		US100303	2102	ZP01		Packaging	<input type="checkbox"/>	1,000	PC	0						
0040		US100303	2102	ZP04		Assembly	<input type="checkbox"/>	1,000	PC	0						

Comments:

- Upon approval of the material in PLM, the SAP material is created
- Material creation in SAP is based on reference materials, which limits the effort for material master data maintenance
- The PLM manufacturing BOM is transferred to SAP and the BOM is created
- The PLM BOP data is transferred to SAP and the routing is created

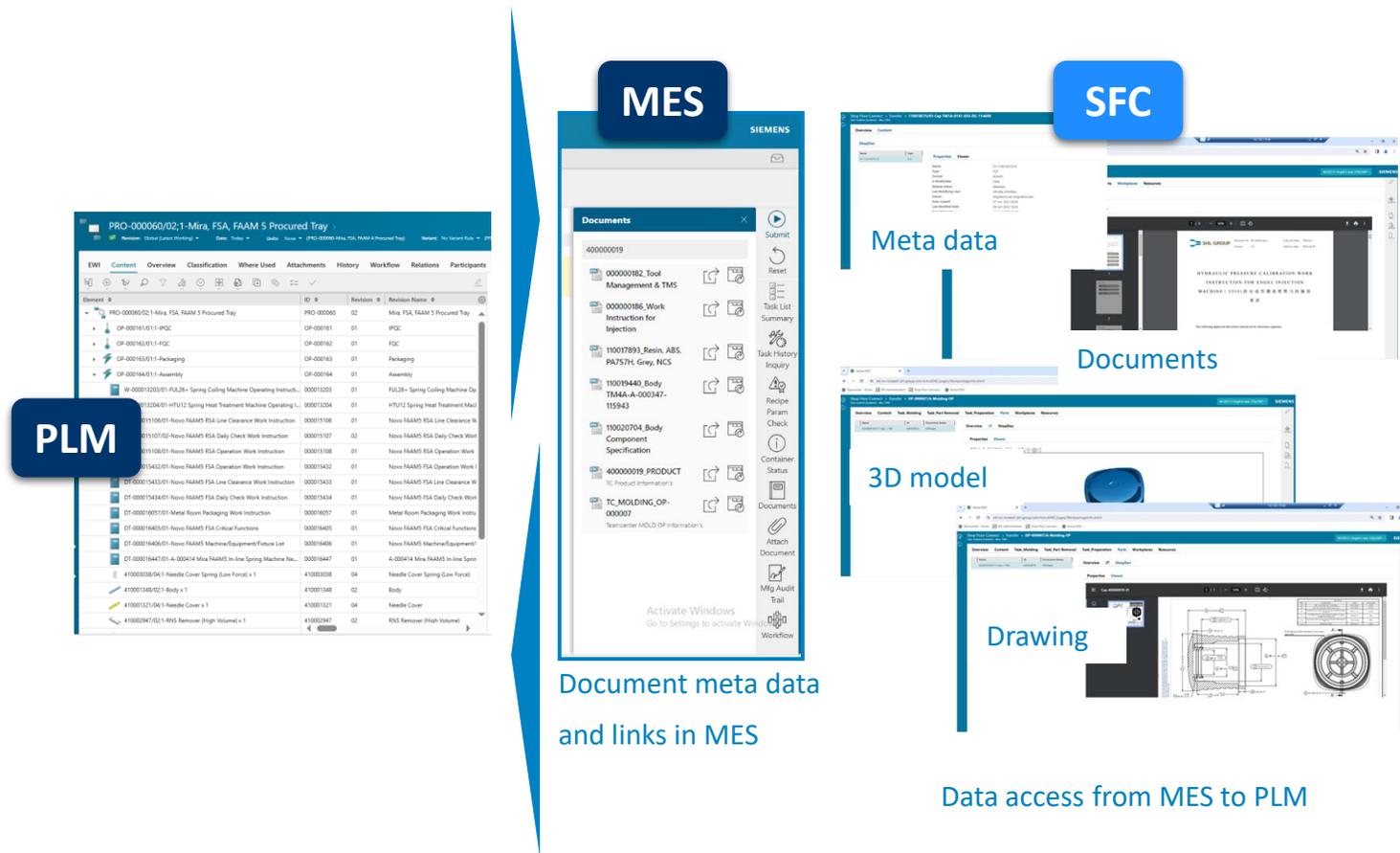
Depending on the approval status of BOM and BOP the SAP item are free for engineering or serial production:

- PLM approved = engineering production
- PLM released = serial production
- With transfer of the routing information the production version is created automatically in SAP



Manufacturing execution in MES

Example of document transfer to MES



Comments:

- Process-specifying documents (DMR) are attached to the respective items in the BOP
- Triggered by a specific workflow the document meta data is sent to MES, including a link to the document
- A documents set containing the relevant documents is automatically created in MES and linked the correct product revision
- The PLM data can be accessed by clicking on the link in MES – the shop-floor-connect application acts as a “gateway” to PLM to display the data
- Documents meta data is stored in MES for the eDHR



Questions?

Wirklichkeit



Wie starten? – how to slice the elephant

- Wir wollten keine **Big-Bang**
- 3 Fokus Punkte: **QMS**, Projekt **Dokumentation**/Entwicklungsprozess und **Requirements Engineering**
- **Schrittweise** Einführung und Erweiterung der Funktionen
- Prozesse werden nun **transparent** -> Unterschiede erkennbar -> mehr Prozessharmonisierung nötig
- Prozesse müssen auf “**digital**” angepasst werden – Viele Übersichts-Dokumente müssen abgelöst werden
- In einer frühen Phase wird klar, dass wir Ende 2024 ein weiteren Produktionsstandort in **USA** und 2026 in Zug erweitern müssen
- Das macht weitere **Interfaces** zu ERP und MES nötig
- Seit November 2021 etwa 12 releases, teilweise **schnelle Fixes** nötig

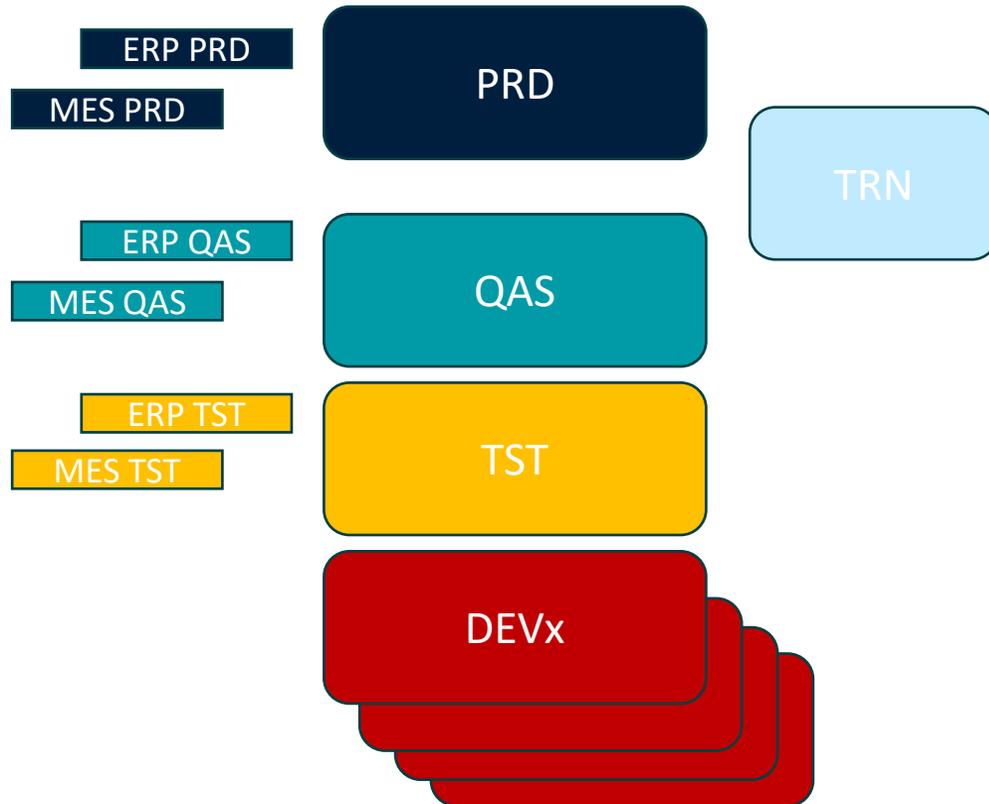


Herausforderungen

- 3 – 4 Releases pro Jahr
- Parallele Entwicklung und gleichzeitige Nutzung der Lösung
- Keine vergessenen Dateien beim Deployment
- Zu Beginn Papier-gebundene Dokumentation / Validierung
- Verfügbarkeit und Performance Start von 3 Jahren mit geplanten 200 usern
- Anpassungen der Infrastruktur im laufenden Betrieb für heute 1.100 user auf 3 Kontinenten
- Geplanter Umstieg auf einen Hyperscaler für eine größere Flexibilität



Staging Environment



PRD: Produktive Umgebung für den täglichen Betrieb mit allen Stamm und Bewegungsdaten

QAS: pre-Produktion für die formellen Tests

TST: Integrations System für End-to-End und Interface tests

DEVx: Entwicklungssysteme für die Weiterentwicklung der Lösung

TRN: dediziertes Instanz für Training und Anwender playground



SHL PLM Server Infrastructure Landscape





Lösung



Was ist DevOps? Was bedeutet CI/CD?

DevOps integrates and automates the work of software development (Dev) and IT operations (Ops) as a means for improving and shortening the systems development life cycle.^[1]

CI/CD is the combined practices of continuous integration (CI) and continuous delivery (CD) or, less often, continuous deployment.^[2]

Beides sind Methoden, kombiniert mit Tools, welche eine parallele Software-Entwicklung durch mehrere Programmierer und eine kontinuierliche Weiterentwicklung der Softwarelösung ermöglichen. Sehr häufig wird es mit agilen Methoden in der Umsetzung angewendet.

- Damit lässt sich ein Software-Projekt **Stück-für-Stück** umsetzen und funktionelle Einheiten bereits den Anwendern zur Verfügung stellen, während parallel noch an weiteren Einheiten gearbeitet wird
- Es kann **parallel** programmiert, getestet und ausgerollt werden
- Die **Rückverfolgbarkeit** von Änderungen jedes Einzelnen ist dokumentiert (Traceability), auf **Zwischenstände** kann zurück gesprungen werden (Roll-back)
- Der Schwerpunkt liegt in der **Automatisierung**, regelmäßige Tätigkeiten und Dokumentation wird durch die Tool-Chain ausgeführt.

[1] [DevOps - Wikipedia](#)

[2] [CI/CD - Wikipedia](#)



AUFBAU & KONFIGURATION

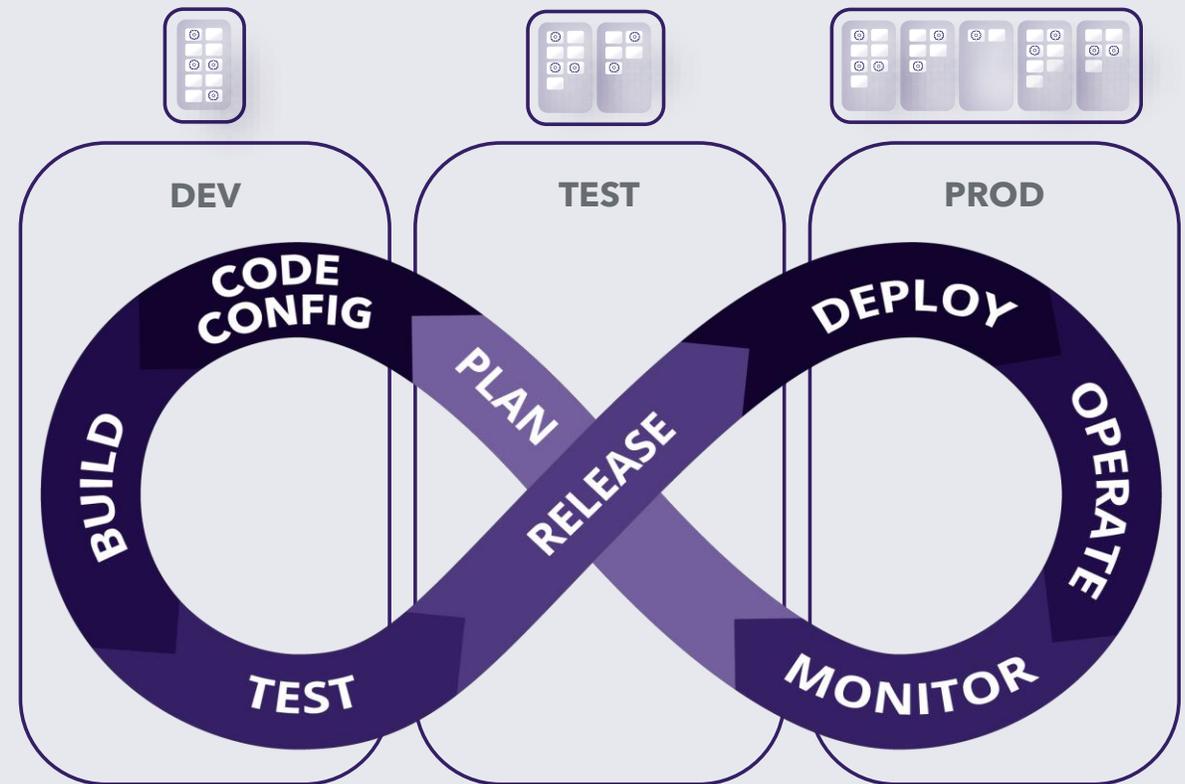
avaToolsuite



Über die avaToolsuite stellen wir **Prozesse und Automatisierungen** zur Verfügung, mit deren Hilfe Ihr Development und Operations-Team **kontinuierlich sowie optimal zusammenarbeiten** kann.

Vorteile:

- Zeit- und Kostenersparnis durch Automatisierung
- Transparenz und Nachvollziehbarkeit
- Schnellere Fehlererkennung
- Minimierung von Fehlerquellen
- Erhöhte Qualität der Deployments
- Bessere Zusammenarbeit intern/extern
- Kürzere Release-Zyklen
- Risikominimierung
- Effizientere Ressourcennutzung
- Skalierbar und Erweiterbar
- Parallelisierung
- Freie Lösungen verfügbar (Open Source)
- Keine Personenabhängigkeiten
- Bedienung über einfaches Web-UI
- Jederzeit Umstieg möglich - aber angepasste Arbeitsweise
- Lösung über Docker Container

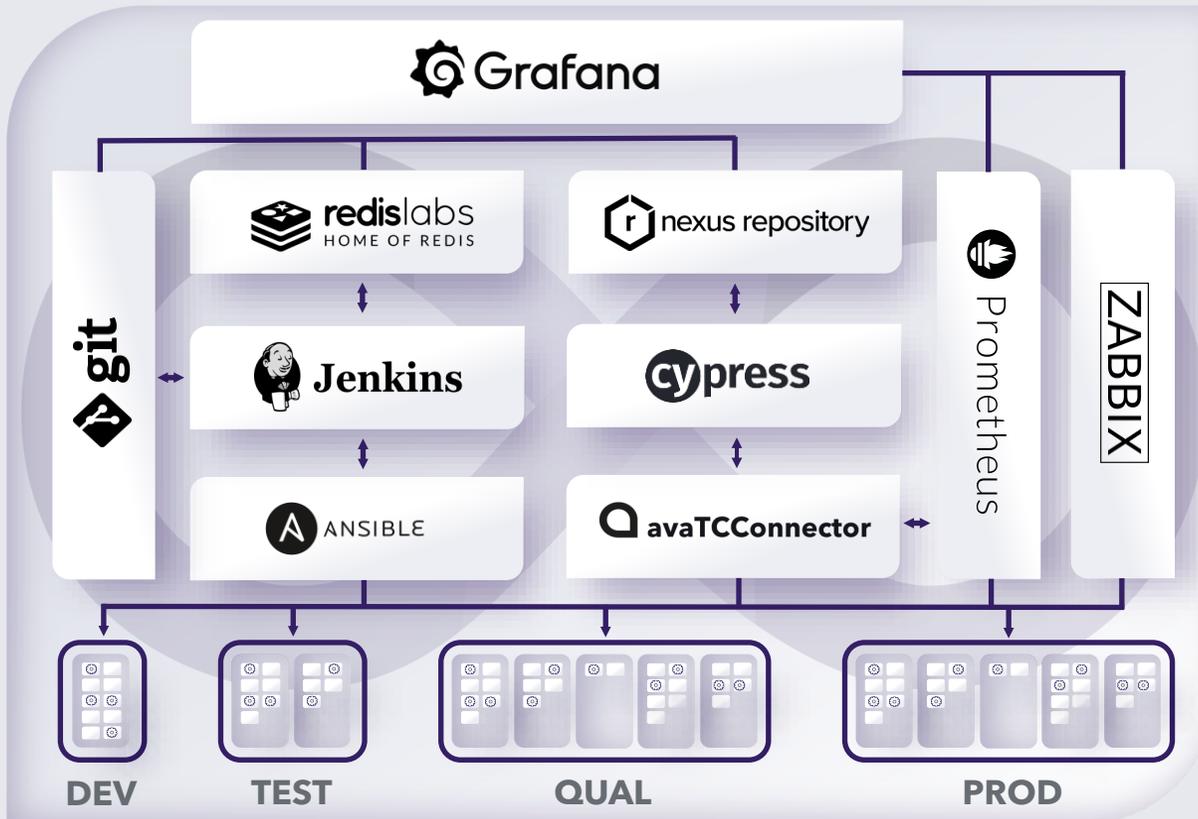


ARCHITEKTUR

avaToolsuite



Die "avaToolsuite" ist eine **spezialisierte Kombination** aus verschiedenen Applikationen und Software-Tools, die für die **Unterstützung des "avaDigiflow"** entwickelt wurde. Sie integriert die Aspekte von Continuous Integration and Continuous Deployment (**CICD**), Development and Operations (**DevOps**) sowie **Managed Services**.



Grafana: Visualisierungstool für Metriken und Logs aus verschiedenen Datenquellen.

Zabbix: Echtzeitüberwachung für Netzwerke und Anwendungen.

Prometheus: Monitoring- und Alarmsystem für Metriken und Zeitreihendaten.

Git: Quellcodeverwaltung und Teamzusammenarbeit.

Redis Labs: In-Memory-DB für schnelle Datenzugriffe und Caching.

Nexus Artefakt Repository: Verwaltung von Build-Artefakten und Abhängigkeiten.

Jenkins: Automatisierungsserver für kontinuierliche Integration und Bereitstellung.

Cypress: End-to-End-Tests für Webanwendungen.

Ansible: Tool zur Automatisierung von Deployment und IT-Konfiguration.

avaTCCconnector: Flexible Schnittstelle zu Teamcenter über REST API.



REST Kommunikation - avaToolsuite Komponenten

Jenkins

Pipeline AVA.DeployConfiguration

This build requires parameters:

TARGET_ENV
Please select an environment.

- TC-DEV-01
- TC-DEV-02
- TC-DEV-03
- TC-INTEG
- TC-REVIEW

ARTIFACT_VERSION
Please select a artifact version.

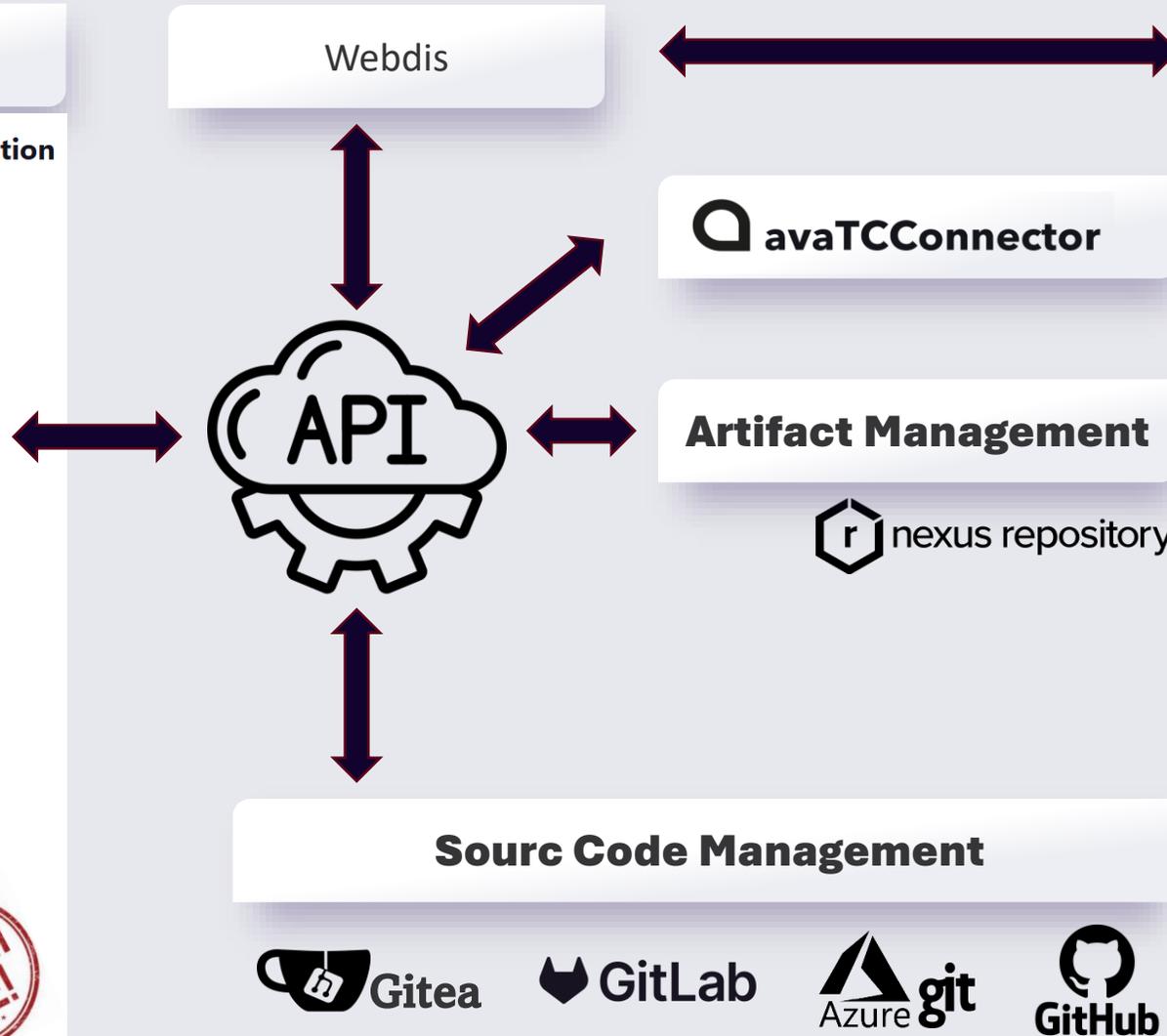
2.14.0.1

TARGET_CONFIGS
Please select configuration(s) to deploy.

- excel_templates
- eda_definitions
- dm_templates
- datasets
- creo_templates
- batch_lovs
- aw_ui_config
- aw_tiles
- aw_rb_config
- attrmapping
- workflows

WATCH LIVE!

Build Cancel



Database

redislabs
HOME OF REDIS

KEY	VALUE
TRG-1	TC-DEV01
TRG-2	TC-DEV02
TRG-3	TC-DEV03
TRG-4	TC-INTEG
TRG-5	TC-REVIEW

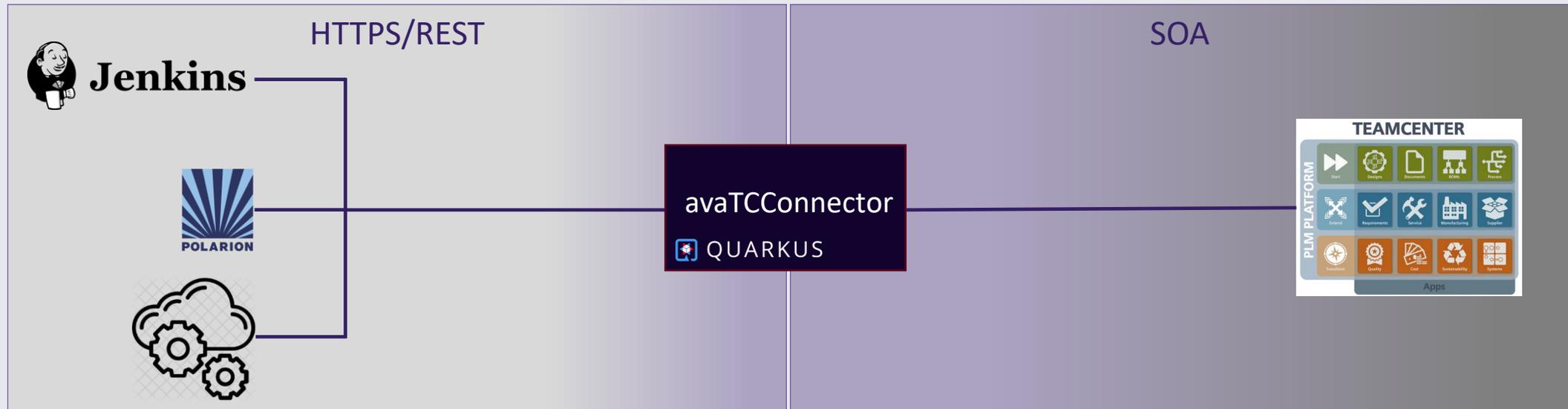


avaTCConnector – REST-Schnittstelle zu Teamcenter

Definition:

Der avaTCConnector ist eine leistungsfähige Schnittstelle, die speziell dafür entwickelt wurde, Teamcenter über das REST-Kommunikationsprotokoll von externen Systemen zu erreichen. Durch die Verwendung des Quarkus-Frameworks bietet der avaTCConnector schnelle Startzeiten, geringen Speicherbedarf, native Kompilation, Entwicklerproduktivität, Integration mit Cloud-Plattformen, Containerisierung, reaktive Programmierung und eine breite Erweiterbarkeit.

REST: Representational State Transfer
SOA: Service-Oriented Architecture





Was haben wir erreicht?

- DevOps und CI/CD tool chain implementiert
- Arbeitsweise umgestellt
- Keine “vergessenen Dateien” mehr
- QAS und PRD sind nachweislich gleich konfiguriert
- Automatischen Anpassungen an die unterschiedlichen Stages (Overlay) wie z.B. Server Pfade
- Deployment Teil der Validierungsaktivitäten (Traceability)

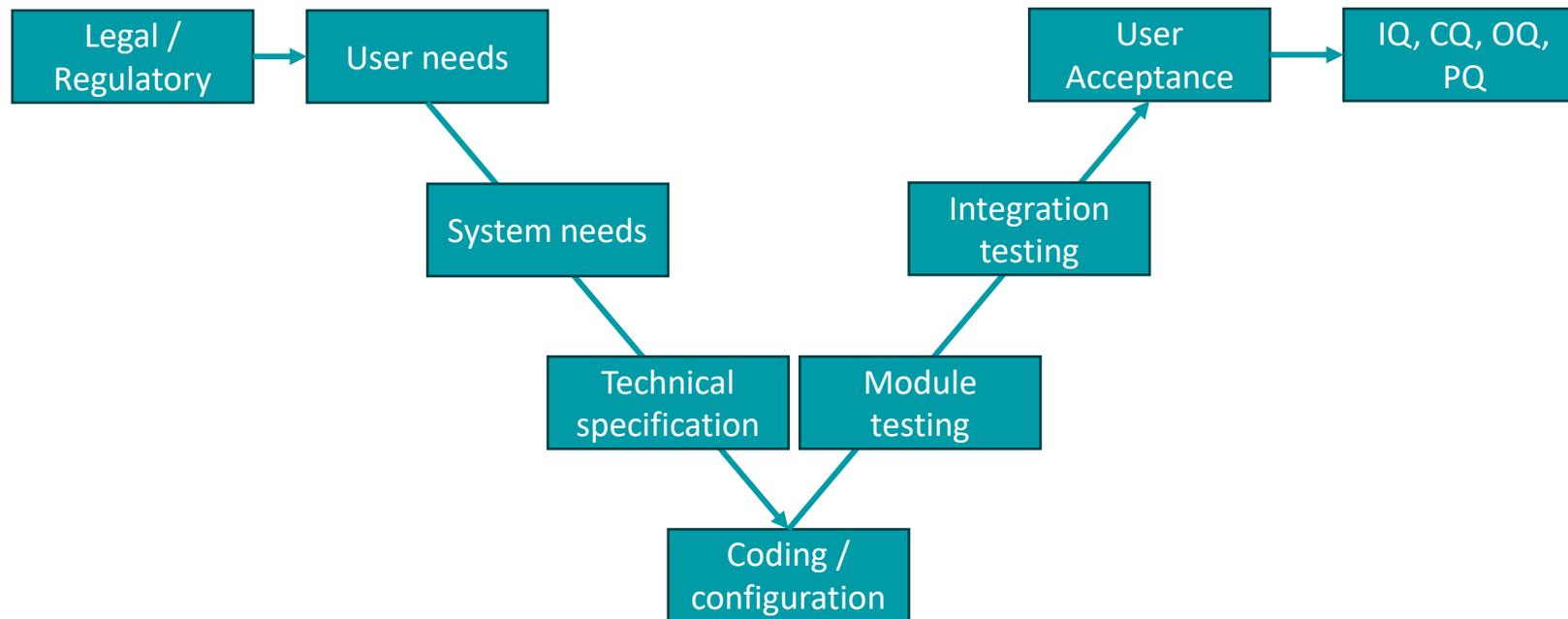


Questions?

(Alb)Traum Validierung



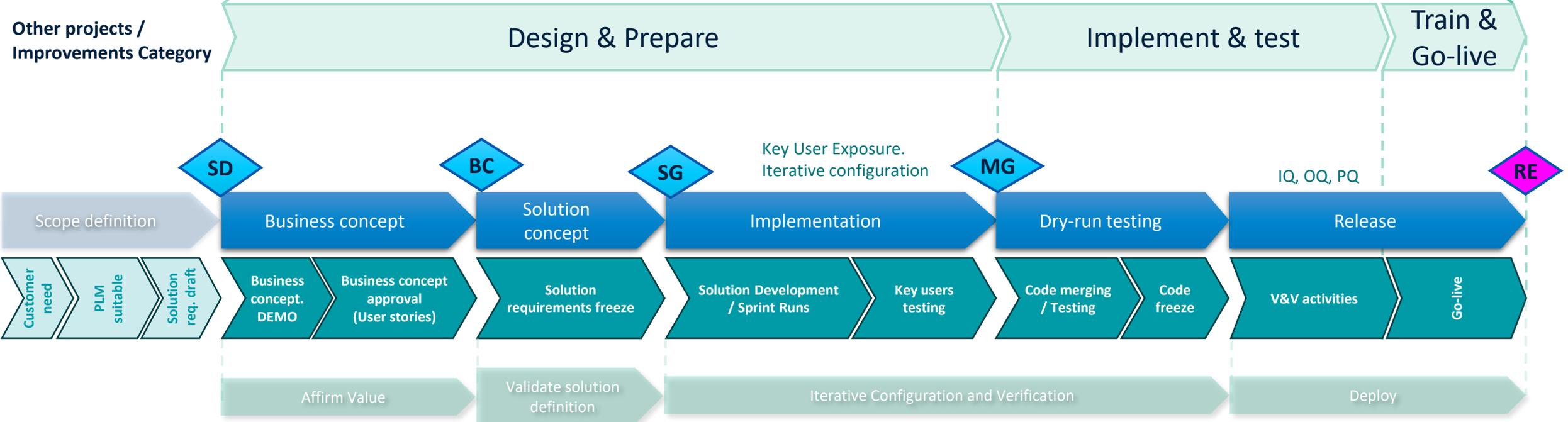
V-Model





Validation Approach

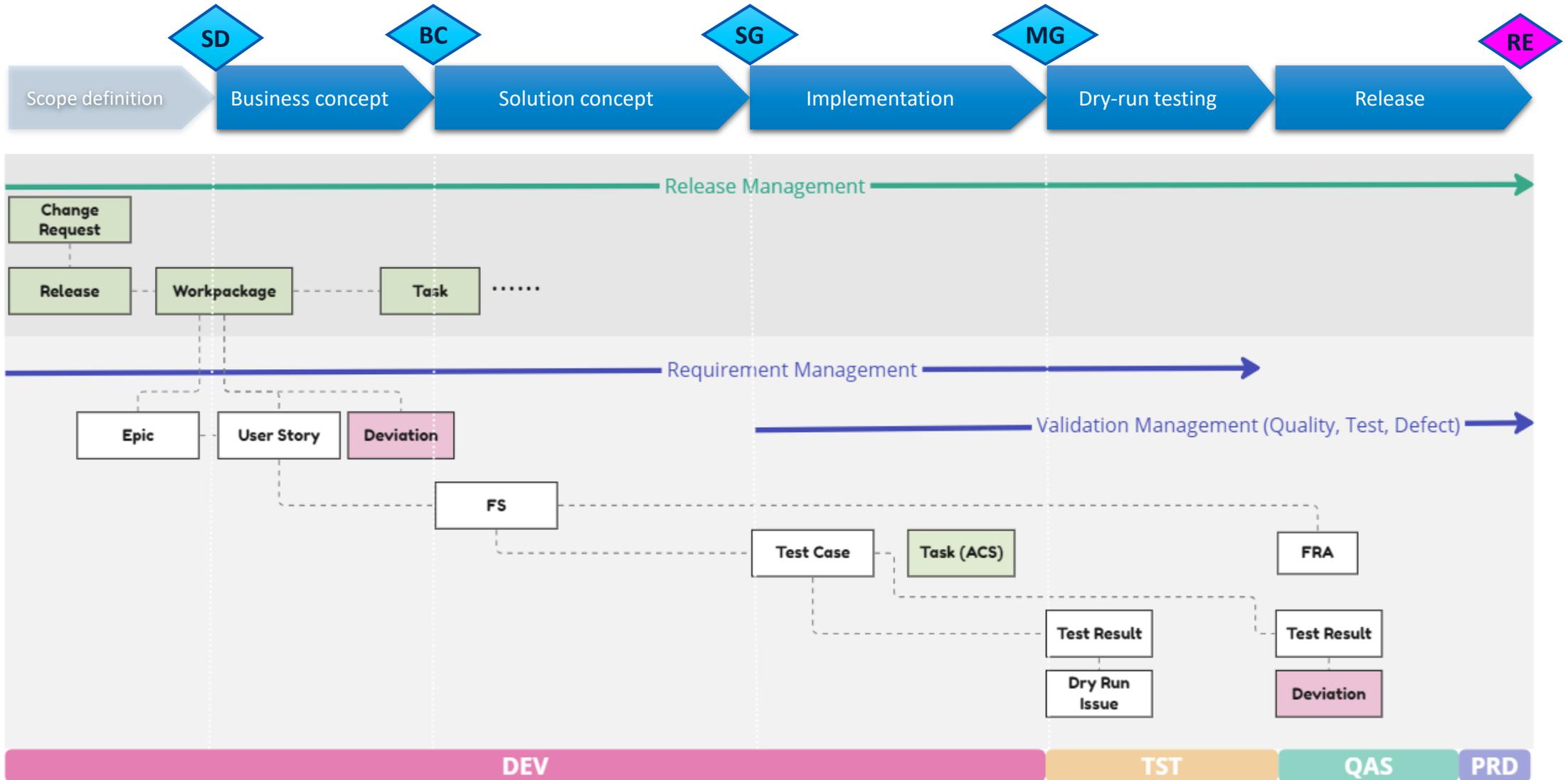
- Validierung nach Computer System Validierung (CSV)
- System und Prozesse GxP relevant und nach GAMPP 5 klassifiziert
- Staging mit dedizierten DEV, TST, QAS und PRD Stufen
- Interfaces mit ERP und MES
- End-to-End Testung der Prozesse
- Installation Qualifikation (IQ) und Konfigurations Qualifikation (CQ) werden auf QAS und PRD durchgeführt
- Operation Qualifikation (OQ) wird auf QAS ausgeführt
- Performance Qualification (PQ) nur auf PRD
- QAS und PRD sind gleich aufgesetzt und haben die gleiche Konfiguration
- Damit argumentieren wir, das die Funktionalität die gleiche für den produktiven Betrieb ist



Siemens AdvantEdge Methodology

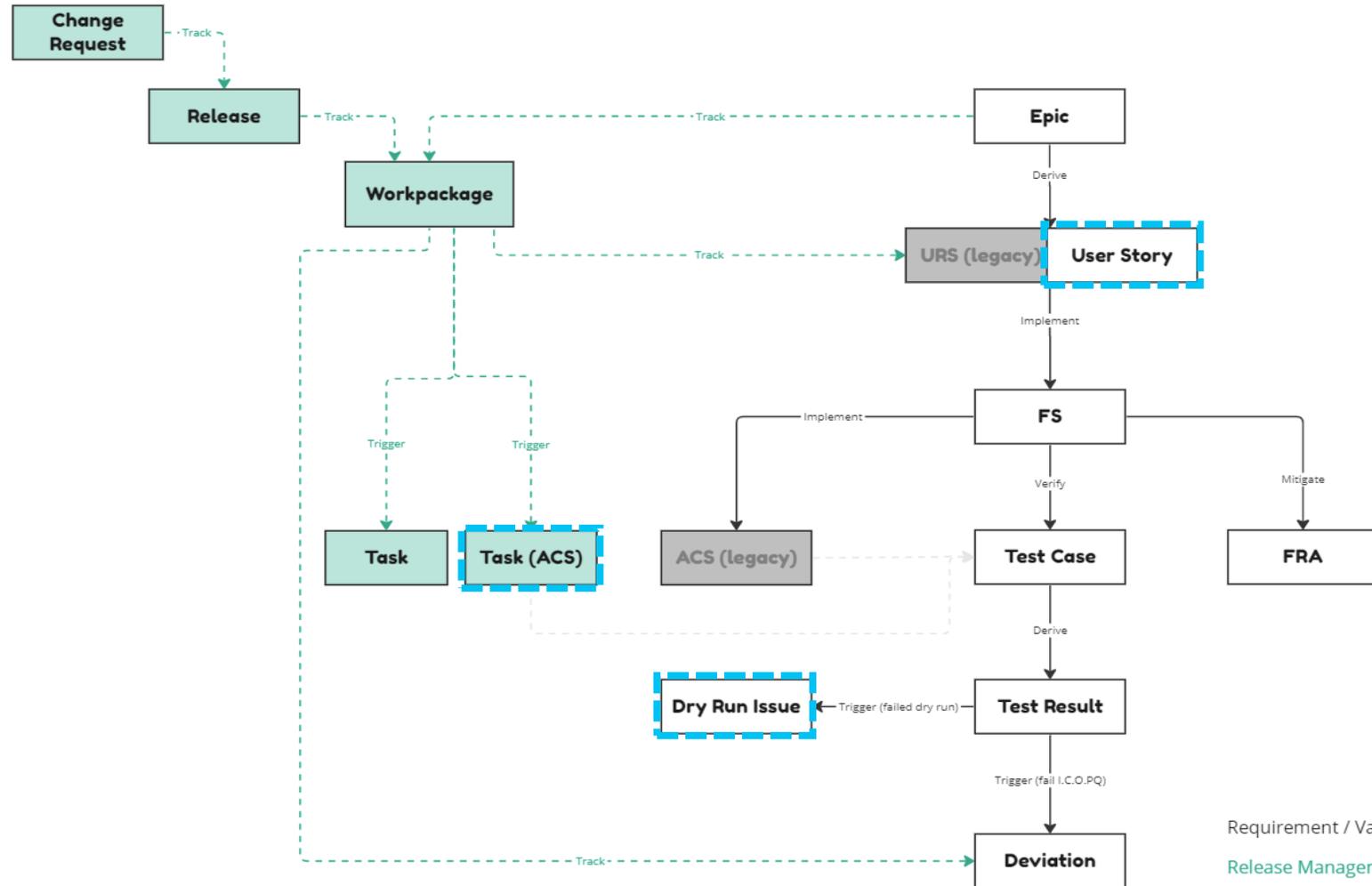


Lösung





Work Items und deren Abhängigkeiten



Requirement / Validation Traceability
Release Management Traceability



Traceability Tree

ID	Type	Status	Title
<input checked="" type="checkbox"/> PLMA-2967	Epic	✓ Done	CHN-1363 TEST
<input type="checkbox"/> PLMA-2969	User Story	✗ Obsoleted	CHN-1363 test obsolete
<input type="checkbox"/> PLMA-2966	User Story	✓ Released	CHN-1363 test
<input type="checkbox"/> PLMA-2968	FS	✓ Verified	CHN-1363 test
<input type="checkbox"/> PLMA-2972	Test Case	✓ Executed	CHN-1363 tc
<input type="checkbox"/> PLMA-2978	Test Result	✗ Approved with Deviation	Fail: CHN-1363 tc
<input type="checkbox"/> PLMA-2980	Deviation	✓ Closed	Fail: CHN-1363 tc
<input type="checkbox"/> PLMA-2977	Test Result	✓ Approved	Pass: CHN-1363 tc
<input type="checkbox"/> PLMA-2973	Test Result	⚠ Failed Dry Run	Pass: CHN-1363 tc
<input type="checkbox"/> PLMA-2975	Dry Run Issue	✗ Rejected	CHN-1363 test2
<input type="checkbox"/> PLMA-2974	Dry Run Issue	✓ Resolved	CHN-1363 test



PLM ALM – Polarion in the center

Scope of this Release

The Release: 2024.3.0 covers the following topics:

- Teamcenter Upgrade to version 2406 (including TCMDS, functional fixes and related CAD changes)
- Polarion Upgrade to version 2404
- Risk Management File Migration Package

Associated Work Package

Associated Work Packages

Total No. of Workpackages items covered in the Release is: 5

Release and Linked Work Package

Release	Work Package
PLMA-3091 - PLM Release 2024.3.0 - Due Date: 2024-12-09 Scope Freeze Date: 2024-07-30	PLMA-3644 - Teamcenter Technical - Status: Reviewed Assignee(s): Ricardo Lopez Initial Estimate: 160h Affected System: Teamcenter
	PLMA-3669 - Teamcenter CAD Technical - Status: Reviewed

User Story

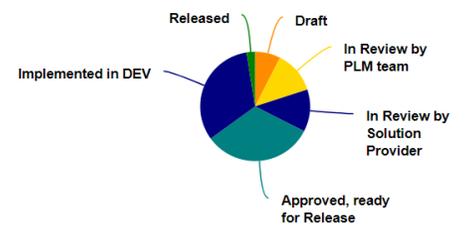
3 Draft	5 In Review by PLM team	5 In Review by Solution Provider
0 In Approval	13 Approved, ready for Release	13 Implemented in DEV
0 Ready for testing	0 Obsolete	0 In Review
1 Released		

FS

18 Draft	0 In Review	3 In Approval
0 Approved	0 Accepted FS	1 Obsolete
1 In Review	0 Verified	

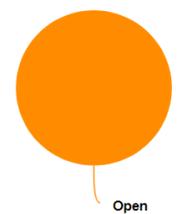
Associated User Story, Deviation

Associated User Stories



Total No. of User Story items covered in the Release is: 40

Associated Deviations



Total No. of Deviation items covered in the Release is: 6



PLM ALM – Polarion in the center

Planned User Stories, Deviations, and Task

43 In Planning 6 In Review 0 In Approval 18 Approved, ready for Release / In Progress 13 Implemented in DEV 0 Ready for Testing 2 Released/Resolved

🔍 PLMA-3671 - Teamcenter and Polarion Functional

- Failure of PDP Ownership Transfer (PLMA-42...)
- Not all changes are shown in "Changes" (PLMA-45...)
- issue: copy content of Comment field of decision a (PLMA-40...)
- issue: access level for Change Editor not working fully (PLMA-40...)
- Fail: Approval Workflow - Dispatcher - pdf generatio (PLMA-39...)
- Additional spaces not visualized in AW but transferred (PLMA-45...)
- issue: CR8 members could be modified after approval (PLMA-40...)
- issue: Comment field of decision approved/rejected i (PLMA-40...)
- CN workflow stuck (PLMA-25...)
- Where used and Revision Rules - switch for "used in" (PLMA-45...)
- Warning for license run output on Polarion not visible f (PLMA-37...)
- issue: [save edits] is not working after revisioning of (PLMA-40...)
- add task deliverables only possible after 2nd open (PLMA-19...)
- Remove MFGPilot preference (PLMA-45...)
- User Assignment (PLMA-625)
- ID column disappearing in a CR (PLMA-36...)
- Fail: OQ - Polarion: Create, submitting an object to su

PLMA-3702 - Risk Management File Migration Package

ID-Title	Link Role	Status	Suspect
PLMA-3713 - Establish and Maintain Protojector Project Template for Product Variants in PLM Polarion			
PLMA-4069 - Build Mechanism for Polarion Projects	is implemented by	Draft	
PLMA-3715 - Use Protojector Project Template to Derive Product Variants in PLM Polarion			
PLMA-4069 - Build Mechanism for Polarion Projects	is implemented by	Draft	
PLMA-3110 - Work concurrently with PRAM-based & RAC-based RM Packages during Migration			
PLMA-3921 - PRAM / REE Import	is implemented by	Draft	
PLMA-3705 - Establish and Maintain Platform Project Template			
PLMA-3978 - Plattform Libraries	is implemented by	Draft	
PLMA-3107 - Create D-FMEA from PRAM			
PLMA-3921 - PRAM / REE Import	is implemented by	Draft	



PLM ALM – Polarion in the center

Open Deviation

Deviations that are still open in .

ID	Title	Type	Status	Severity	Target Version	Remarks
PLMA-1797	Pass: Check resource load spread of schedule (Retested: Fail)	Deviation	Open	Acceptable	Release 2024.3.0	The root cause is currently under investigation. We think that this might be connected to the time zone, you are logged in. This has no direct impact on the usage, as this is only a visualization of the workload. This is not blocking the go-live.
PLMA-1958	add task deliverables only possible after 2nd open	Deviation	Open	Acceptable	Release 2024.3.0	The inability to add a deliverable to It is not a blocker for go-live. Updated in R2023.3.0: As per the fee
PLMA-2555	CN workflow stuck	Deviation	Open	Acceptable	Release 2024.3.0	Siemens fixed this issue in a higher i AVA003274

OQ-20240913-0843 - OQ Hotfix R2024.2.2 - Polarion

Test Run Overview



Test Run Status

Closed
2024-09-26 12:07

(click to change status)

On-line Execution

Execute Test
0 waiting Test Case execution(s)

Off-line Execution

1. Download Pre-execution Template
2. Import Post-execution Result

Test Run Signatures

Closed (2024-09-26 05:34)		
Kay Su	Signed	2024-09-26 05:34
Reopened (2024-09-26 11:25)		
Kay Su	Signed	2024-09-26 11:25
Closed (2024-09-26 12:07)		
Kay Su	Signed	2024-09-26 12:07

Test Run Results

[Browse All Test Run Results](#)



Was haben wir erreicht?

- Saubere Validierungskette von der Anforderung bis zum Test
- Validierungsplan -> Validierungsreport
- Vollständige Integration in Polarion
- Freigaben und Übersicht
- Keine Papier Dokumentation mehr



Questions?

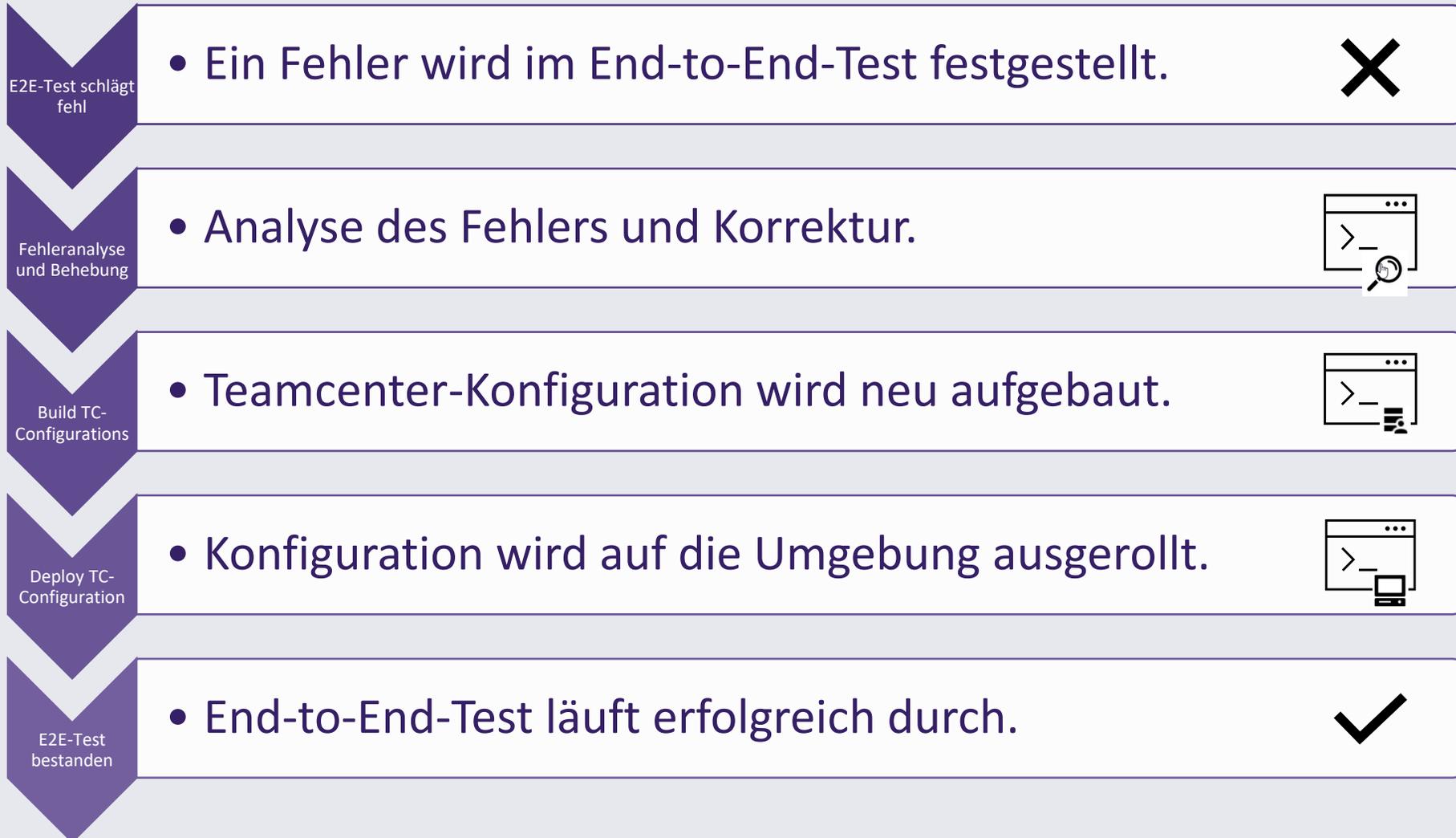
Hands On

Beispiel 1:

Build & Deployment and
E2E-Test



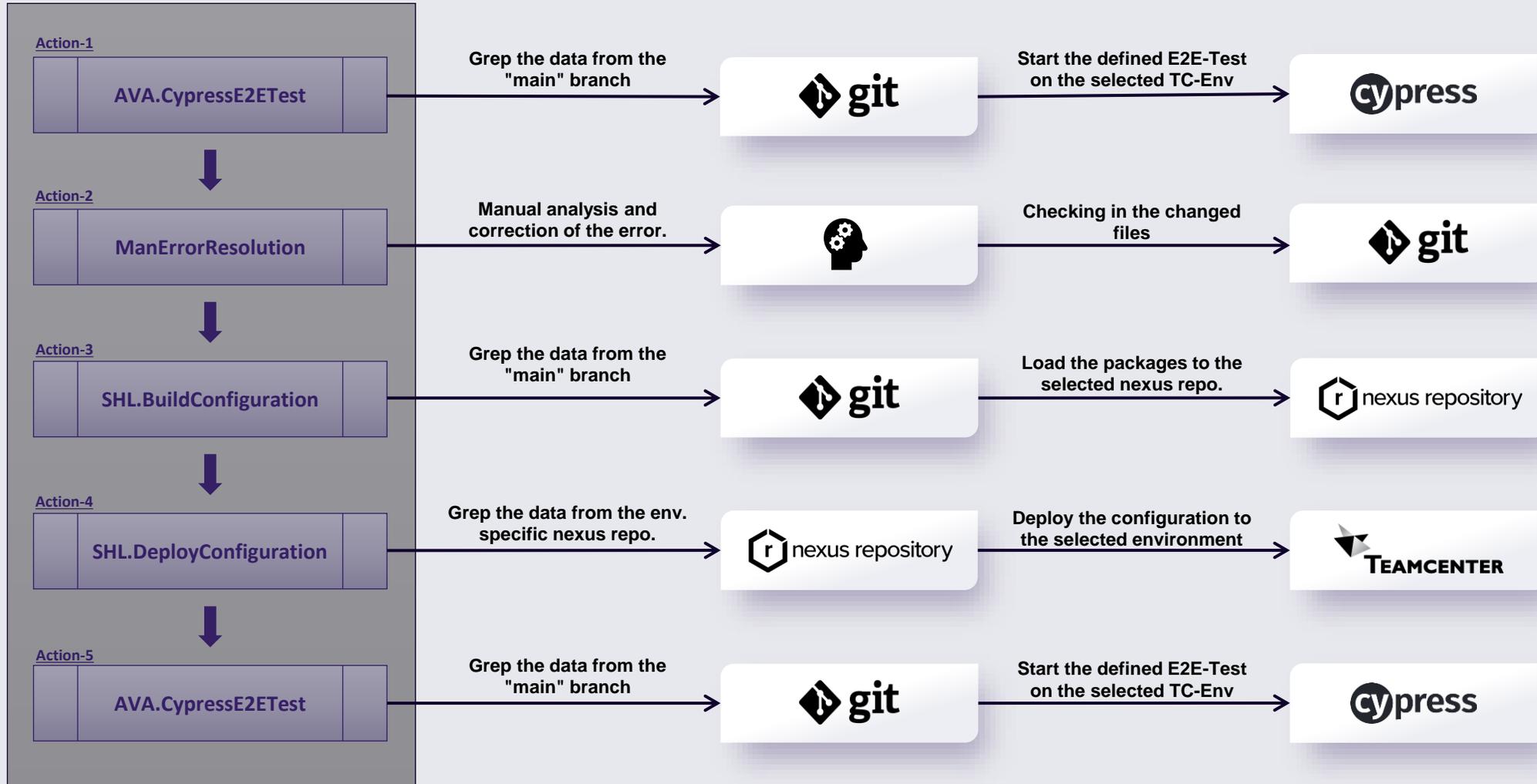
E2E-Test mit Cypress und Build & Deployment Szenario





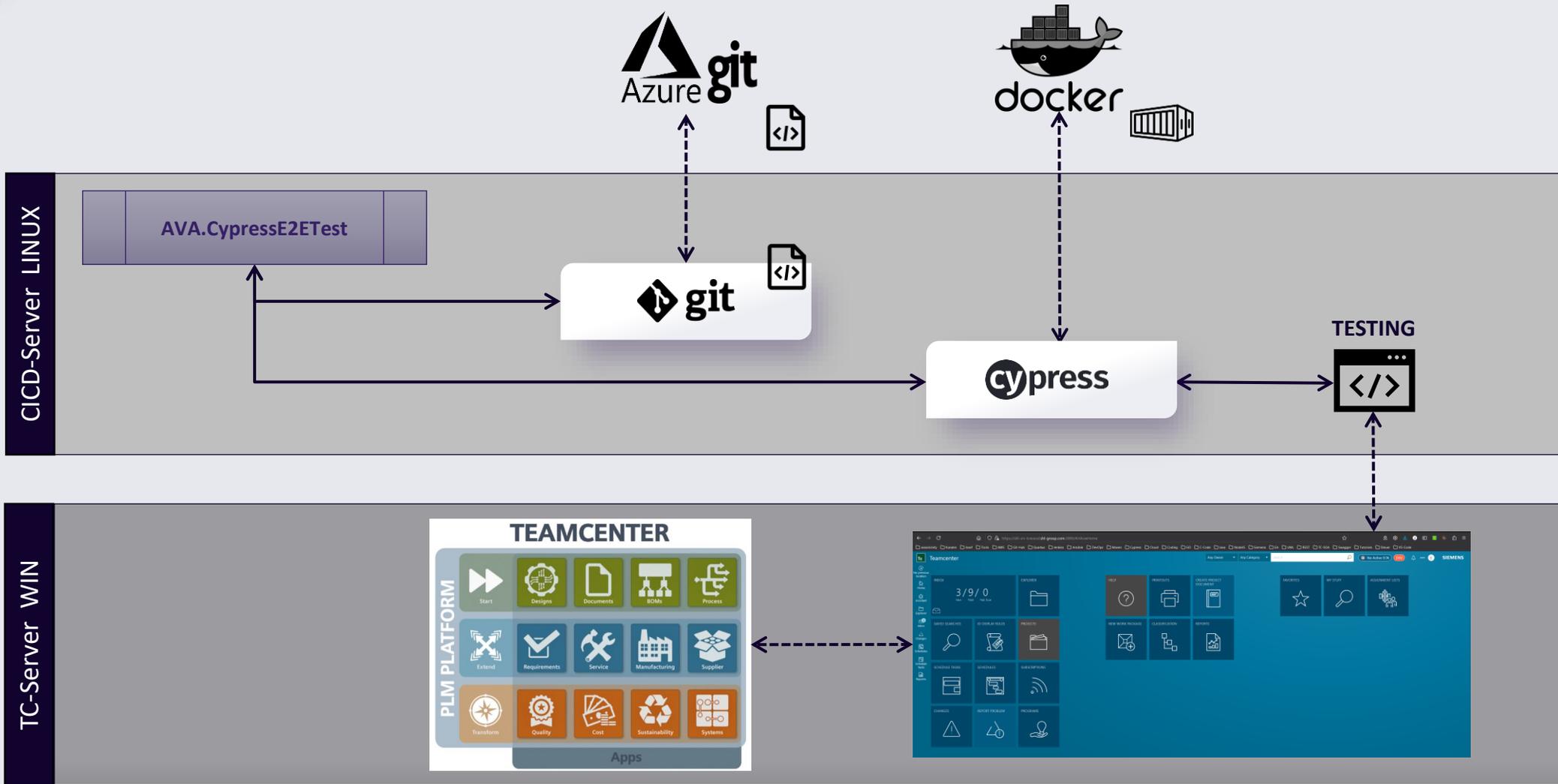
E2E-Test mit Cypress und Build & Deployment

Action flow



E2E-Test

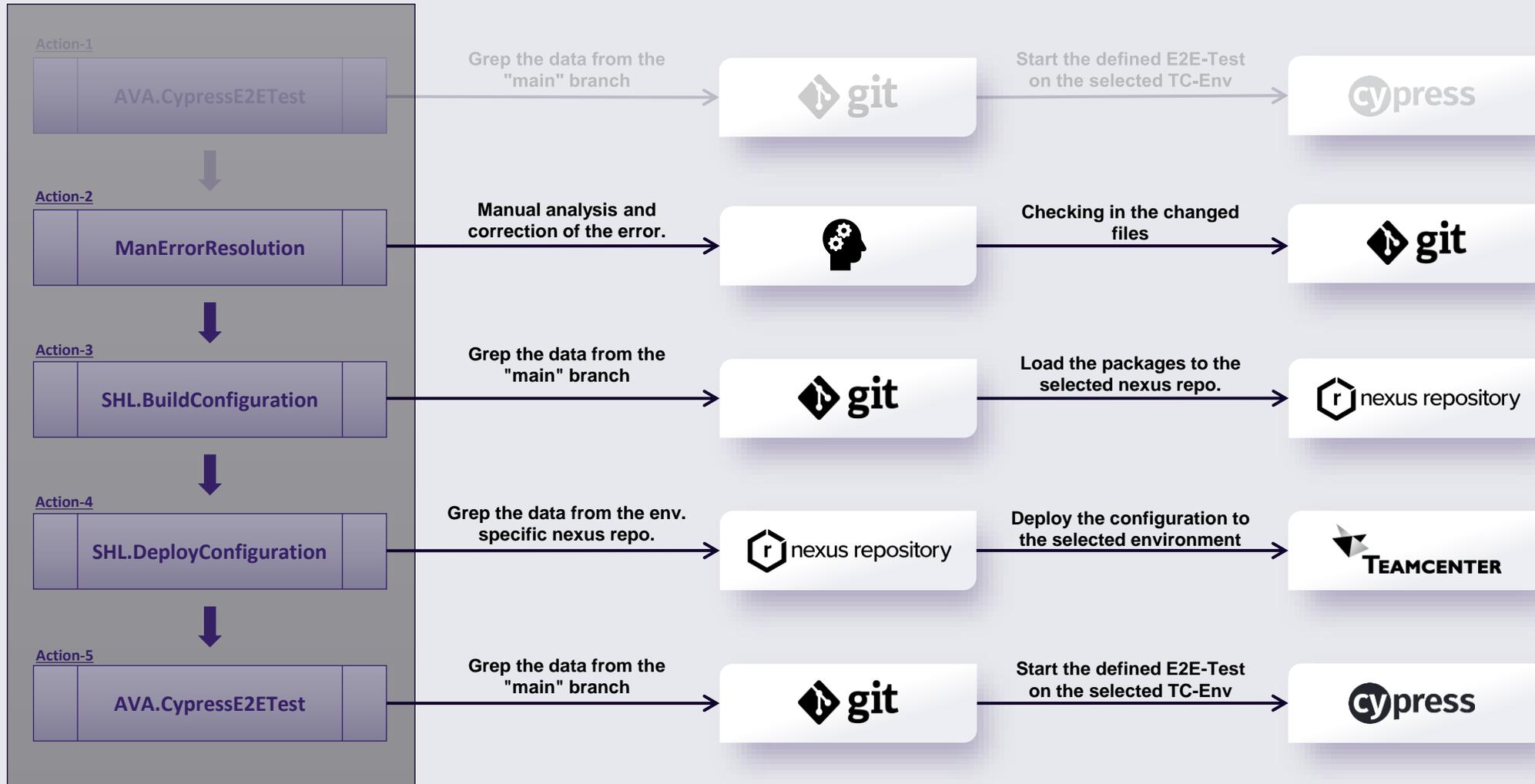
Action-1





E2E-Test mit Cypress und Build & Deployment

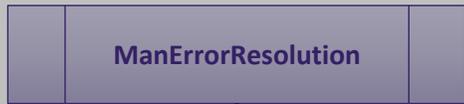
Actions



E2E-Test

Action-2

Developer Laptop



```
<content visibleWhen="object_type==SHL4ProjectDocRevision">
  <section title="SHL.Attributes">
    <property name="shl4IRDC_Template"/>
    <property name="shl4reviewer"/>
    <property name="shl4reviewDate"/>
    <property name="shl4approver"/>
    <property name="shl4approvalDate"/>
    <property name="shl4trainingMatrix"/>
    <property name="shl4confidLevel"/>
    <property name="shl4nameCh"/>
    <property name="shl4origDocNr"/>
    <property name="shl4origDocVers"/>
  </section>
</content>
```

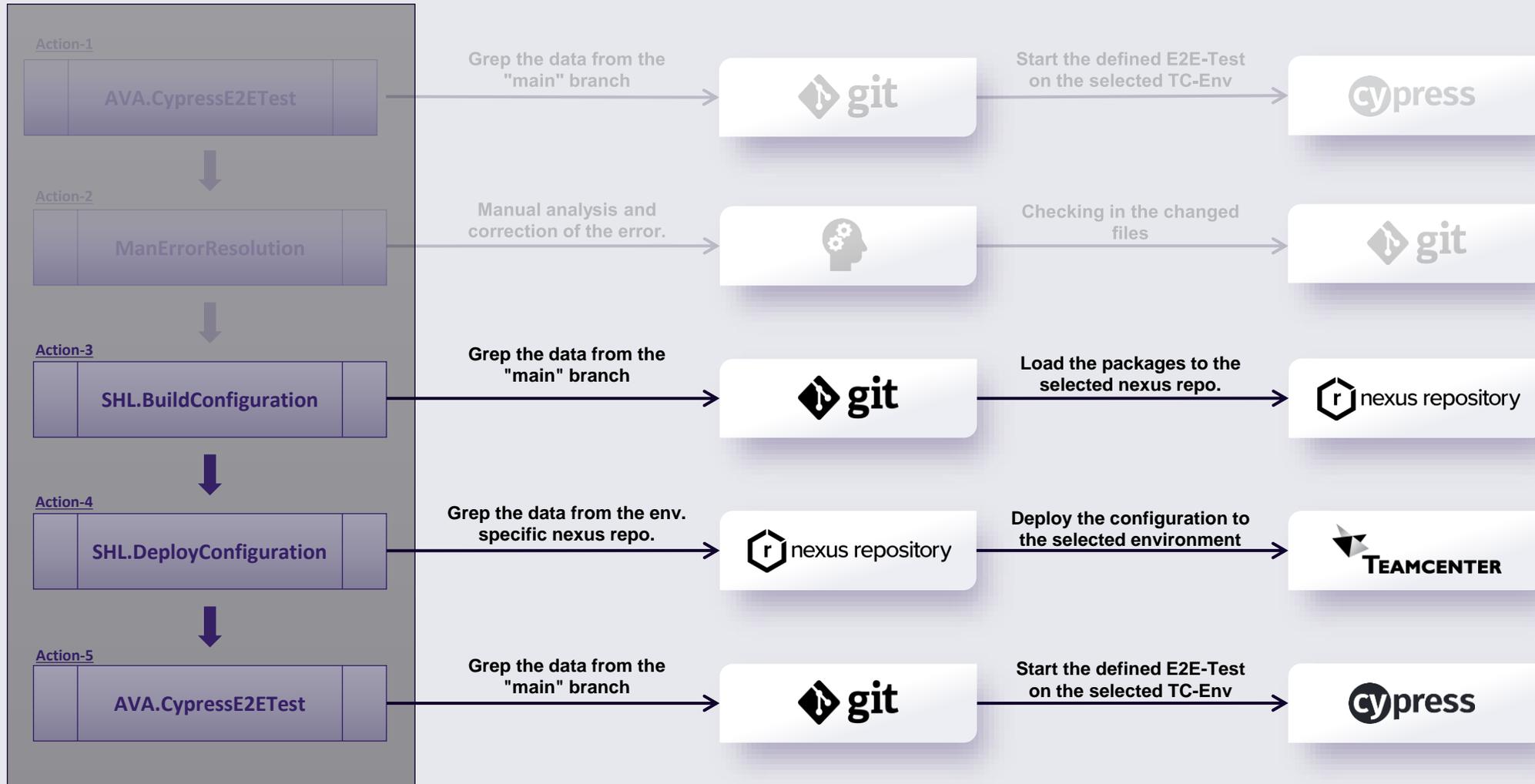


```
<content visibleWhen="object_type==SHL4ProjectDocRevision">
  <section title="SHL.Attributes">
    <property name="shl4IRDC_Template"/>
    <property name="shl4reviewer"/>
    <property name="shl4reviewDate"/>
    <property name="shl4approver"/>
    <property name="shl4approvalDate"/>
    <property name="shl4trainingMatrix"/>
    <property name="shl4confidLevel"/>
    <property name="shl4nameCh"/>
    <property name="shl4changeDesc"/>
    <property name="shl4origDocNr"/>
    <property name="shl4origDocVers"/>
  </section>
</content>
```



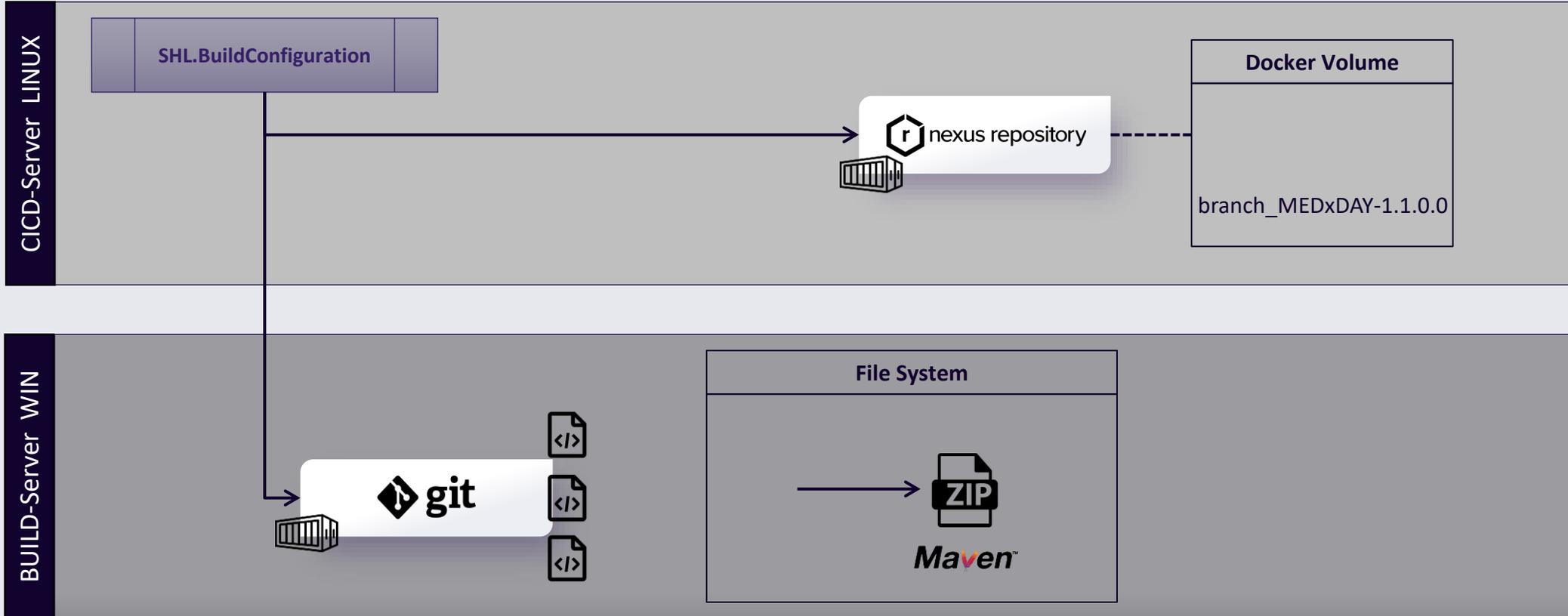
E2E-Test mit Cypress und Build & Deployment

Actions



Build

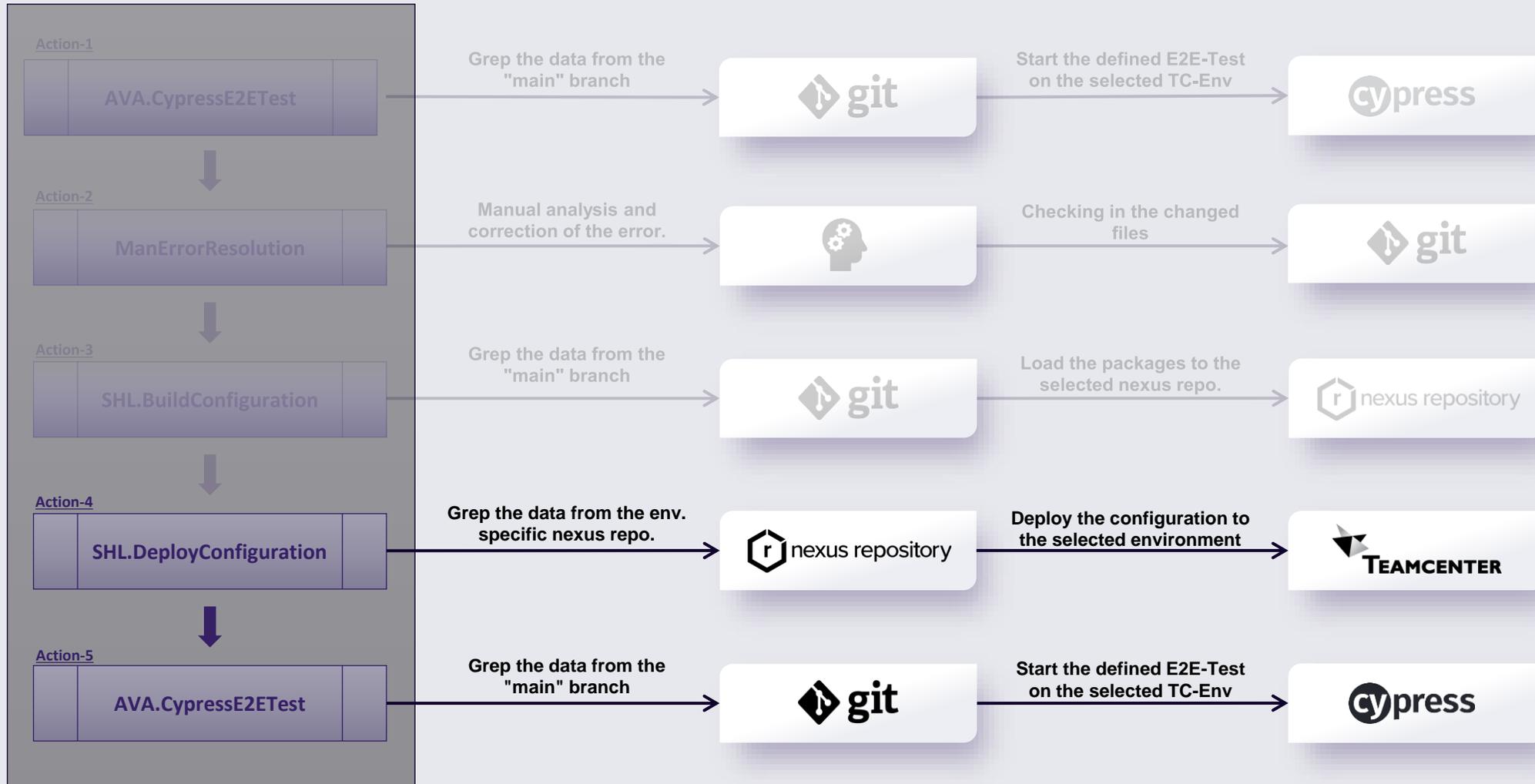
Action-3





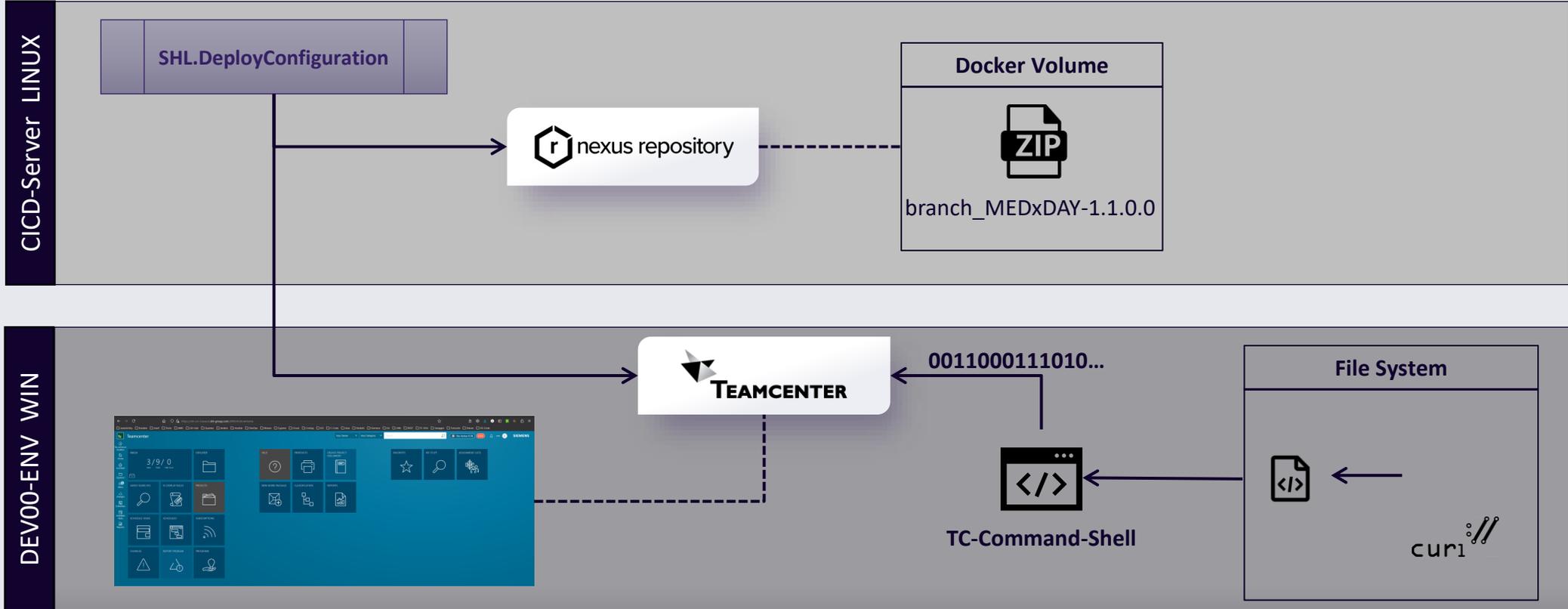
E2E-Test mit Cypress und Build & Deployment

Actions



Deploy

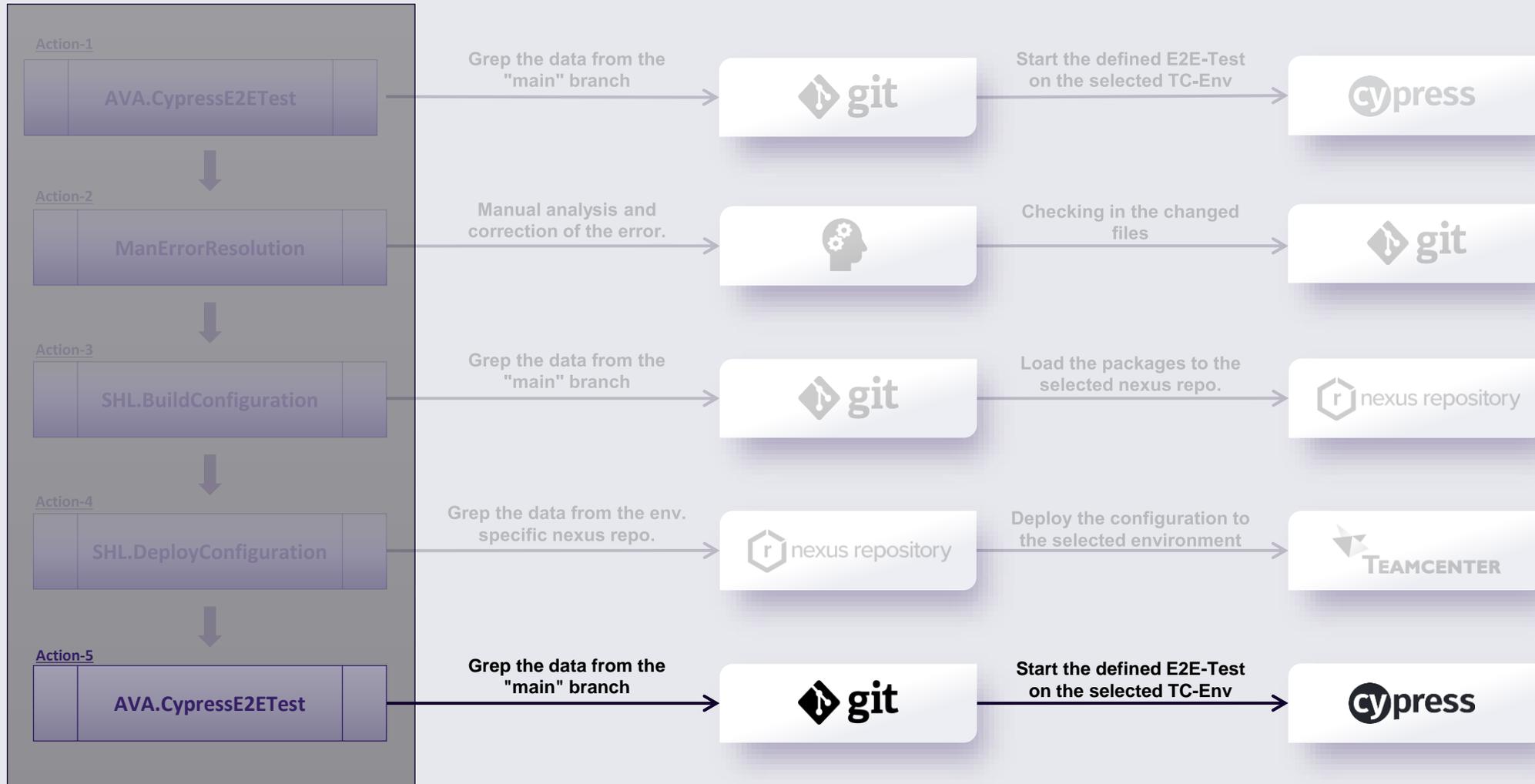
Action-4





E2E-Test mit Cypress und Build & Deployment

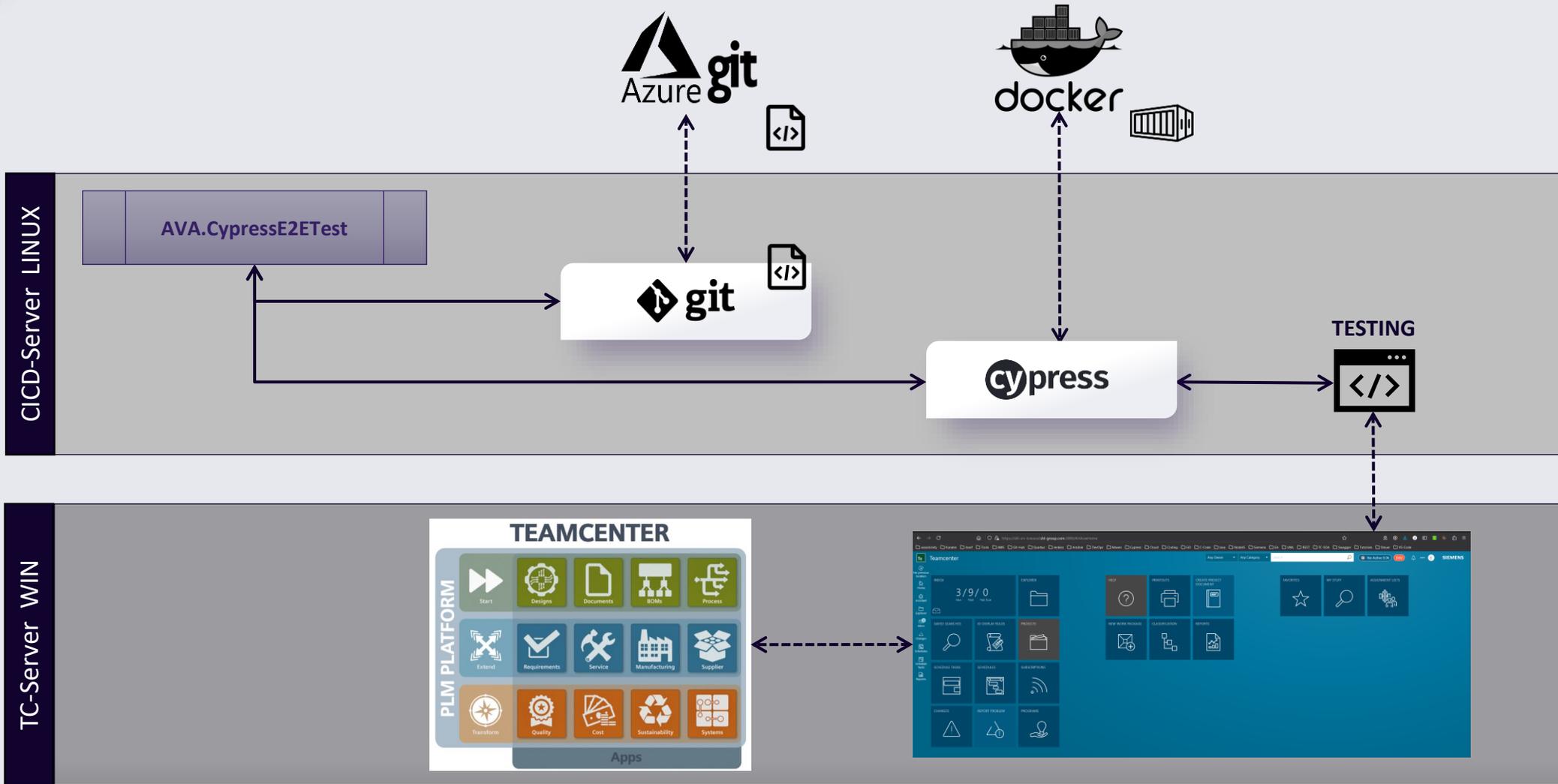
Actions





E2E-Test

Action-5





E2E-Test mit Cypress und Build & Deployment

Actions



Beispiel 2: manuell -> auto



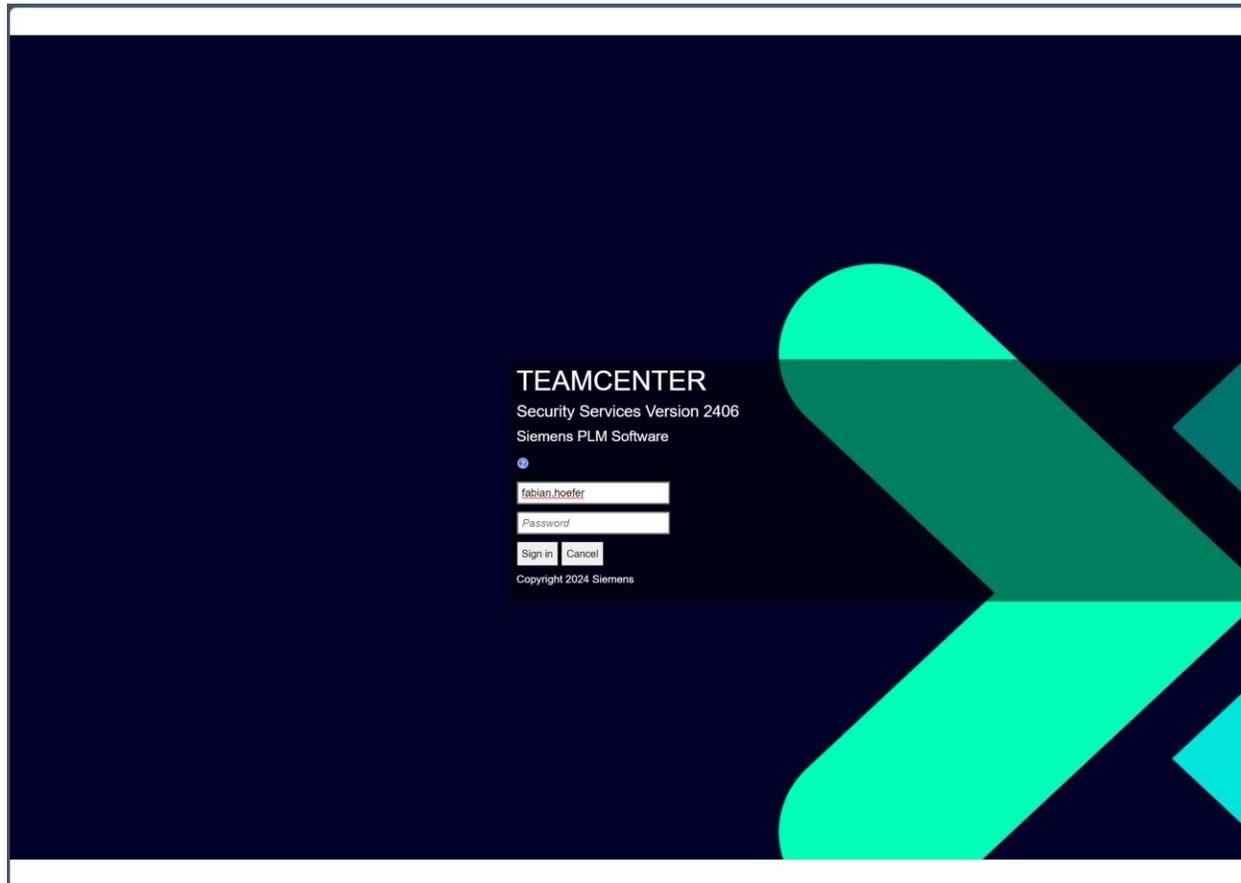
Hochladen von PDFs direkt in ein Teamcenter Objekt

Use case:

- Teamcenter ist ein Expertentool.
 - Dokumente, welche außerhalb von Teamcenter erzeugt werden. Z.B. Test Reports, Kunden Anforderungen, ...
 - Müssen als neue Revision angelegt werden
1. In Teamcenter anmelden
 2. Revision nach Nummer suchen
 3. Neue Revision anlegen
 4. PDF anhängen
 5. In den workflow schicken



1. In Teamcenter anmelden





2. Revision suchen (000016661)

Name	Description	Rele...	C...	L...	Type
Upload 1					Development



3. Neue Revision anlegen

The screenshot displays the Siemens Teamcenter interface for document management. The main window shows the document 'DR-000016661/01-Upload 1' with various tabs like Overview, Changes, Classification, etc. The 'Properties' and 'SHL Attributes' sections are visible. A 'Revise' context menu is open over the document, listing options such as 'Save As', 'Revise', 'Revision Baseline', 'Create Change', 'Create Trace Link', 'Generate Trace Link Matrix', 'Generate Report', and 'Create Alias ID'. The 'Revise' option is highlighted. A secondary window titled 'Revise' is also open, showing fields for 'From' (DR-000016661/01-Upload 1), 'Revision' (02), and 'Name' (Upload 1). The 'Advanced Copy Options' and 'Owning Project' sections are also visible in this window. At the bottom right, there is a checkbox for 'Open New Revision' and a 'Revise' button.



4. PDF anhängen

The screenshot displays the Siemens Teamcenter interface for a specific record, 'DR-000016661/01-Upload 1'. The interface is organized into several key sections:

- Navigation:** A sidebar on the left provides access to Home, Assistant, Explorer, Inbox, Changes, Schedules, Schedule Tasks, and Reports.
- Record Overview:** The top navigation bar shows the record ID and various tabs like Overview, Changes, Classification, etc. The breadcrumb trail indicates the record is under 'DR-000016661/01-Upload 1'.
- Properties:** A section on the left lists key attributes such as ID (000016661), Revision (01), Name (Upload 1), and Release Status (Development Results Revision).
- SHL Attributes:** A central section provides detailed technical specifications, including Deliverable Type (Assembly description), Confidentiality level (Internal Information), and Original Document Number.
- Used in PDP:** A section indicating the record's configuration by a global revision rule, currently set to 'On'.
- References:** A section at the bottom left showing a list of references, with 'Upload 1' being the primary reference.
- Original Files:** A section at the bottom right showing a list of original files, with an 'Add' button for uploading new files.
- Add Panel:** A floating panel on the right titled 'Add' contains an 'Upload File' section. It features a 'Select File' button and a 'Drag and Drop files here' area. A file named 'TC training.pdf' (0.144MB) is shown as being added to the record. Below this, there are input fields for 'Name' (TC training), 'Description', 'Type' (Original PDF), and 'Relation' (Specifications).



5. Workflow starten

The screenshot displays the Siemens Teamcenter interface for a development results revision. The main window shows the 'Overview' tab for 'DR-000016661/01-Upload 1'. The interface is divided into several sections:

- Properties:** ID: 000016661, Revision: 01, Name: Upload 1, Description: Upload 1, Type: Development Results Revision, Release Status: Development Results Revision, Date Released: (empty), Owner: teamcenter_testuser (teamcenter_testuser), Group ID: CorpSvc.Medical.SHL_Group, Last Modifying User: teamcenter_testuser (teamcenter_testuser), Checked-Out: (empty), Checked-Out By: (empty), Current Location Code: (empty).
- SHL Attributes:** Deliverable Type: Assembly description, Assessed by: (empty), Assessment date: (empty), Approver: (empty), Approval Date: (empty), Training Matrix: Not Applicable, Confidentiality level: Internal Information, Name (Chinese): (empty), Change Description: (empty), Original Document Number: (empty), Original Document Version: (empty).
- Used in PDP:** Configured by Global Revision Rule: SHL Latest Working No Baseline (On), The selection is not used in any structure.
- Rendered PDFs:** A table with columns for Object, References, and Type.

A context menu is open over the 'Submit to Workflow' button, showing options: Submit to Workflow, Add to My Changes, Mark as Suspect, Pin to Home, and Add to Favorites. A tooltip for 'Submit to Workflow' reads: 'Submit "DR-000016661/01-Upload 1" to a workflow.'

An inset window titled 'Submit to Workflow' is shown, displaying the 'Workflow' configuration. The 'Name' field is populated with 'DR-000016661/01-Upload 1'. The 'Description' field is empty. Under 'Targets', the 'Upload 1' target is selected, showing its ID '000016661' and Revision '01'.



Automatisiert

1. PDFs mit der ID im Namen im Upload Folder ablegen
2. Warten
3. Neue Revisionen sind erzeugt und Workflow gestartet

Vorteile

- User braucht kein Teamcenter Wissen
- Kann von einem Netzlaufwerk gestartet werden
- Keine Wartezeiten in Teamcenter

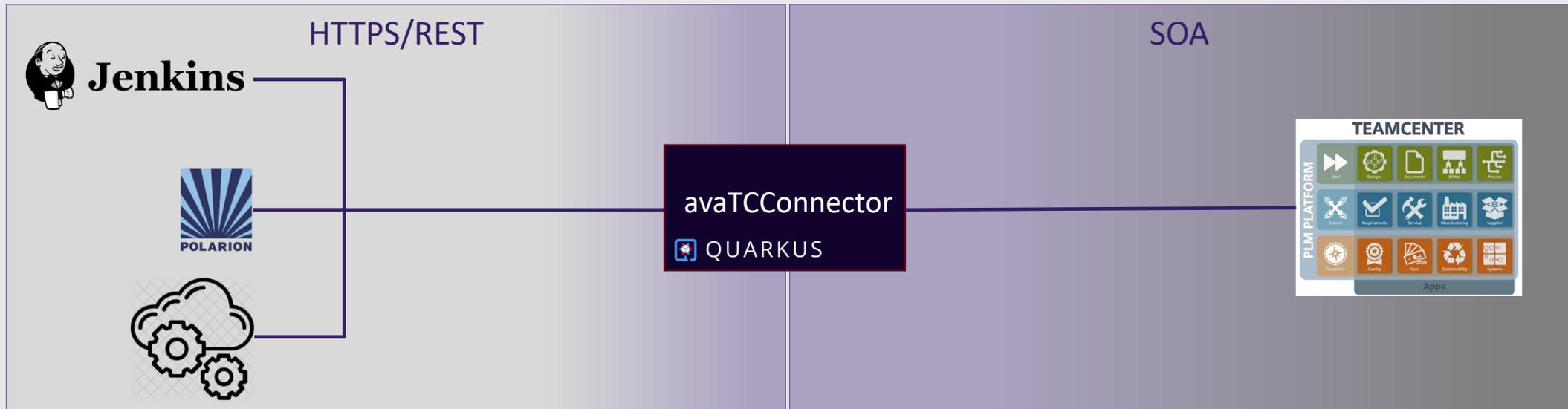


avaTCConnector – REST-Schnittstelle zu Teamcenter

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REST: Representational State Transfer
SOA: Service-Oriented Architecture



Zusammenfassung & Ausblick

Presenter



Was wollen wir noch erreichen?

- Umstieg auf von Hosted Infrastructure auf Hyperscaler
- Nötige Anpassungen an unserer Tool Chain
- Installation / Aufsetzen von (virtuellen) Maschinen automatisieren (terraform)
- Einbindung und Implementierung eines vollständigen Monitorings (Zabbix)
- Mehrere parallele DEV stages mit einer Zusammenführung auf TST
- Globale Verteilung der Server, Loadbalancing und Erhöhung der Performance (insbesondere der Anwenderzufriedenheit)
- Null-Fehler-Deployments mit vollständiger Traceability
- Fast Recovery und Scalability
- 4 Releases pro Jahr – Paralleler Definitions- und Entwicklungsstrang
- Test Automatisierung (cypress)
- Hin zu mehr Managed Infrastructure



Egal ob der eigneschlagene Wege so oder so aussieht ...





IT'S A LONG WAY TO PARADISE



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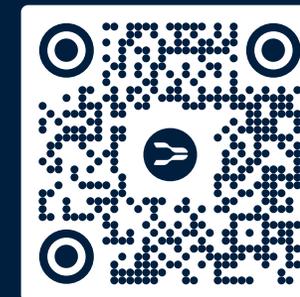
shl-medical.com/about-shl/

shl-medical.com/products-services/drug-delivery-solutions/

shl-medical.com/sustainability/

shl-medical.com/category/news/

shl-medical.com/careers/



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