



**MEDTECH
MEETS
DIGITAL**

CHANGE MANAGEMENT

07. - 08.11.2024 | Berlin - DIN e.V.

CHANGE MANAGEMENT – ALWAYS ONE STEP AHEAD OF CHAOS?



Is that change management?

No.

This is the answer
of the AI
from Microsoft Designer
to the task
"How can chaos theory be
represented in a picture?"

PRACTICAL EXPERIENCE WITH CHANGE MANAGEMENT

Internal audits, external audits, inspections, and your own concerns.

Problem/Question	Short answer
When is a change a change?	Whenever an approved product/process is changed.
How can the complexity of change management be reduced?	DIGITALIZATION = tool-supported work is easier + faster; reduction of involved persons (1 st /2 nd level); Differentiation of "significant/non-significant change"; Decision trees & Checklists => Standardization; Fast track for "harmless" + Urgent track for "burning" issues
Who is responsible for the changes?	The change owner (Highlander principle: "There can only be one!"). Appointment depends on the type and content of the change.
Who all needs to be involved?	Consider all relevant topics and then involve relevant departments/persons. Depends on the type and content of the change. Checklists help.
How do I know when it's my turn?	DIGITALIZATION = tool-supported workflows inform automatically
Why does the cycle take so long?	DIGITALIZATION = tool-supported work is more reliable and faster; Automated review + approval processes with audit trail.
How do you achieve traceability?	DIGITALIZATION = tool-supported work is more transparent = Automatic traceability provided overview of open changes and their status at the touch of a button at any time
Use the same process for product/QMS changes?	This works in principle, but is usually not expedient, as the Product Change Process is much more complex and the QMS Change Process usually has far fewer steps.

THEORY: A SIMPLE CHANGE MANAGEMENT PROCESS IN MEDTECH

Change Initiation

Identify change
Change
Document change request



Impact Assessment

Risk assessment, Regulatory Impact
Analysis, Review of affected areas



Change Approval

Cross-Funktional Review
Formal approval & documentation



Change Implementation

Update documentation, Training &
Communication, Change execution



Verification & Validation

Verification to ensure quality
Validation to ensure performance, ...



Post-Implement. Review

Monitor market feedback
Review change effectiveness

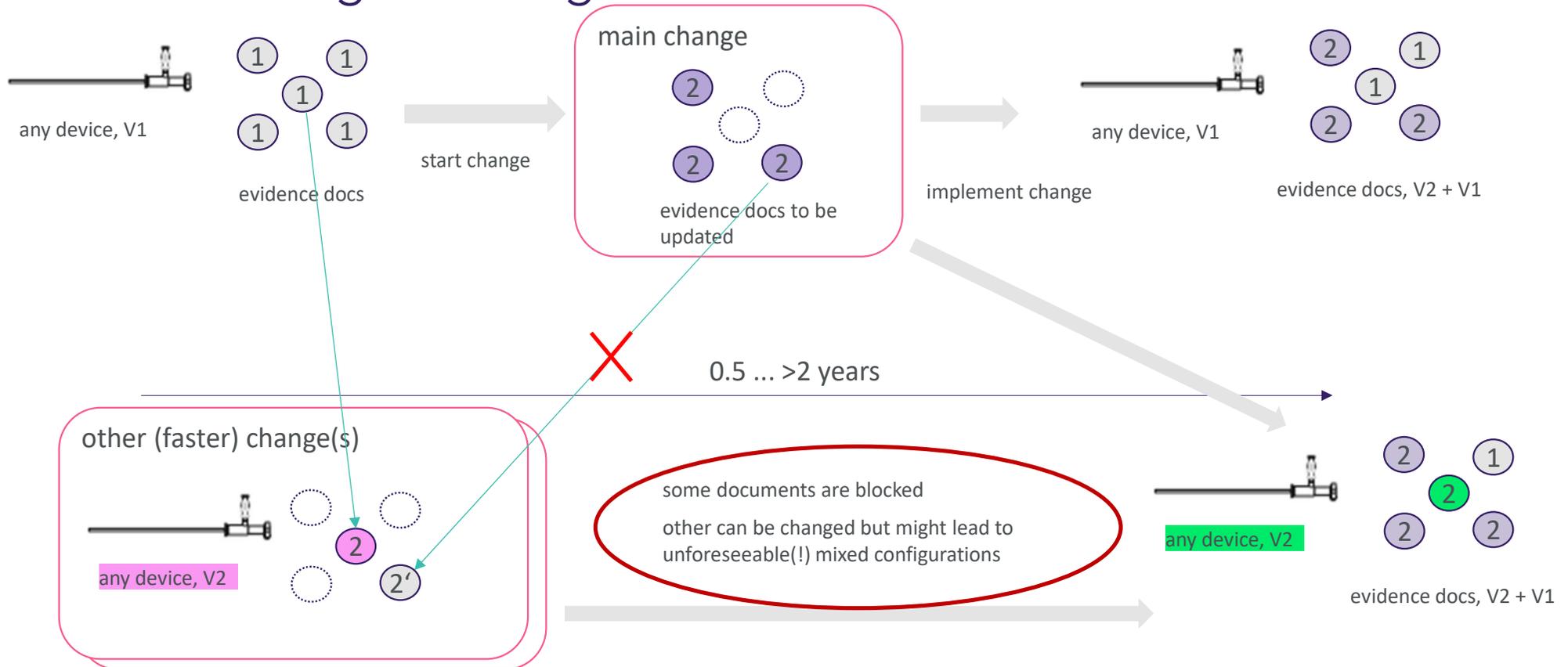


Close Change Request

Finalize documentation
Archive Records

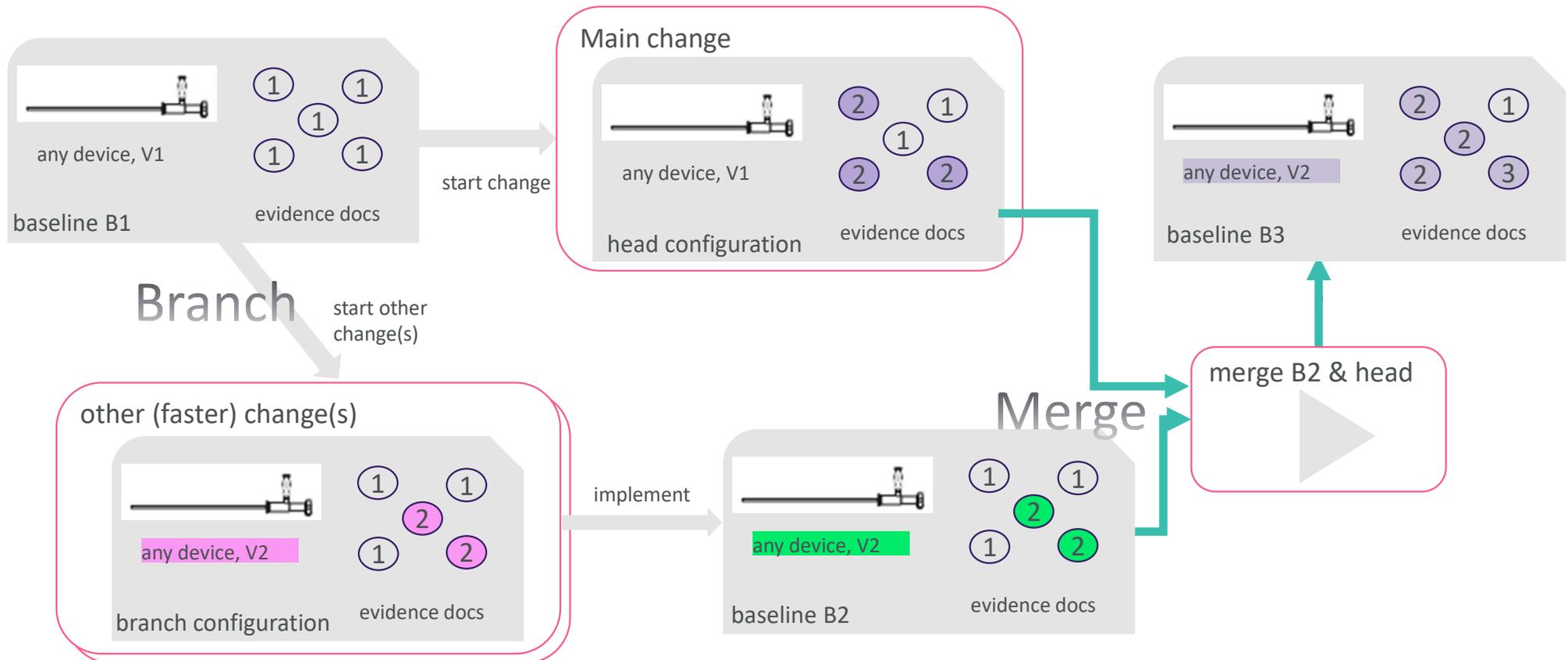
PRACTICE: CHANGES THAT OVERTAKE EACH OTHER

Without Managed Configurations



PRACTICE: CHANGES THAT OVERTAKE EACH OTHER

With Managed Configurations



TYPES OF CHANGES AND THEIR REGULATORY IMPACT

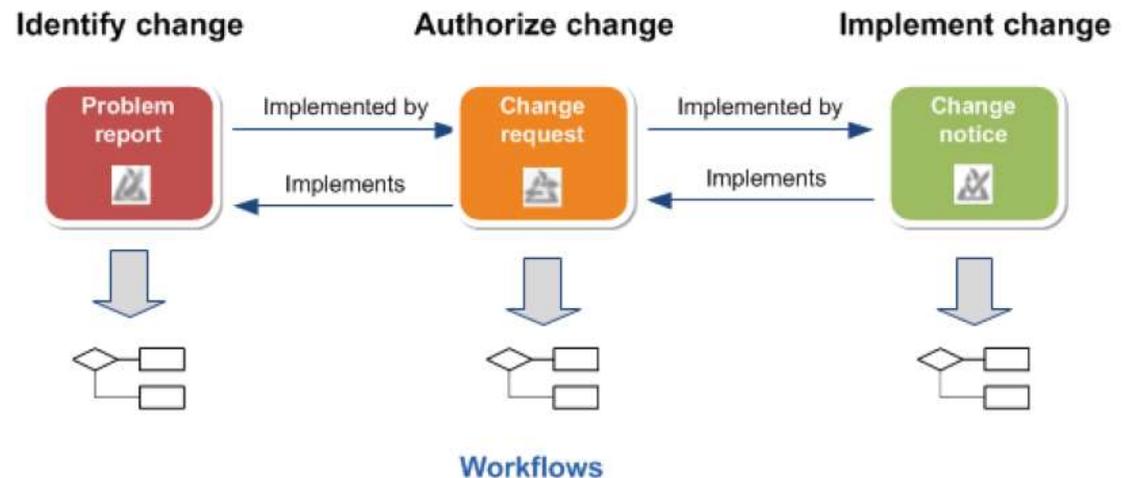
For approved medical devices, every change must be evaluated in terms of its regulatory relevance.

Type/content of change	Possible regulatory impact
New/modified feature: Market or customer requirements change	Loss of approval due to change of medical intended purpose or safety/performance-related changes
Change of manufacturing site: Change of location or entity or outsourcing to 3rd party	Loss of certification due to change of manufacturing site
Supplier related change: Change of component manufacturer or supplier due to delivery or cost issues	Influencing approval if the new supplier is not sufficiently qualified/certified or does not comply with certain regulatory requirements or is not even aware of them
Supplier related change: Components/parts are no longer available	Loss of CB certification or others due to replacement of critical components
Feedback/complaints from or corrective measures in the field: Errors have to be eliminated	Changes under market/time pressure can lead to non-compliance with regulatory processes/requirements, resulting in non-compliant products
Regulatory driven changes: Legal, normative or technical requirements change	The product can no longer be adapted to the changed requirements, loses its approval and must be withdrawn from the market
Process change: The manufacturing or testing process is modified to optimize costs or in the event of production equipment failure	The manufacturing or testing process is no longer validated and may not be used in this state for the manufacture of approved medical devices

KERNELEMENTE DES CHANGE MANAGEMENT PROZESSES DIGITALISIEREN

Drei Haupttypen von Änderungsobjekten implementieren die wichtigsten Elemente von Änderungsverwaltung:

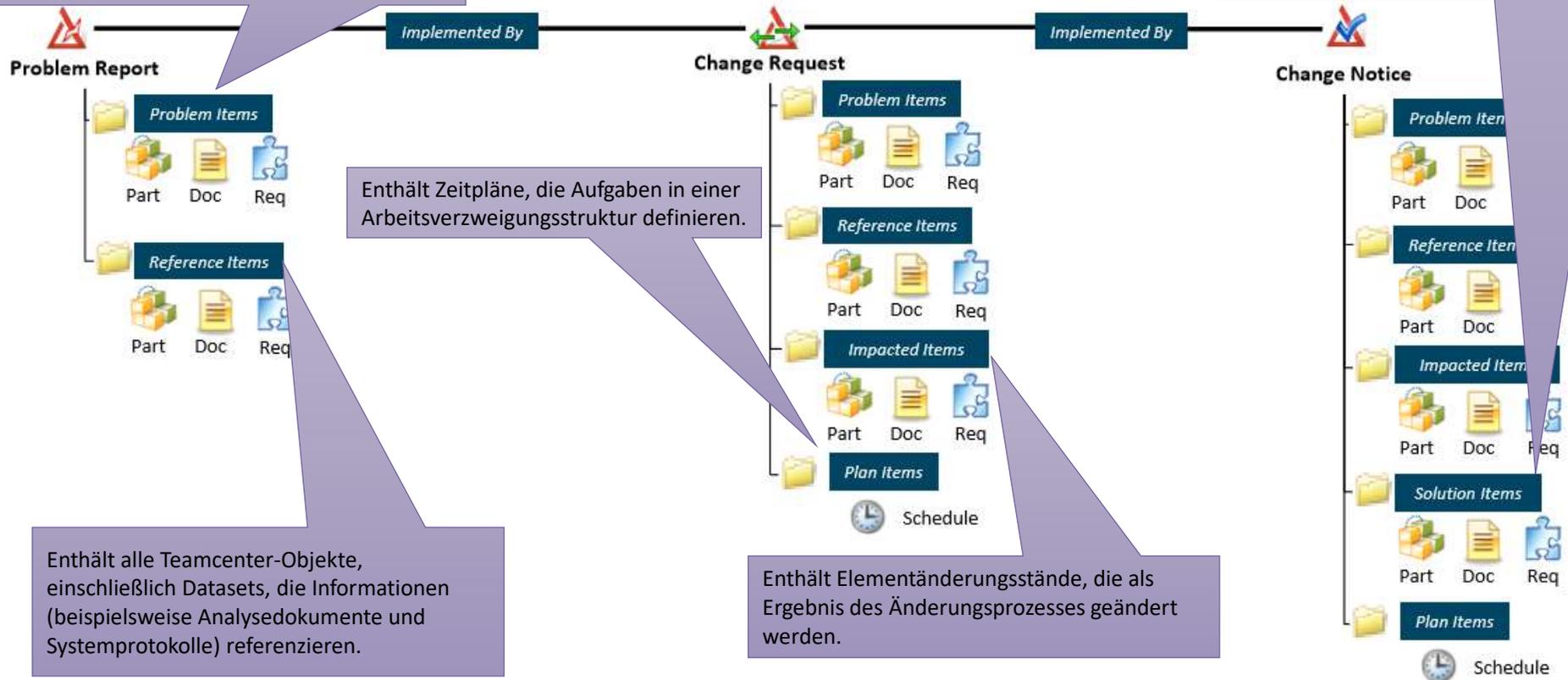
- Problembenachrichtigung (**PR**) enthält z. B. die Daten, die das Problem definieren
- Unternehmensänderungsanforderung (**ECR**) enthält die Analyse der Auswirkung des Problems
- Unternehmensänderungsbenachrichtigung (**ECN**) enthält die Daten für die Implementierung der Lösung



CHANGE OBJEKTE & CHANGE RELATIONEN

Enthält Elementänderungsstände mit den Problemen, die die Änderung behandeln muss. Dies könnte die übergeordnete Baugruppe sein.

Enthält Elementänderungsstände, die als Folge der Änderung generiert werden (z. B. die neuen Einzelteile und der neue Änderungsstand der übergeordneten Baugruppe, in der sie enthalten sind).



Enthält alle Teamcenter-Objekte, einschließlich Datasets, die Informationen (beispielsweise Analysedokumente und Systemprotokolle) referenzieren.

Enthält Elementänderungsstände, die als Ergebnis des Änderungsprozesses geändert werden.

ANLAGE EINES PROBLEM REPORTS IN TEAMCENTER MIT MS TEAMS



WORKSHOP

AUF WELCHEM DETAILLEVEL MÖCHTEST DU ÄNDERUNGEN VERWALTEN
KÖNNEN?

VERKNÜPFUNG VON PDP STRUKTUREN ZWISCHEN POLARION UND TEAMCENTER

000312/A;1-PDP Demo-Product

Overview | **TC MDS** | Collections | Checker | Where Used | Attachments | History | Participants | Reports

Start Date Phase/Ms: 16.10.2024
End Date Phase/Ms: 21.10.2024

Object	State	Record Type	Name	Requisites	Owner	Group ID	Release Status
- Market Analysis	!	Market Analysis	Market Analysis	required			
000314/A;1-Intended Purpose	!	Intended Purpose	Intended Purpose	required	Engineer, Ed (ed)	Engineering	
- User Needs	!	User Needs	User Needs	required			
- Stakeholder Requirements	!	Stakeholder Requirements	Stakeholder Requirements	required			
- General Safety and Performance Requirements (GSPR)	!	General Safety and Performa...	General Safety and Performance Re...	required			
- Clinical Evaluation Report	!	Clinical Evaluation Report	Clinical Evaluation Report	required			
- Sys-FMEA (Systems Failure Mode and Effects Analysis)	!	Sys-FMEA (Systems Failure M...	Sys-FMEA (Systems Failure Mode an...	required			
000315/A;1-Systems & Functional Requirement Specifi...	!	Systems & Functional Requi...	Systems & Functional Requirement ...	required	Engineer, Ed (ed)	Engineering	
- Systems Requirement Traceability Matrix	!	Systems Requirement Tracea...	Systems Requirement Traceability M...	required			
- Systems Architecture (MBSE)	!	Systems Architecture (MBSE)	Systems Architecture (MBSE)	required			
- APQP (Advanced Product Quality Plan)	!	APQP (Advanced Product Qu...	APQP (Advanced Product Quality PL...	required			
000316/A;1-List of suppliers	!	List of suppliers	List of suppliers	required	Engineer, Ed (ed)	Engineering	
000317/A;1-SWOT analysis	!	SWOT analysis	SWOT analysis	required	Engineer, Ed (ed)	Engineering	
Risk			Risk				

VERKNÜPFUNG VON PDP INHALTEN ZWISCHEN POLARION UND TEAMCENTER

The screenshot displays the avasis MDS Polaron Integration web interface. The browser address bar shows the URL: `tcpipolava-dev.avasis-doud.private/polarion/#/project/mdsIntegrationDev/wiki/Custom Demo/Document Plan - Demo Product_from TC_`. The interface includes a left-hand navigation pane with a search bar and a tree view of folders and documents. The main content area displays a document plan for '000312/A;1-PDP Demo-Product'.

Document Plan - Demo Product (from TC)

Table of Contents

- 1 Requirements & Design Input
- 2 Product Design & Engineering
- 3 Manufacturing Process Engineering
- 4 Verification & Validation
- 5 DT

000312/A;1-PDP Demo-Product

1 Requirements & Design Input

000314/A:1-Intended Purpose

Status	Draft
Teamcenter ID	000314
Teamcenter Name	Intended Purpose
Teamcenter Owner	Ed Engineer
Teamcenter Type	Av5_Record

000315/A:1-Systems & Functional Requirement Specification

Status	Draft
Teamcenter ID	000315
Teamcenter Name	Systems & Functional Requirement Specification
Teamcenter Owner	Ed Engineer
Teamcenter Type	Av5_Record

SCHAFFUNG DER DATENGRUNDLAGE FÜR KI

The screenshot shows the Siemens Teamcenter interface. On the left, a tree view displays the product structure for 'New Consumer Hand Drill', including domains like Mechanical, Electrical, and Software. The main area shows a list of requirements:

- 2.5 REQ-000009-Added work light**
The hand drill shall have an added work light at the front-lower side of the grip so that the user can see the drill or screw very clear even in dark environments. At least a small bulb light is required, or an LED may also be used. The light shall have no lens and the light may stick out but with a maximum of 5 mm.
- 2.6 Lighter weight**
The new consumer hand drill shall have a maximum weight of 3.5kg
- 2.7 More stable base**
From the customer feedback that the hand drill falls forward when a long tool is inserted, the base of the housing needs to be extended at least 30mm.
- 2.8 Longer battery life**
Consumers expect the hand drill to be operated on a single battery charge. The current Ni-Cad battery needs to be replaced with the newer Lithium-Ion battery technology.

At the bottom, a section for '000342-Electrical domain' is visible.

The screenshot shows the Siemens Teamcenter interface displaying a list of requirements for a hand drill. The requirements are:

- 00014/A:1-Intended Purpose**
Status: Draft
Teamcenter ID: 00014
Teamcenter Name: Intended Purpose
Teamcenter Owner: Ed Engineer
Teamcenter Type: Int_Record
- 00015/A:1-System & Functional Requirement Specification**
Status: Draft
Teamcenter ID: 00015
Teamcenter Name: System & Functional Requirement Specification
Teamcenter Owner: Ed Engineer
Teamcenter Type: Int_Record
- 00016/A:1-List of suppliers**
Status: Draft
Teamcenter ID: 00016
Teamcenter Name: List of suppliers
Teamcenter Owner: Ed Engineer
Teamcenter Type: Int_Record
- 00017/A:1-SHOT analysis**
Status: Draft