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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.

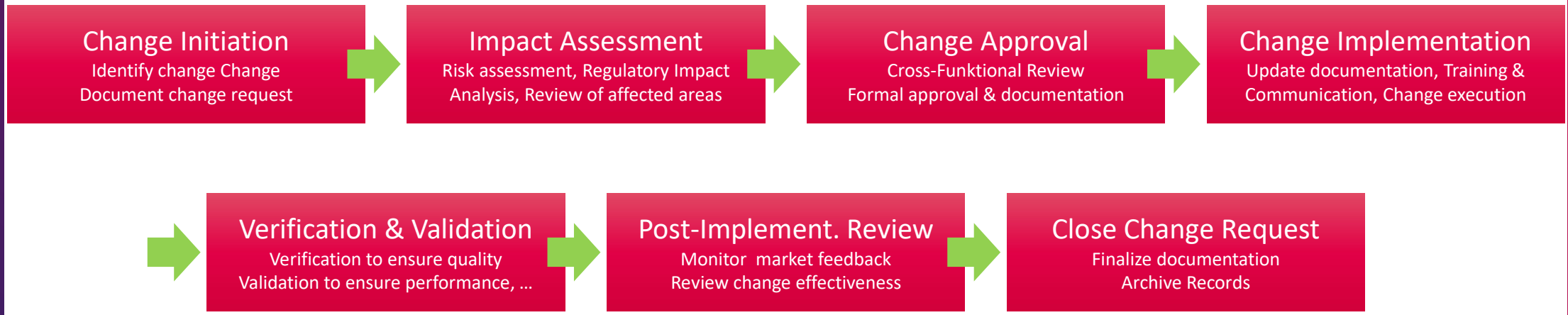
This is the answer
of the AI
from Microsoft Designer
to the task
"How can chaos theory be
represented in a picture?"

PRACTICAL EXPERIENCE WITH CHANGE MANAGEMENT

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

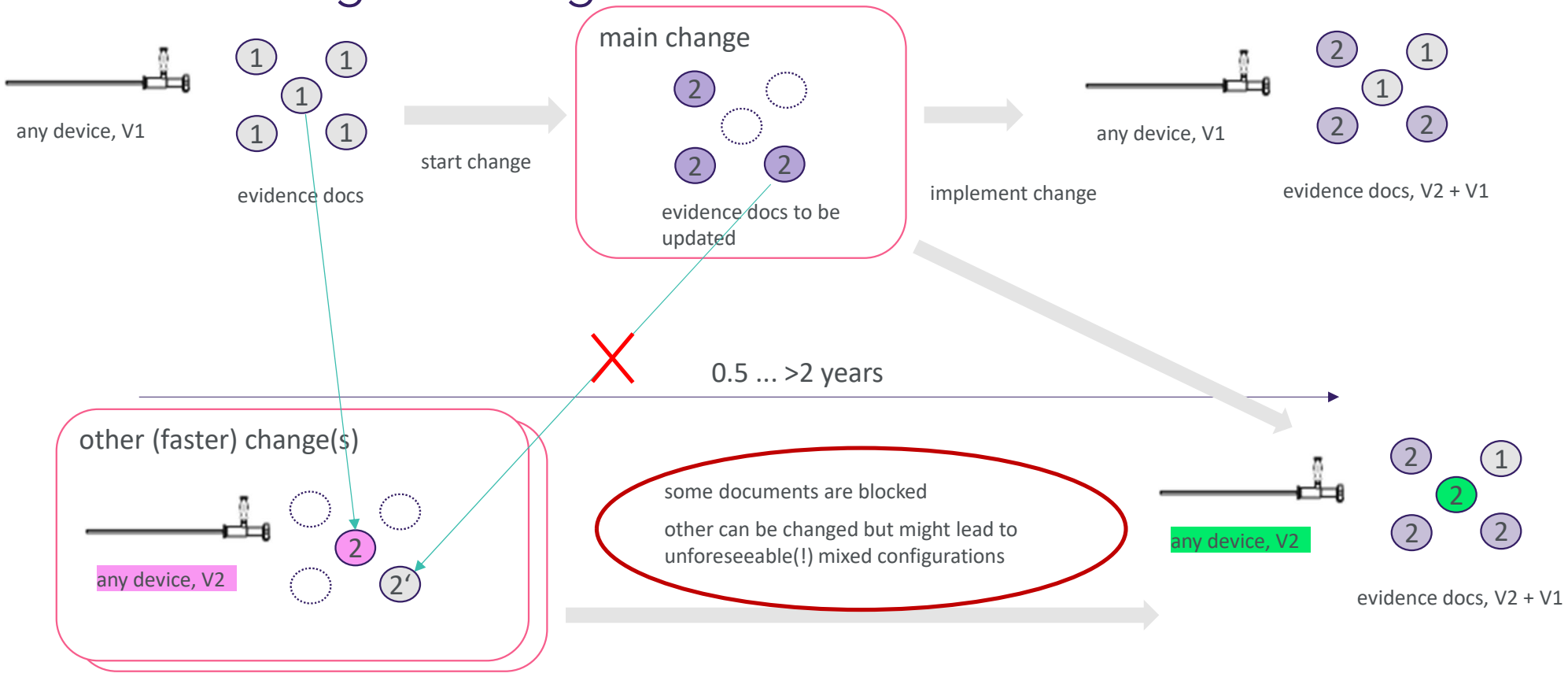
Problem/Question	Short answer
When is a change a change?	Whenever an approved product/process is changed.
How can the complexity of change management be reduced?	DIGITALIZATION = tool-supported work is easier + faster; reduction of involved persons (1st/2nd level); Differentiation of "significant/non-significant 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



PRACTICE: CHANGES THAT OVERTAKE EACH OTHER

Without Managed Configurations



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PRACTICE: CHANGES THAT OVERTAKE EACH OTHER

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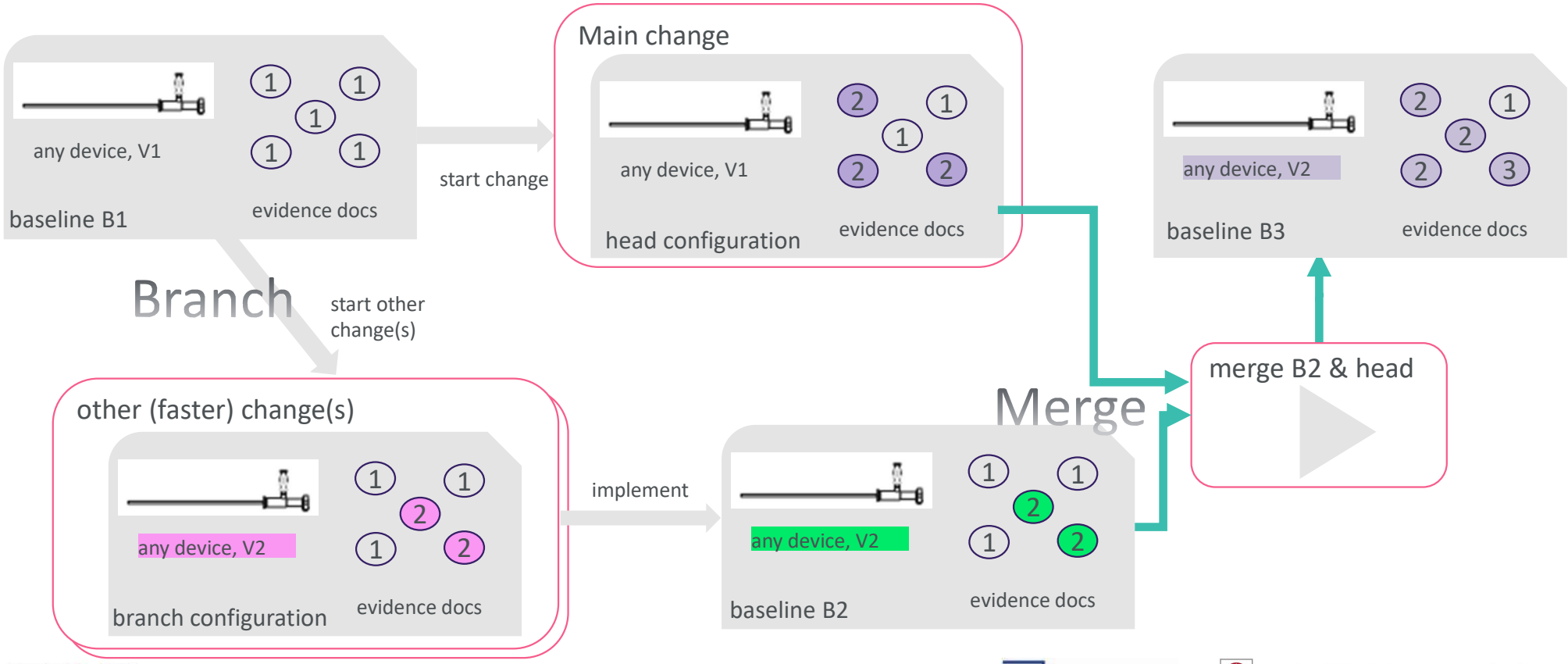

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TYPES OF CHANGES AND THEIR REGULATORY IMPACT

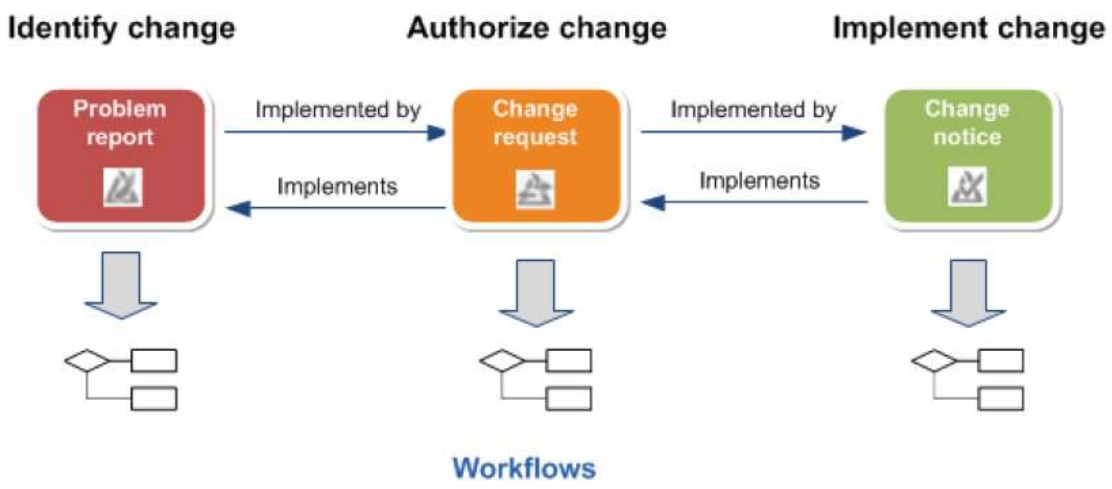
For approved medical devices, every change must be evaluated in terms of its regulatory relevance.

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:

- Problembericht (**PR**) enthält z. B. die Daten, die das Problem definieren
- Unternehmensänderungs-anforderung (**ECR**) enthält die Analyse der Auswirkung des Problems
- Unternehmensänderungs-benachrichtigung (**ECN**) enthält die Daten für die Implementierung der Lösung



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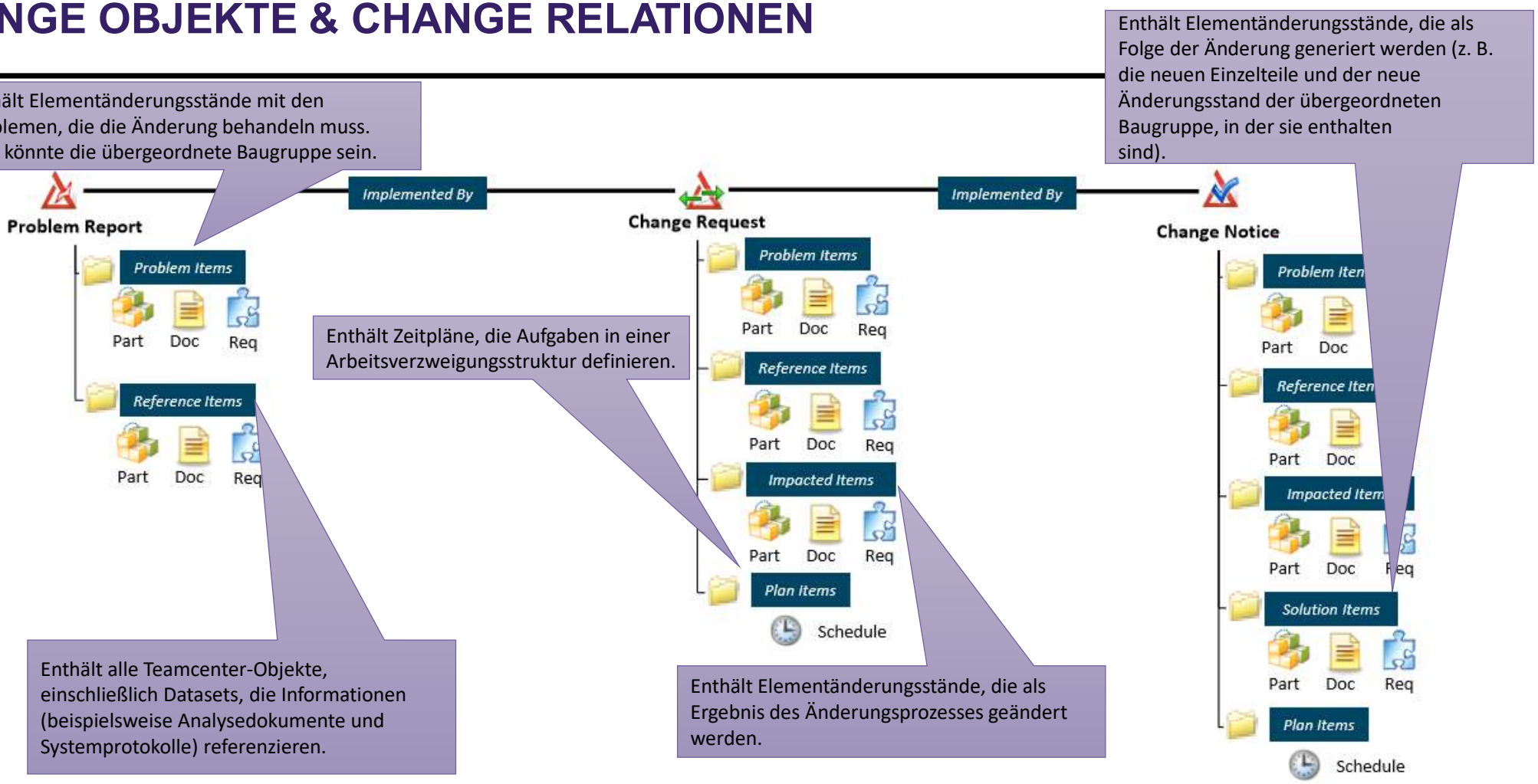
CHANGE OBJEKTE & CHANGE RELATIONEN



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ANLAGE EINES PROBLEM REPORTS IN TEAMCENTER MIT MS TEAMS

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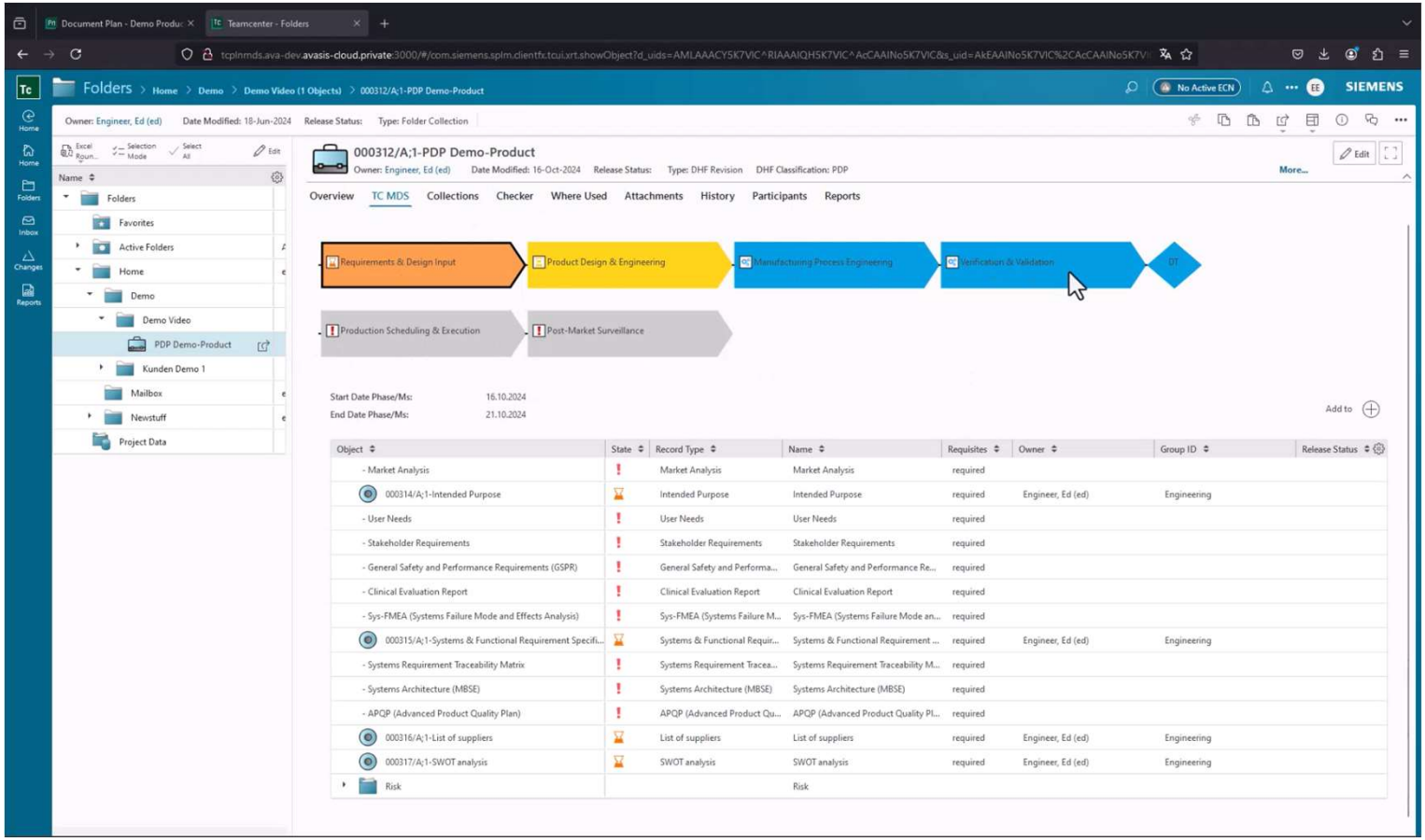
WORKSHOP

AUF WELCHEM DETAILLEVEL MÖCHTEST DU ÄNDERUNGEN VERWALTEN KÖNNEN?

VERKNÜPFUNG VON PDP STRUKTUREN ZWISCHEN POLARION UND TEAMCENTER



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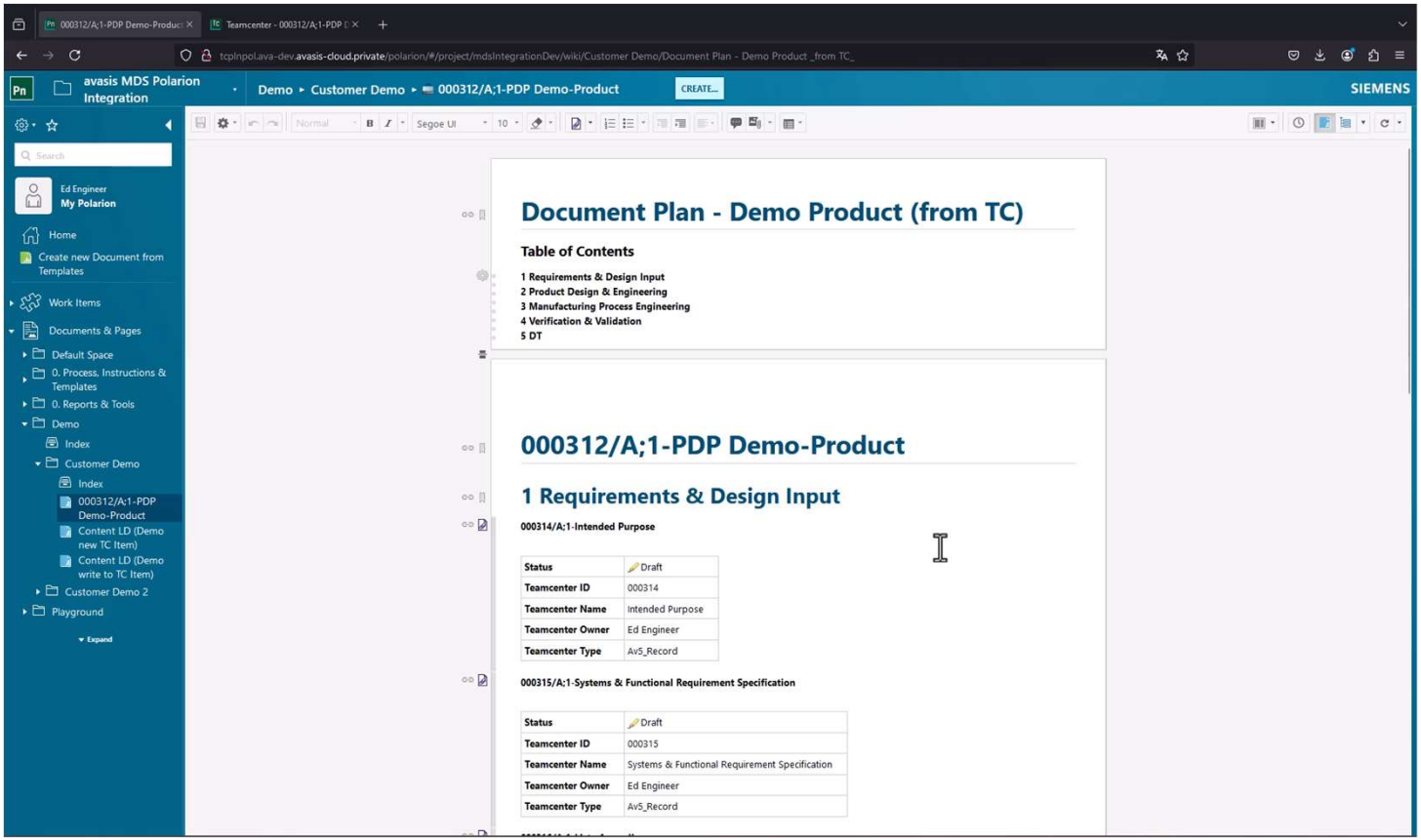
VERKNÜPFUNG VON PDP INHALTEN ZWISCHEN POLARION UND TEAMCENTER



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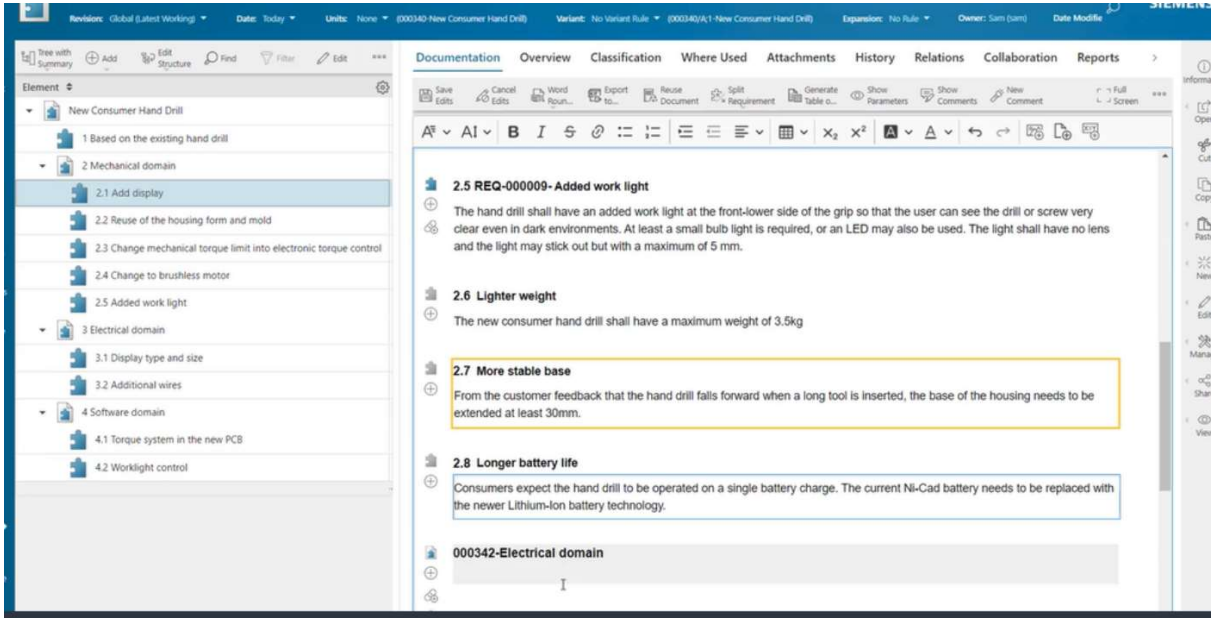
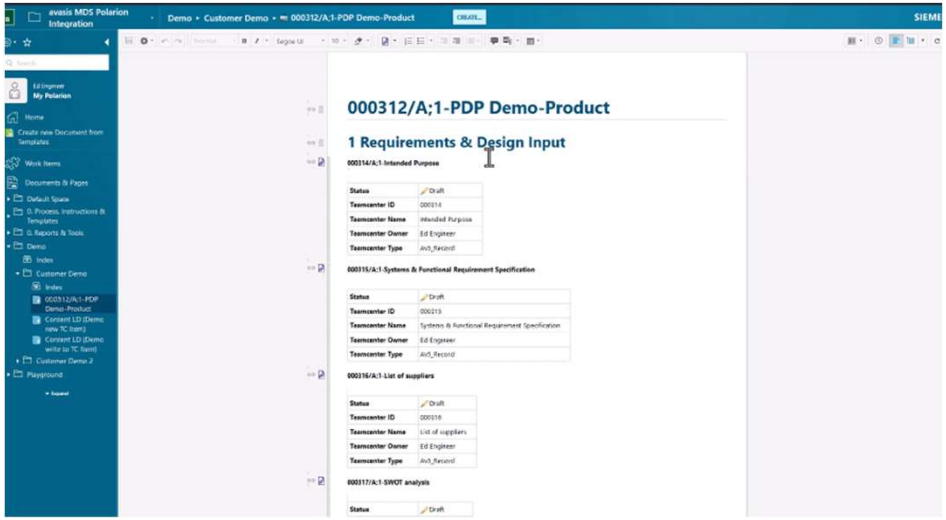
SCHAFFUNG DER DATENGRUNDLAGE FÜR KI





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