De-Risking Use

How to integrate Human Factors Engineering into your Risk Management File without Duplicating Work

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Introduction

- **Christian Schmid**
  - Senior Human Factors Manager
    Science and Evidence Department at Ypsomed
  - with Ypsomed since 2020
  - Gerresheimer 2014-2020
  - Background in Industrial Design
  - Areas of specialization:
    usability engineering, ergonomics, user experience, user interface design, medical devices, drug-device combination products
  - pen injectors, patch injectors, connected devices, and insulin pumps.

Introduction | Abbreviations

- What is shown:
  - Current situation (mistakes made/learnings)
  - Requirements from Regulators
  - Solution of Ypsomed to stop friction between Risk Management and Human Factors
- What not:
  - Exact examples from real products due to confidentiality
  - Recipe to break the silos of HF and Risk in your organization

- Abbreviations
  - HFE/UE: Human Factors Engineering Usability Engineering
  - PCA: Perception-Cognition-Action
  - RM: Risk Management
  - RCM: Risk Control Measure
  - TA: Task Analysis
  - URRA: Use Related Risk Analysis
  - Val: Validation
  - UEA: Use Error Analysis
  - UI: User Interface

The Industry Problem

A “tendency” of HFE and RM working separated

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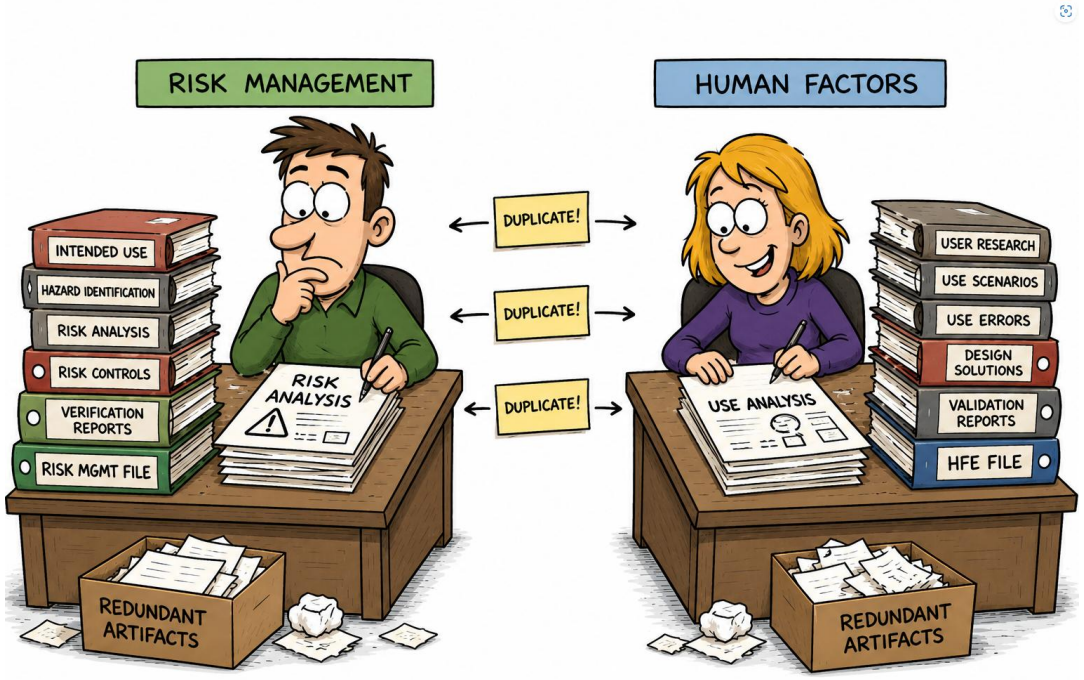
«Many teams are compliant — but inefficiently compliant.»

The Industry Problem – A “tendency” of HF and RM working separated

- **Most* organizations run:**
  - Usability Engineering
  - Risk Management

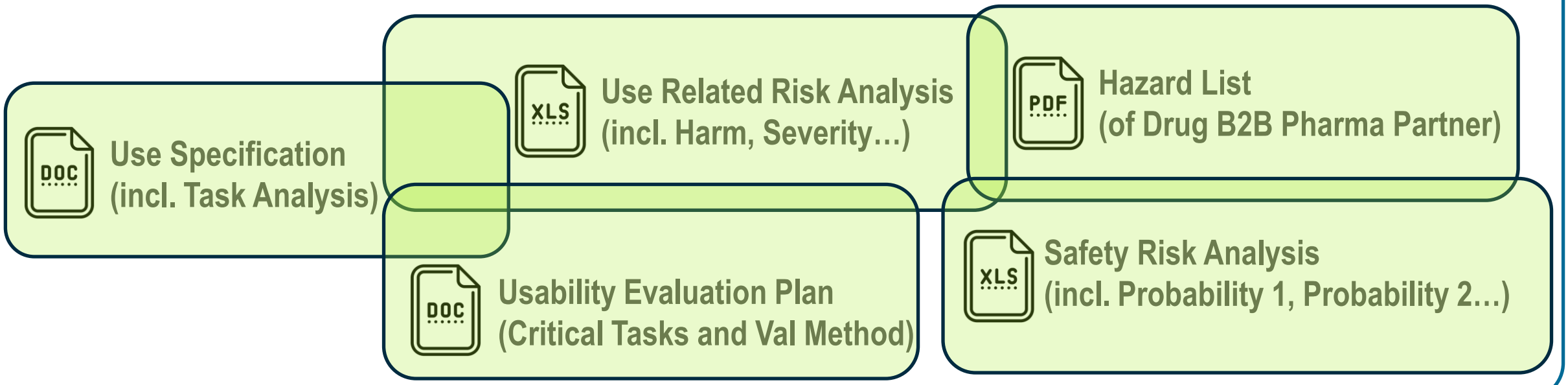
  As paralell systems with redundant artifacts.

*the ones I worked for and what I saw from customers of those organizations.



The Industry Problem – A “tendency” of HF and RM working separated

- **Ypsomed process before change:**
  - Same content in different documents…
  - …and different document types
  - Overlap creates friction and immense effort to avoid traceability issues



The Industry Problem – A “tendency” of HF and RM working separated

Pain points

- Duplicate task analyses and inconsistent terminology
- Effort to avoid traceability gaps (Tool to Tool)
- Different ownerships and reviewers across departments poor cross-functional collaboration
- Audit findings due to disconnected rationale
- Documentation maintenance burden after release or during development
- Very hard change impact assessment

Example of maintenance burden

After Formative Study, additional Critical Task «to unlock XY» necessary as Risk Mitigation:

- Change impact assessment
- Update Use Spec. with TA and release
- Update UEA and release
- Update Usability Evaluation Plan and release
- Update Safety Risk Analysis and release

Rootcause of Duplication and Regulators expectations

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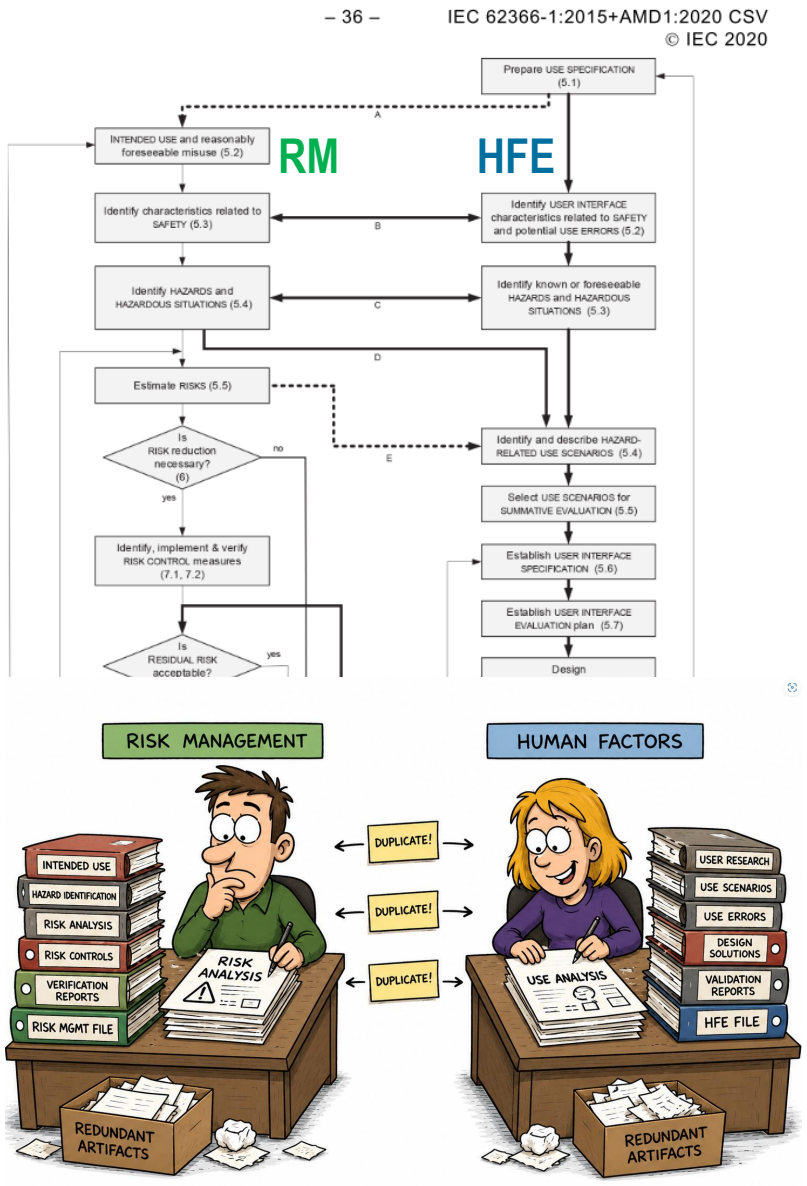
«The silos of HFE and RM start with Figure A.5 in IEC 62366-1:2015»

Rootcause of Duplication and Regulators expectations

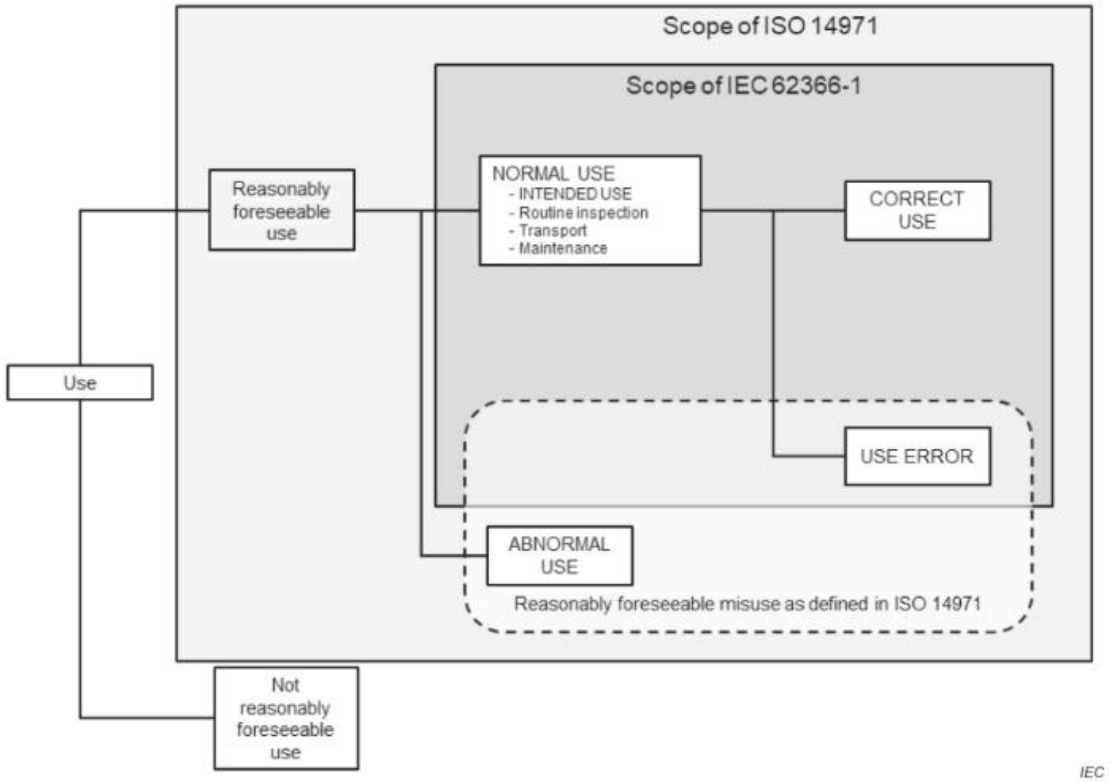
- Related information in >1 document (non-exhaustive)
  - List of tasks
  - Characteristics related to safety
  - Identification of Hazards and Hazardous situations
  - Hazard related Use Scenarios / Critical Tasks
  - Risk Controls / Design Solutions

Rootcause:

- Paralell part on top AND not possible in the past to work on a document at the same time
- Ypsomed specific: Risk alone responsible for UEA



Rootcause of Duplication and Regulators expectations



- 62366-1:2015 and 14971:2019
  - Scope of 14971 is wider, overlaps and often needs HFE expertise for assessment
  - Abnormal Use as part of reasonably foreseeable misuse needs to be documented and assessed but not mitigated

Examples of Regulators Expectations and Formats we encountered:

- FDA asked us for:
  - URRA without Probabilities in Summative Protocol
  - Severity not as number, as Low/Medium/High
  - Critical Task includes: «Compromised Medical Care» it must be shown if task criticality is related to compromised medical care
  - …
- 62366-1:2015 and 14971:2019
  - Use Error Analysis
  - Severity as numbers 1-5
  - Hazard Related Use Scenarios
  - …

New process – Single Source of Truth for Multiple Documents

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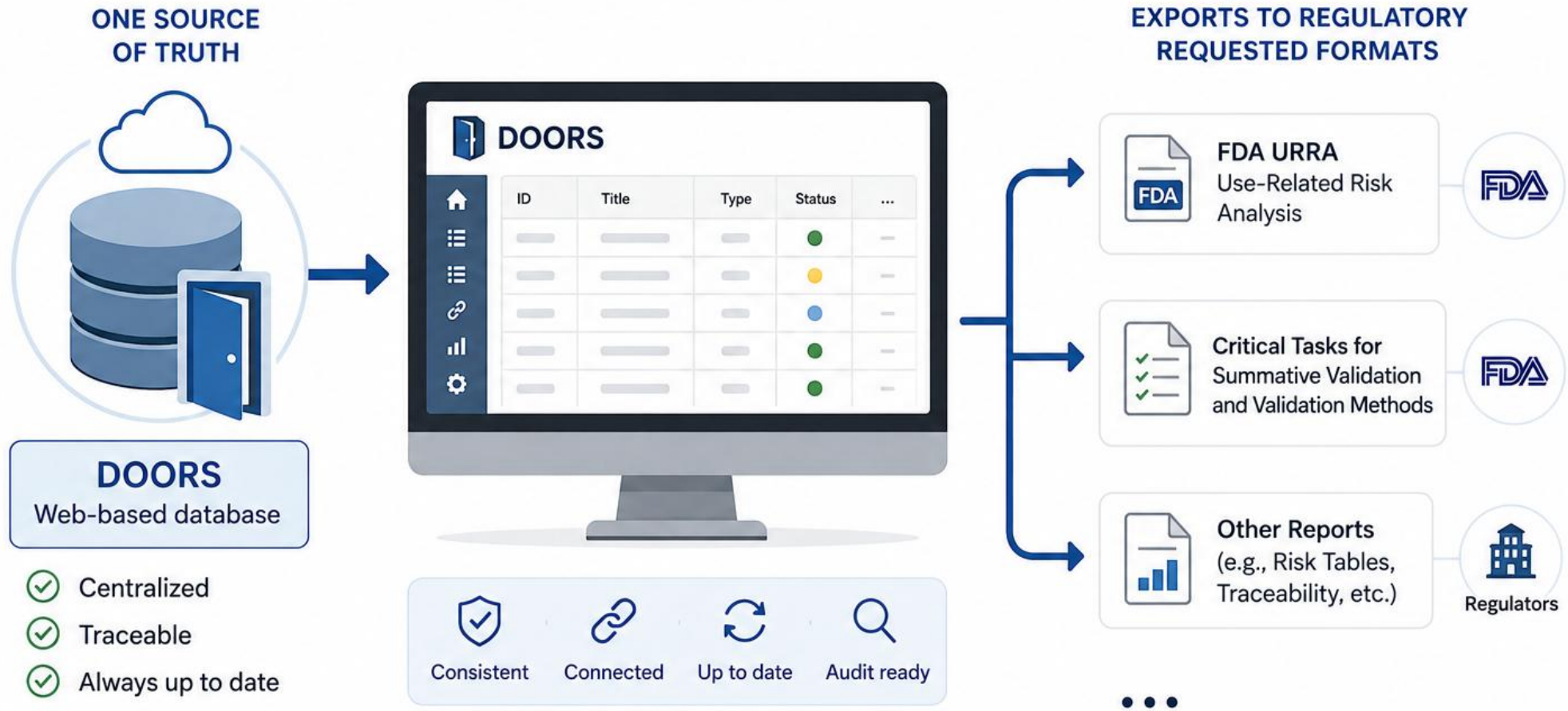
«Not merging documents — creating a single source of truth for all of them.»

A Single Source of Truth – Cloud based database (DOORS)



New process – Single Source of Truth for Multiple Documents

- After change:
  - «One table to rule them all…»
  - Before database same content in one document and single document type (Excel) (relies on change control of MS Sharepoint)
  - Less friction due to one single source of truth and clear responsibilities of HFE and RM

Task Analysis

Use Related Risk Analysis (incl. Harm, Severity…)

Usability Evaluation Plan (Critical Tasks and Val Method)

New process – Single Source of Truth for Multiple Documents

Human Factors part:

- Step 1: Include task analysis from the Use Specification
- Step 2: Define task completion criteria
- Step 3: Define evaluation method in a Human Factors Study
- Step 4: Determine Use Error Cause through the Perception-Cognition-Action (PCA) cycle

Identifies

- Tasks including task completion criteria necessary for Evaluation Protocols
- one or more task completion criteria, such as correctly performing an action or understanding information in the user interface, i.e., on the device, in the user manual, or on the packaging
- Evaluation methods (Simulated Use or Knowledge Task)
- PCA method Use Error Cause helps to inform useful Risk Control Measures

New process – Single Source of Truth for Multiple Documents

Human Factors part:

- Step 5: Identify reasonably foreseeable misuse
- Step 6: Propose fields of Hazards
- Step 7: Define risk control measures for each use error

Identifies

- Reasonably foreseeable misuse (Use Errors in Normal Use and Abnormal Use)
- Proposes fields of Hazards on a high level (Underdose, Overdose, Environmental…)
- Tailored Risk Control Measures after PCA (Perception issue needs Perception enhancement)

New process – Single Source of Truth for Multiple Documents

Task·ID¤	Task¤	Task·description¤	Task·completion·criterion¤	Evaluation·method·HF·validation·study¤	PCA¤	Reasonably·foreseeable·misuse·(UE·/·AU)¤	Risk·control·measure¤
¤	¤	¤	¤	¤	¤	¤	¤

Human Factors Part Table

- ID automatically given and unique in DOORS
- Task Description can be used for Use Scenario Wording
- Perception-Cognition-Action with Use Error Cause (E.g. P – does not recognize start click)
- Use Errors and abnormal Use are separated (AU – knowingly keeps using needle)
- Risk Control Measure tailored to PCA (Design, Labeling, …)

New process – Single Source of Truth for Multiple Documents

Risk Management part:

- Step 1: Identify potential hazards (failure modes)
- Step 2: Evaluate probability of occurrence of each hazardous situation (failure effect) ($P_{_I\text{-}BRC}$ & $P_{_I\text{-}ARC}$)
- Step 3: Identify potential hazardous situations (failure effects) of each use error
- Step 4: Evaluation of probability of occurrence of hazardous situations leading to harm ($P_{_II\text{-}BRC}$ & $P_{_II\text{-}ARC}$)

- Risk identifies with SME's (e.g. Medical) hazards and hazardous situations
- Estimates probabilities before and after introduction of Risk Control Measures

New process – Single Source of Truth for Multiple Documents

Risk Management part:

- Step 5: Calculate overall probability of occurrence (P_{BRC} & P_{ARC})
- Step 6: Identify potential harms with linked severity ratings for the harm (S_{BRC} & S_{ARC})
- Step 7: Determine overall risk ($Risk_{BRC}$ & $Risk_{ARC}$)

New process – Single Source of Truth for Multiple Documents

Risk Management part:

- Step 8: Determine for each use error if it may lead to compromised medical care
- Step 9: Determine if task is critical
- Step 10: Risk Control Measure classification and determination of residual risk

- Compromised Medical Care is determined with subject matter experts
- Criticality of Task is determined according Severity and Compromised Medical Care
- RCM Status is tracked

New process – Single Source of Truth for Multiple Documents

Hazard	P_I -BRC	P_I -ARC	Hazardous Situation	P_II -BRC	P_II -ARC	P_{BRC}	P_{ARC}	Harm	S_{BRC}	S_{ARC}	Risk BRC	Risk ARC	Compromised medical care	Criticality of task	RCM Status

Risk Management Part Table

- Compromised Medical Care is determined by SME's with Risk
- Task Criticality (Yes / No)
- Risk Control Measure Status is tracked (proposed, confirmed, implemented, declined)

Organizational and Strategic Impact

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Organizational and Strategic Impact

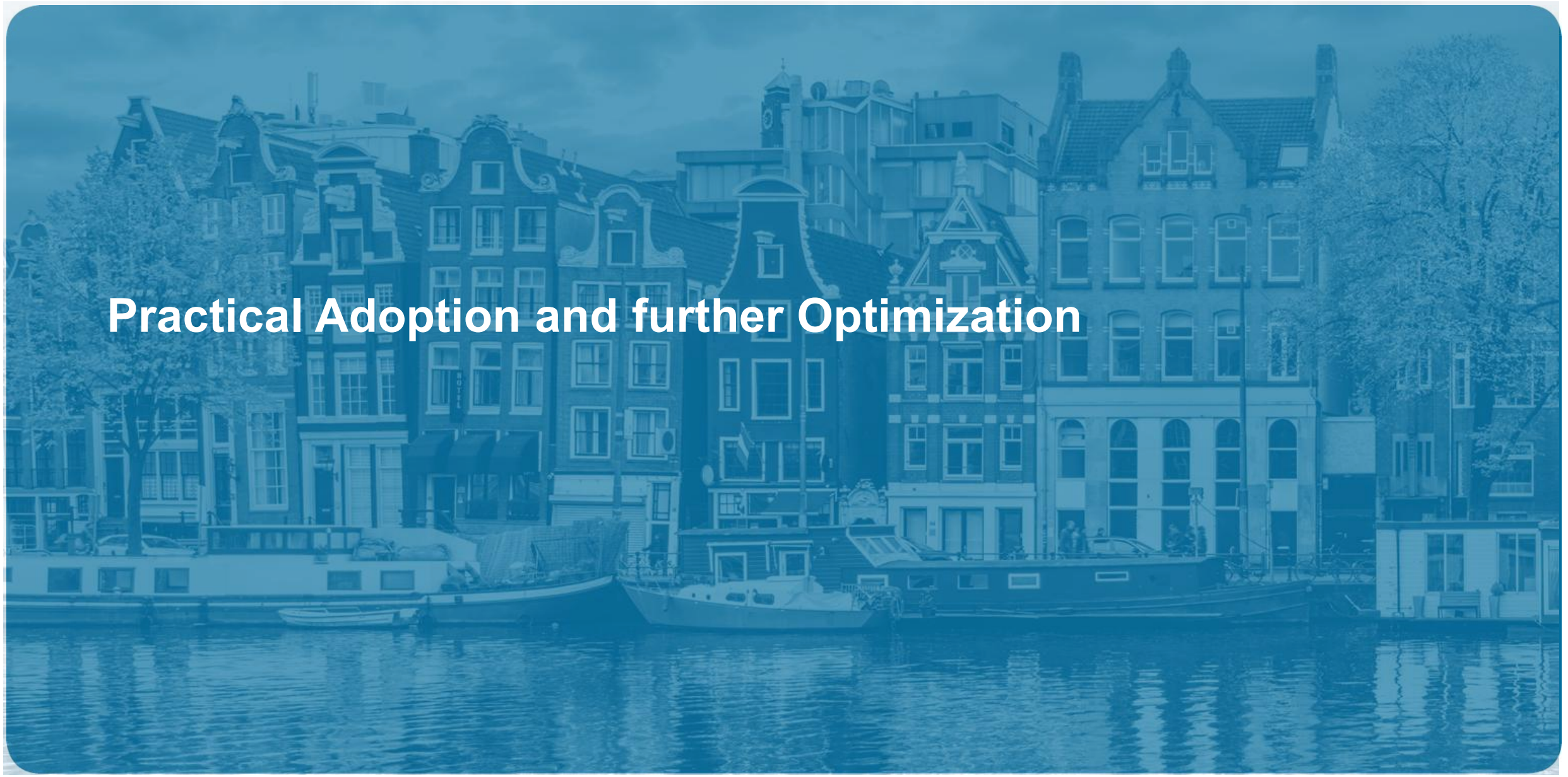
- **Documentation wise:**

  - Lower documentation maintenance
  - Easier change impact assessment
  - Enables better cross-functional collaboration
  - Stronger traceability and audit readiness
  - Faster submissions

- **Product wise:**

  - More time for solution engineering
  - More targeted mitigation decisions (PCA)
  - More willingness for change after Formative Evaluations
  - Stronger traceability and audit readiness
  - Faster submissions

«Value for our customers and ourselves in a more coherent safety argument»



Practical Adoption and further Optimization

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Practical Adoption

Innovation Department as test site

- **2 innovation projects tested new process**

3 Development Projects on new process

- **From begin of June 2026**

Meetings RM and HFE reduced recognizably

Further Optimization and Testing

Create drug agnostic platform files

- Reusable foundation for efficiency and consistency

Marking of risks that are drug agnostic

- Device platform inherent risk, not to be changed

Marking of drug related risks and tasks for our customers

Discussion and Q&A

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