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Navigating Constraints: A Lightweight Systems Engineering Journey in Pharma and Medical Devices

SwissED 2025 – SE: Stories Experienced

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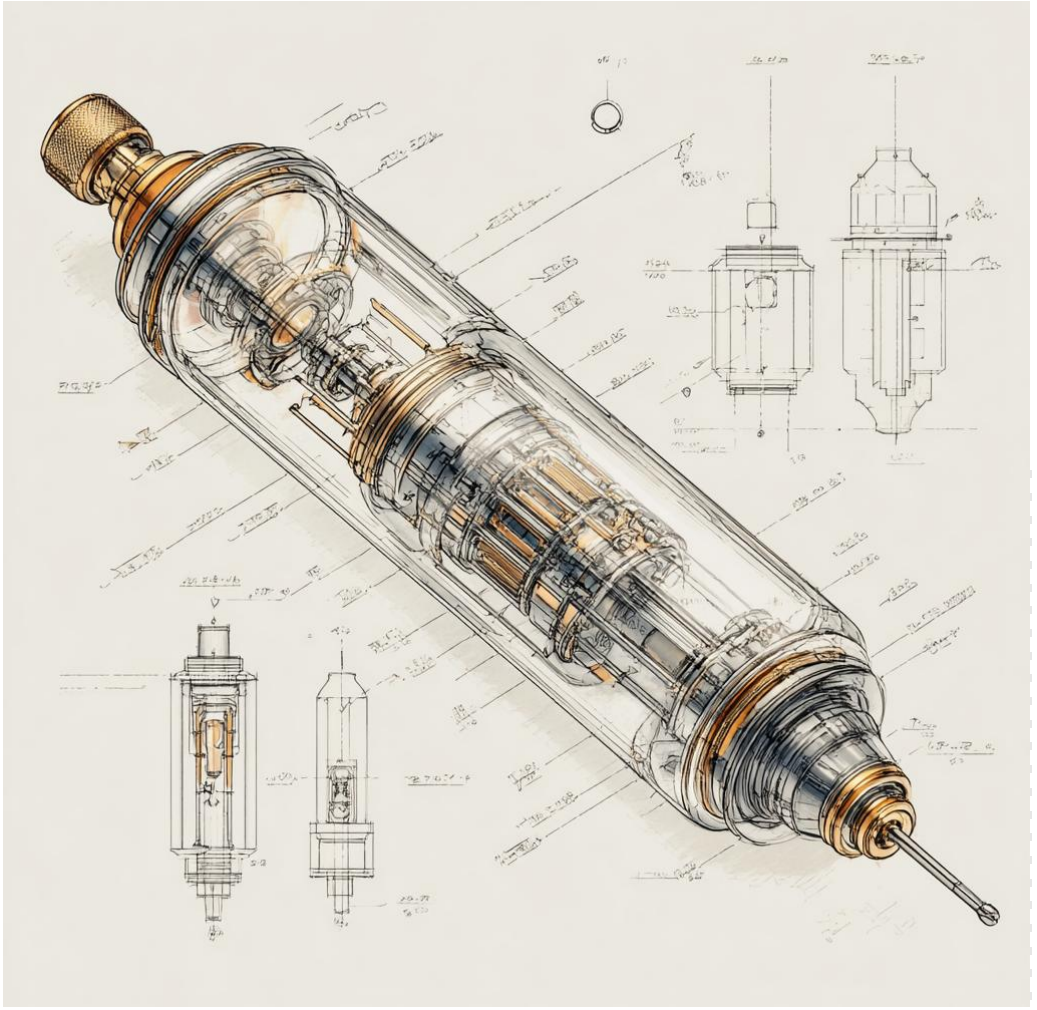

AI generated picture: A 3D CAD drawing of an autoinjector

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Senior Project Manager • Systems Engineer

- Leading cross-functional R&D team with focus on Medical devices, diagnostics & lab automation
- Systems Engineering & Architecture (ISO 13485, ISO 14971, IEC 60601-1, IEC 62304)

📍 Bern, Switzerland

AI generated picture: a Walt-Disney characterization of myself

The project in a nutshell

The client needs to establish a platform supporting:

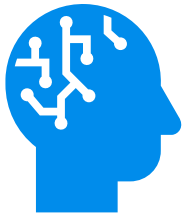
- Communication with stakeholders,
- Elicitation of Verification scope and activities
- Input for Design History File (needed for submission to regulatory entitites)

Starting point

Novel subsystem for autoinjectors

Advanced status of development

Unclear stakeholder needs



Our SE Approach

Reconstruct lifecycle and stakeholder needs

Elicit requirements and architecture

Perform gap-analysis against legacy documentation and design choices

Establish traceability and alignment with V-model and risk management

Key Outcomes

Clarified stakeholder landscape

Defined the System of Interest

Elicited constraints and needs

Aligned requirements to design control

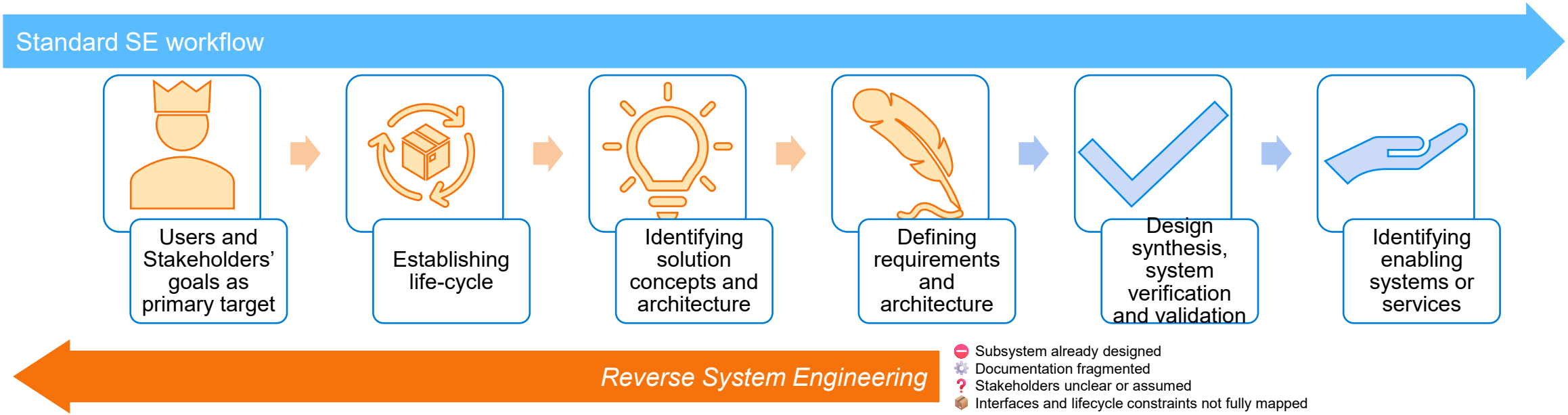
Reverse Systems Engineering

Integration of SE practice in project with existing design

The client was already advanced in the development of the device,

- re-use of outdated and not maintained requirements and lacking inputs of key stakeholder

When reviewing an already-developed system, we must re-integrate key Systems Engineering steps to recover structure, traceability, and stakeholder alignment.



Disclaimer

As SE practitioners we had to navigate this environment and organize the available information.
One of the tasks is to *highlight emergent system properties*

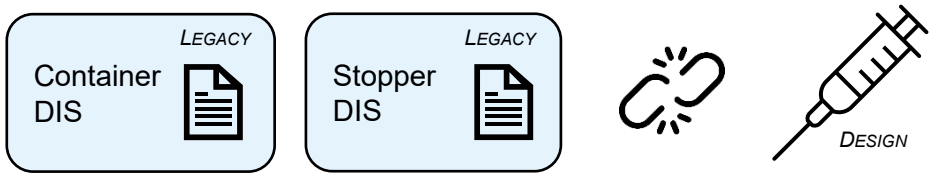
The constraints

The system shall make re-use of legacy components

- Legacy documentation available, but not following systems engineering practice and missing traceability

A design was already established for the product

- … but requirements were not solid, lacking proper traceability and sometimes not being correlated to Stakeholder' needs
- … key functional requirements were vague / open, or being phrased with unrealistic quantitative formulation



Approach

Legacy documentation was treated as constraint requirements tied to a key stakeholder need:

➢ Enable new functions with minimal disruption and leverage existing know-how

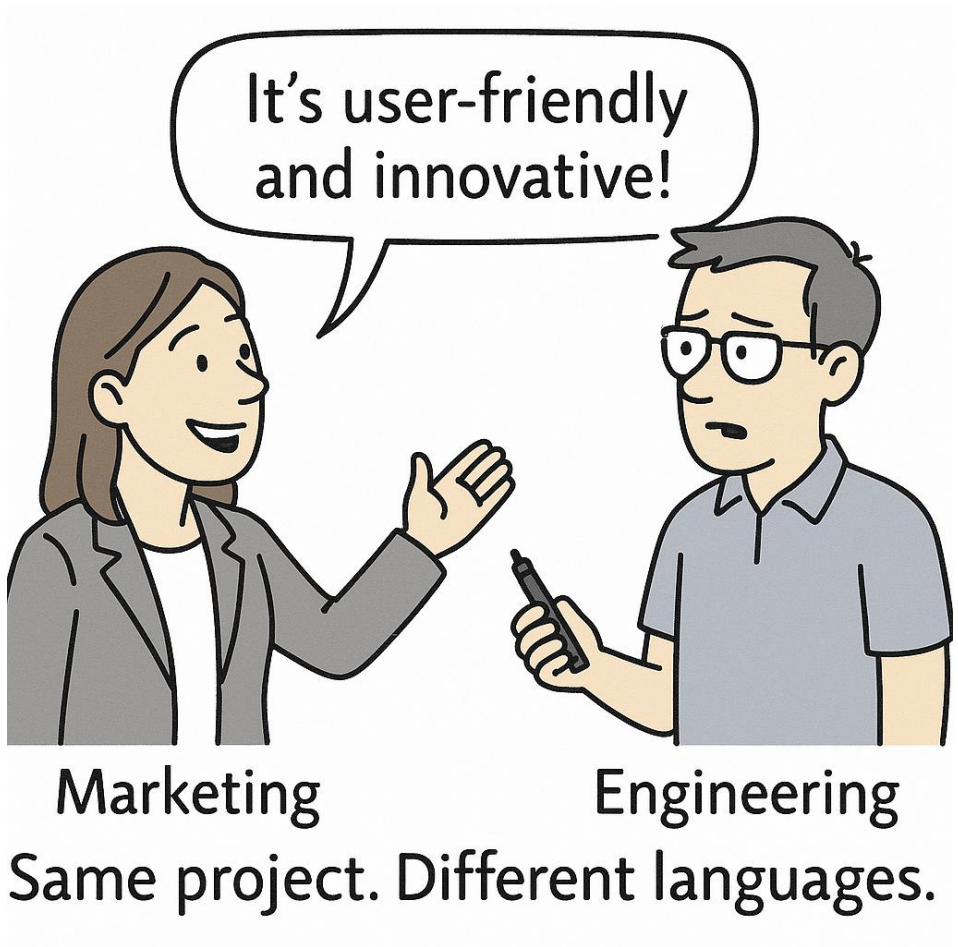
We re-examined the design rationale, mapping Users and Stakeholders needs

This process uncovered requirement conflicts impacting the design

➢ The team was struggling to strike the right balance

*DIS: Design Input Specification

Recognizing gaps between business direction and technical execution



Challenge

The Client struggled to identify Users' and Stakeholders' Need, especially in a B2B context where their role is upstream in the autoinjector supply chain

Problem

Vague strategy left engineering teams to guess the intent, resulting in misalignment and sub-optimal design choices

Our Role as Systems Engineers

We took leadership in

- Eliciting Users' and Stakeholders' Needs
- Translating them into actionable System Requirements

Key question

How do we connect technical design with real user needs across the value chain?

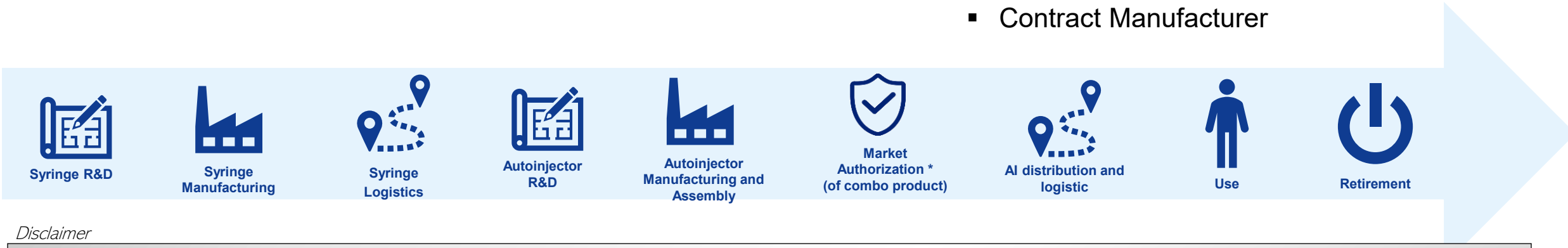
List of Stakeholders

Intended Users

- Patient
- Caregiver
- HCPs / Nurse

Other Stakeholders

- *Our clients' Offices / Departments*
- Pharma companies
- Prescriber / Doctor
- Distributors
- Regulatory Agencies
- Raw Material Suppliers
- Mold maker
- Contract Manufacturer



Disclaimer

➢ Be precise in Stakeholder identification

Stakeholders must be clearly identified and actively involved in requirements elicitation.
(A generic list is shown here to preserve confidentiality.)

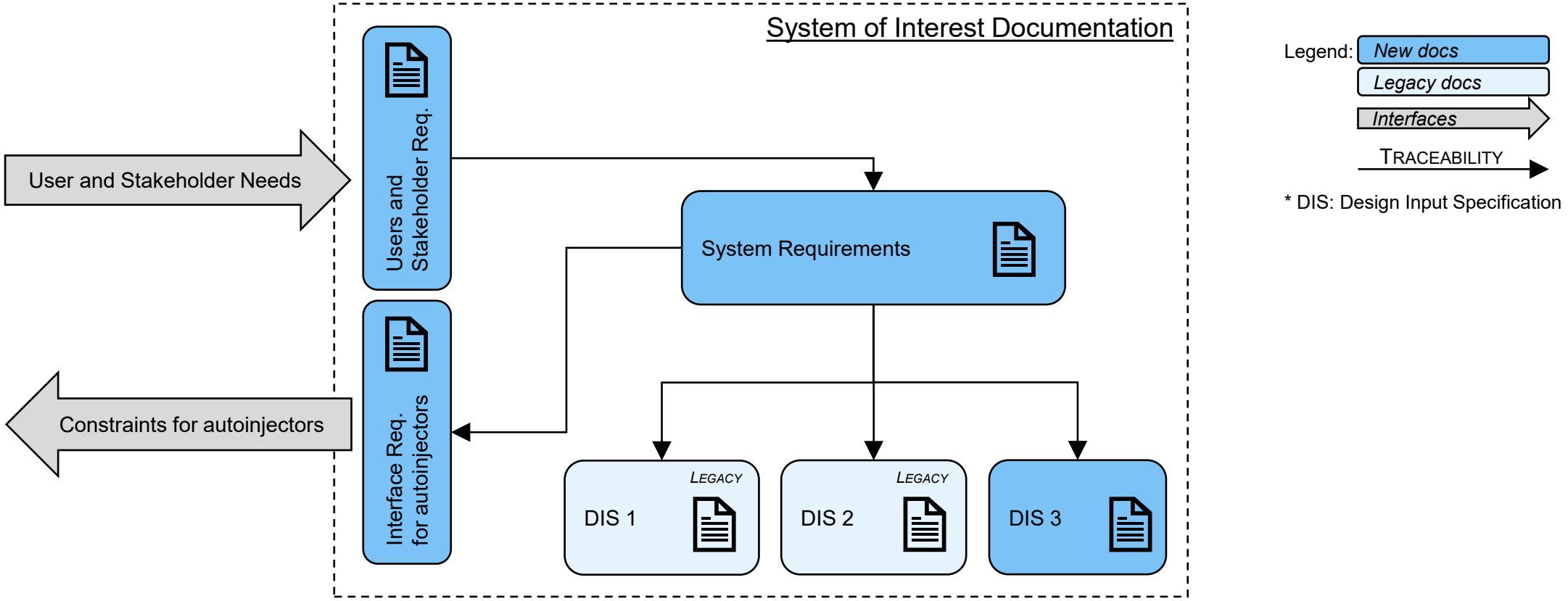
➢ Consider the different stages in the product lifecycle

➢ Plan for late-stage contributors

For entities recognized but not yet known (e.g., subsystem manufacturers),
ensure the process allows their integration later — when refining requirements based on their input.

Tailoring the requirement documentation to our Client's specific issue

Elicitation of dedicated interfaces with the elicited Stakeholders



Disclaimer

To simplify documentation, User and Stakeholder Requirements were consolidated into a single document.
⚠️ Best practice: Keep them separate — User Requirements are key for clinical validation.
👉 In this project, since the client is not accountable for clinical validation, merging was deemed acceptable.

Elicitation of User and Stakeholder Requirements

Methodology

We proposed our Client a step-by-step approach to identify User Requirements, and to select those for which they have a clear contribution or expectation.

The process

- Stakeholder interaction and prioritization
- Mitigation for critical Stakeholder links

- When the client could have an impact or be the driver

- For steps including end-users

- For manufacturing and assembly steps

The Tools

Stakeholder map, Stakeholder matrix	Why / How diagram	Archetypes Users Flow	Elicitation of process diagrams	FAST Context Diagram

Lessons Learned

The structured process helped the client unravel complexity and align perspectives — while enabling us to quickly climb the learning curve.

(*) Here processes analysis had to be included at high-level as the client intend was to develop a sub-system for integration in autoinjectors

Elicitation of User and Stakeholder Requirements

What to aim for?

Validation planning is the key for success

- In a medical environment, Clinical Validation is an essential activity, ensuring that the product can support end-users
  - Keep focus on relevant claims, as Validation is expensive and long
  - *Define the target of clinical validation investigation, and to shape User Requirements accordingly*

- Validation of Stakeholder requirements and Clinical Validation shall be kept separate,
  - a mix of the 2 can impact Clinical Validation studies and Approval as Medical Device

Lessons Learned

When not placing the device on the market, focus clinical validation on critical functions where responsibility remains.

Definition of System of Interest

From a product point of view, the natural choice would have been to focus on the autoinjector (AI) as a SOI, but:

- Our client is developing a part of the solution, a pre-fillable syringe, and the AI as SOI would not fit the Problem statement

The identified the SOI with the ensemble of parts produced by the client:

- Although this sub-system has no obvious emergent use-function, it can be isolated and elicit key-interfaces,
- The SOI shall support multiple AIs leading to emergent features.

Lessons Learned

The emergent properties are not always about User support.

They can come from other Stakeholders requirements, as in this case Marketing.

Systems Engineering is the art of supporting Stakeholder Needs. In this case, the main Stakeholders are the Pharma company/AI manufacturer, as they have a clear connection with our client.

Elicitation of System Features (Functions, Qualities and Constraints)

Methodology

We analyzed the following scenario to identify System Features (Function, Qualities and Constraints)

- User Scenarios: the injection processes and related environmental analysis,
  - According to relevant regulatory documentation (*)
- Autoinjector processes
  - Drug filling steps at the Ai manufacturer, including the stoppering process and their impact on system design
  - Analysis of the autoinjector assembly, with identification of physical interface being used
- Logistic and storage steps
  - Analysis of transport and storage conditions, environmental condition change (temperature and pressure)

Lessons Learned

Once the lifecycle stage is identified, it is not trivial to access the proper information.
In this case, it was difficult to access specialist at the autoinjector manufacturer,
but thanks to the Stakeholder analysis the supplier of the drug filling lines emerged as alternative source of data.

(*) Appendix C of Essential Drug Delivery Outputs for Devices Intended to Deliver Drugs and Biological Products Guidance for Industry

Elicitation of System Requirements

Methodology

Helbling organized elicitation of System Requirements with a series of workshops

- Function and Process analysis
- Elicitation of Regulatory Requirements
- Analysis of User and Stakeholder Requirements and Translation in System Requirements
- Reverse Traceability matrix, to check whether a System Requirement was influenced by multiple User and Stakeholder Needs
- Highlight conflicts among requirements

Lessons Learned

It was beneficial to identify a set of key-requirements,
this gave us opportunity to build a consistent and clear framework focusing on the core features.

It was also important to frame regulatory-requirements at the right abstraction level,
to not be overwhelmed by the regulatory and standards.

Gap-analysis for Legacy sub-systems documentation

At the end of requirement elicitation process, we traced how much of the legacy documentation could be properly traced

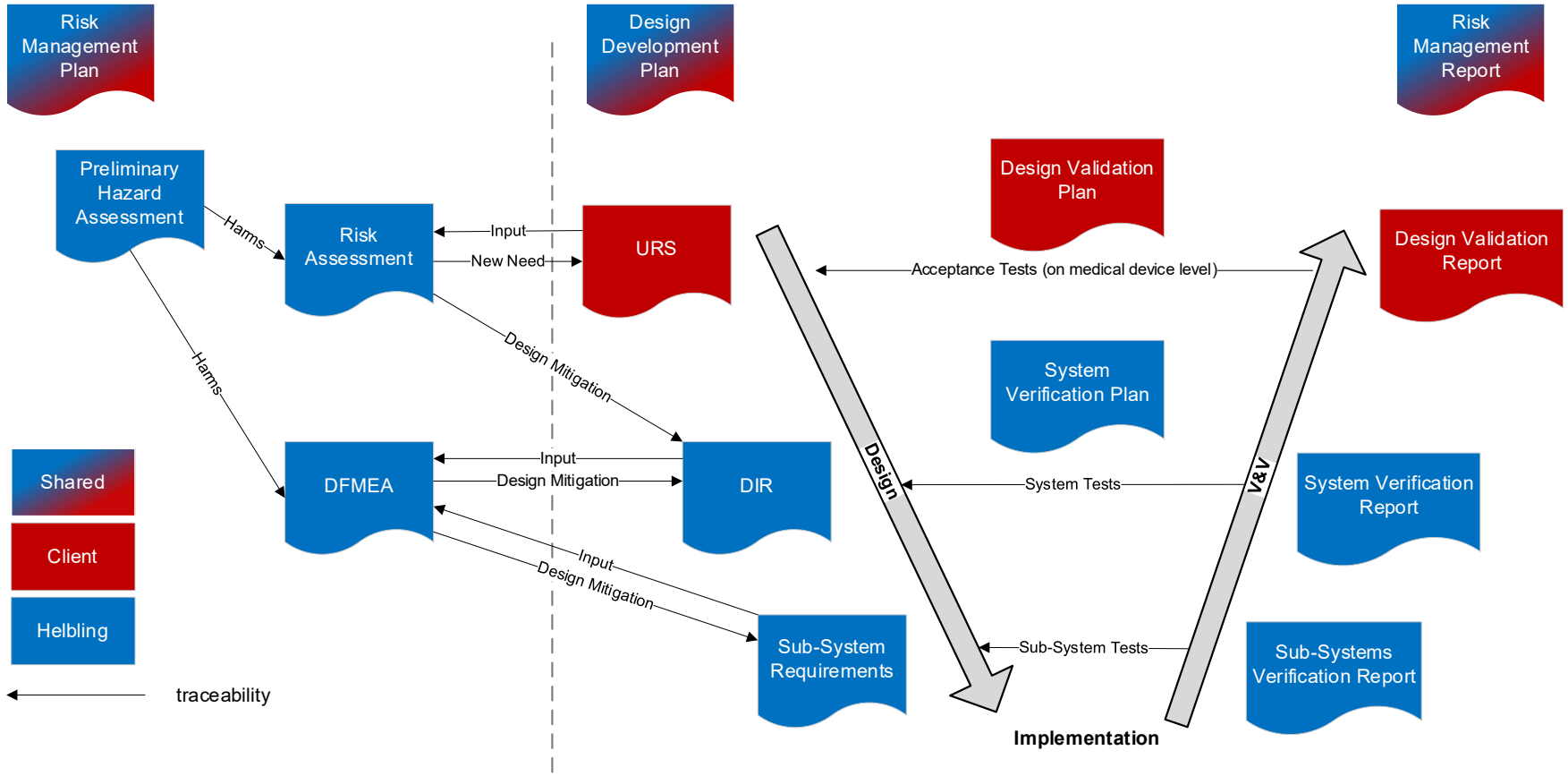
- This revealed to be a powerful tool to promote deeper revision of the legacy documentation
- Suggested approach:
  - use the legacy documentation as master, but picking up only applicable content
  - Generate a variant from the master, by selecting only those applicable requirements

Integration of Risk Assessment

Issue:
Risk Management outputs were not integrated into traceability, leading to fragmented mitigations and a weakened strategy.

Client Challenge:
Risk scope was extended beyond boundaries, introducing unknowns and inflating risk ratings unnecessarily.

Integration of Risk Management with V-model



Lessons Learned

- Establish traceability with Risk Management
- Design clear test procedure covering for Risk Management as they will populate the Risk Management Report
- Constrain the Risk Management to the scope of the service

Main takeaways

Reverse SE as a Tool:
While not ideal, Reverse Systems Engineering demonstrates how SE practices can be implemented to identify gaps and issues in ongoing projects, bringing structure and traceability even when catching up.

Stakeholders are Key:
Clearly identify and actively involve stakeholders to bridge the communication gap between business vision and technical execution.

Focus on Core Needs:
Translate user and stakeholder needs into actionable system requirements, tailoring documentation to your client's specific context.

Define and Constrain:
Precisely define your System of Interest and constrain risk management to relevant boundaries to avoid unnecessary complexity and inflated risk assessments.

Proactive Validation:
Plan for validation at early stage, focusing on critical features and functions to ensure product success and a streamlined approval process.

Thank you

Let’s stay connected

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