# Empowering *Medical Device* Start-Ups and Corporate through *Lightweight Systems Engineering*

SwissED 2024: Building Bridges

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# Helbling Group – Innovating a sustainable future

**We develop innovative products and enhance our clients' overall competitiveness.**

## Helbling Technik

We develop technologically sophisticated products and bring innovation to life – a matter of heart, soul and actions.

## Helbling Business Advisors

We develop and implement sustainable solutions that enhance clients' long-term competitiveness.

## Helbling Beratung + Bauplanung

We bring complex real estate, industrial and infrastructure projects to a successful conclusion.

## Helbling PLM Solutions

We create IT solutions that enable cross-functional collaboration with organizations.

# The dilemma in Medical Device Development

## A constant demand for increasing innovation challenged by a tougher regulatory path towards market approval

FDA

EU -MDR

*QMS*

International Organization for Standardization ISO 13485 Quality Management System

*Risk Management*

International Organization for Standardization ISO 14971 Risk Management

*Environmental Management*

International Organization for Standardization ISO 14001:2015


*Mechanical and Electrical safety*

IEC 60601 COMPLIANT

*Clinical Investigation*

INTERNATIONAL STANDARD ISO 14155

Clinical investigation of medical devices for human subjects — Good clinical practice

*Biocompatibility*

ISO 10993

*Usability*

ISO

ICS › 11 › 11.040 › 11.040.01

IEC 62304:2006

Medical device software

*Active Implants*

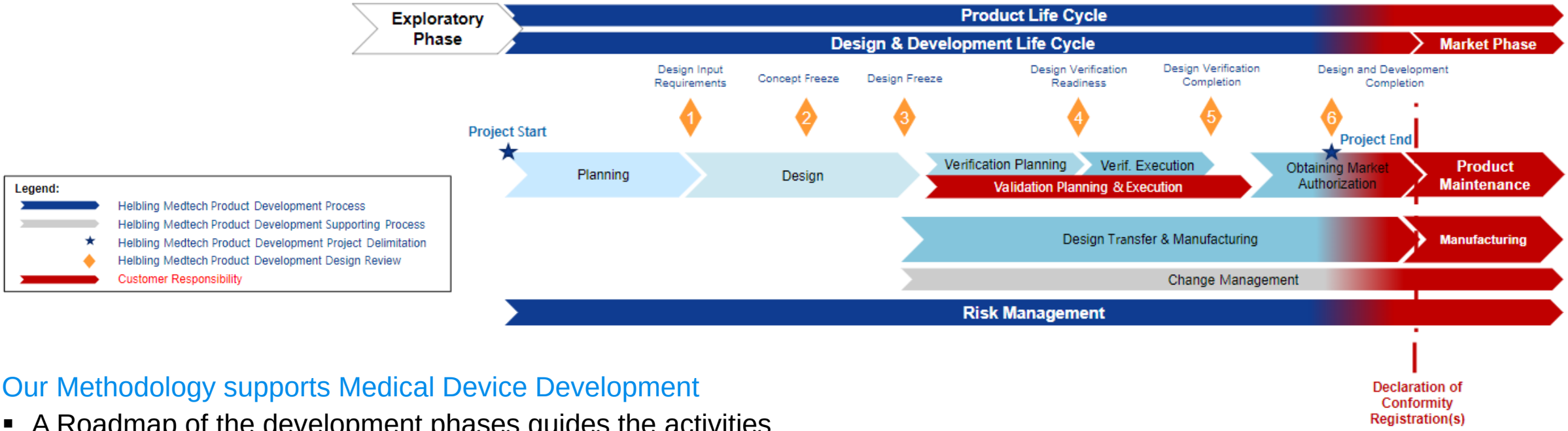
INTERNATIONAL STANDARD ISO 14708-1

Implants for surgery — Active implantable medical devices —

*AI generated picture: A futuristic implantable medical device (in LEGO style)*

# The Medical Device Development

## An established QMS according to ISO 13485




## Our Methodology supports Medical Device Development

- A Roadmap of the development phases guides the activities
- Clear borders in between customers and Helbling responsibilities
- Regular Milestones review guiding Design Control

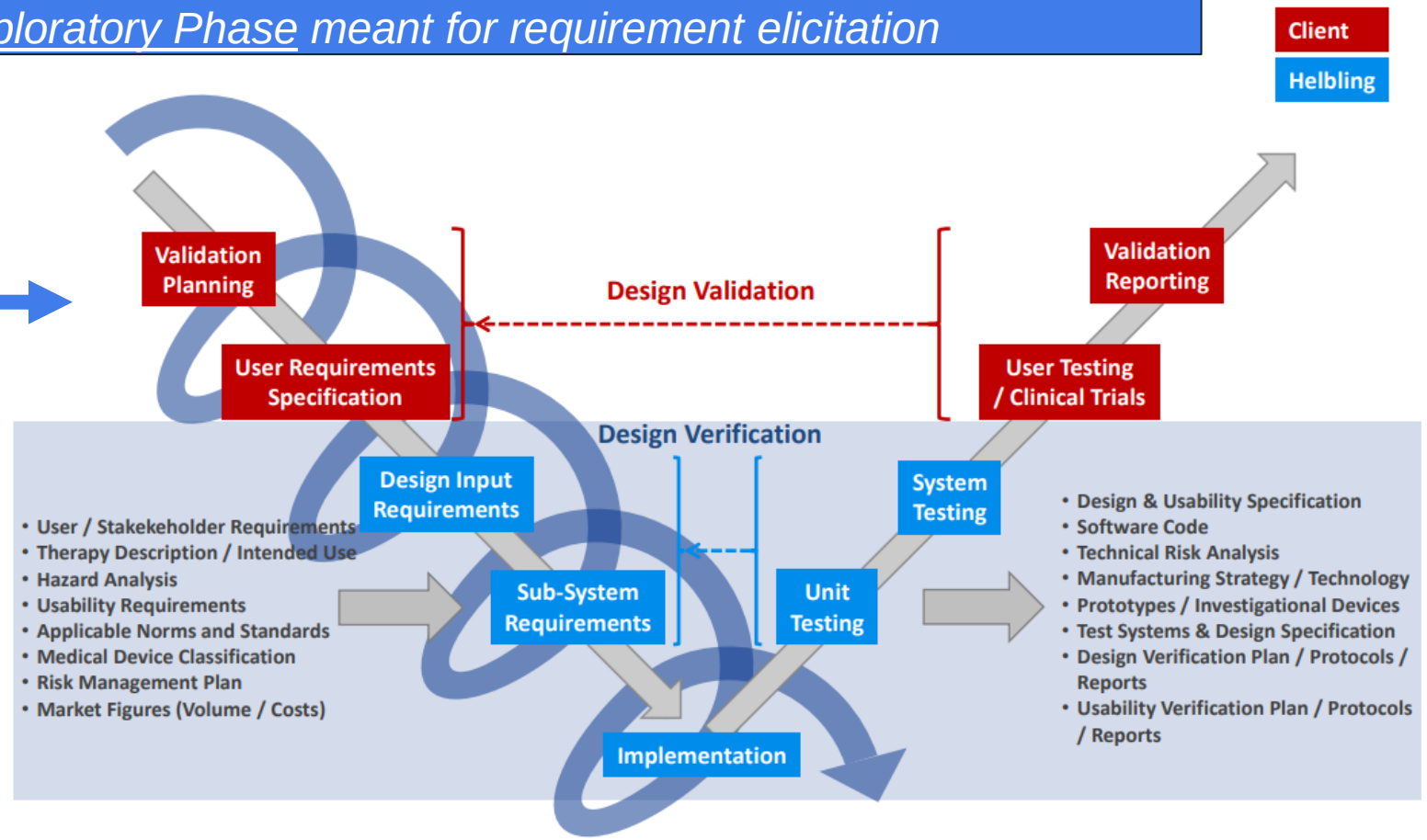
## This can be applied as skeleton for the customer QMS

# The V-Model

## The typical Systems Engineering approach when supporting development steps

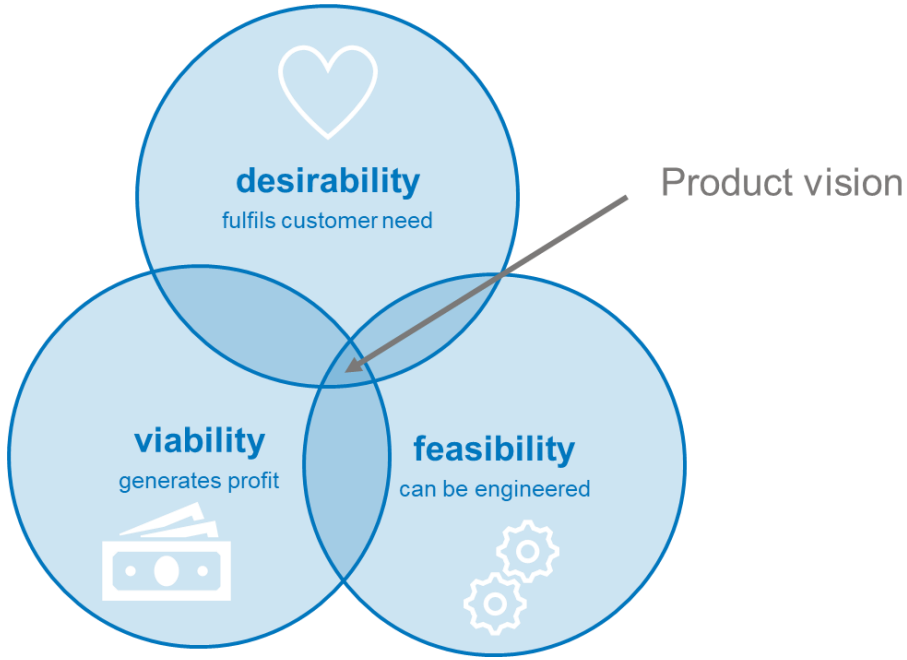
*A usual challenge is that customers is not able specify the User Requirements at the Project starts. Helbling support this an Exploratory Phase meant for requirement elicitation*

*Lightweight Systems Engineering approach*



# The development methodology at Helbling

## Exploratory Phase: the Lightweight support at project starts




### Exploratory Phase prepares Medical Device Development for Design Control

### Main objectives is Elicitation of Product Vision by

- drafting User Requirement Specification (client responsibility)
- drafting Design Input Requirements (Helbling responsibility)

### Scope of the Exploratory Phase can include support for

- Intended Use, Use Specification, User Requirement Specification
- Draft of the Hazards
- Developing Proof-of-principle and Proof-of-concepts prototypes
  - Functional and non-functional prototypes design and build
  - Feasibility studies: in vitro, ex vivo, in vivo

### Align on the scope of the project before embarking the journey of detailing documentation for submission to FDA / MDR

# Exploratory Phases

## Systems Engineering role in Exploratory phase

### Exploratory Phases serve the project that are in research state, not yet mature to transition to Design Control

The approach at Helbling is to clarify System Architecture and main Functional and Performance requirements by investigating main functions, performances and risks with prototypes

### Progressing within the Exploratory Phase the complexity increases, as the maturity of Product Development

### The typical path of Exploratory Phases at Helbling involves

**Ideation Workshops**

- Usability analysis
- Problem space investigation
- Solution space investigation
- Concept selection

**Proof-of-Principle investigation**

- Identification of most prominent risks
- Feasibility analysis
- Test of critical function and performance in early prototype

**Proof-of-Concept investigation**

- Test of full functionalities
- Addressing critical sub-systems implementation

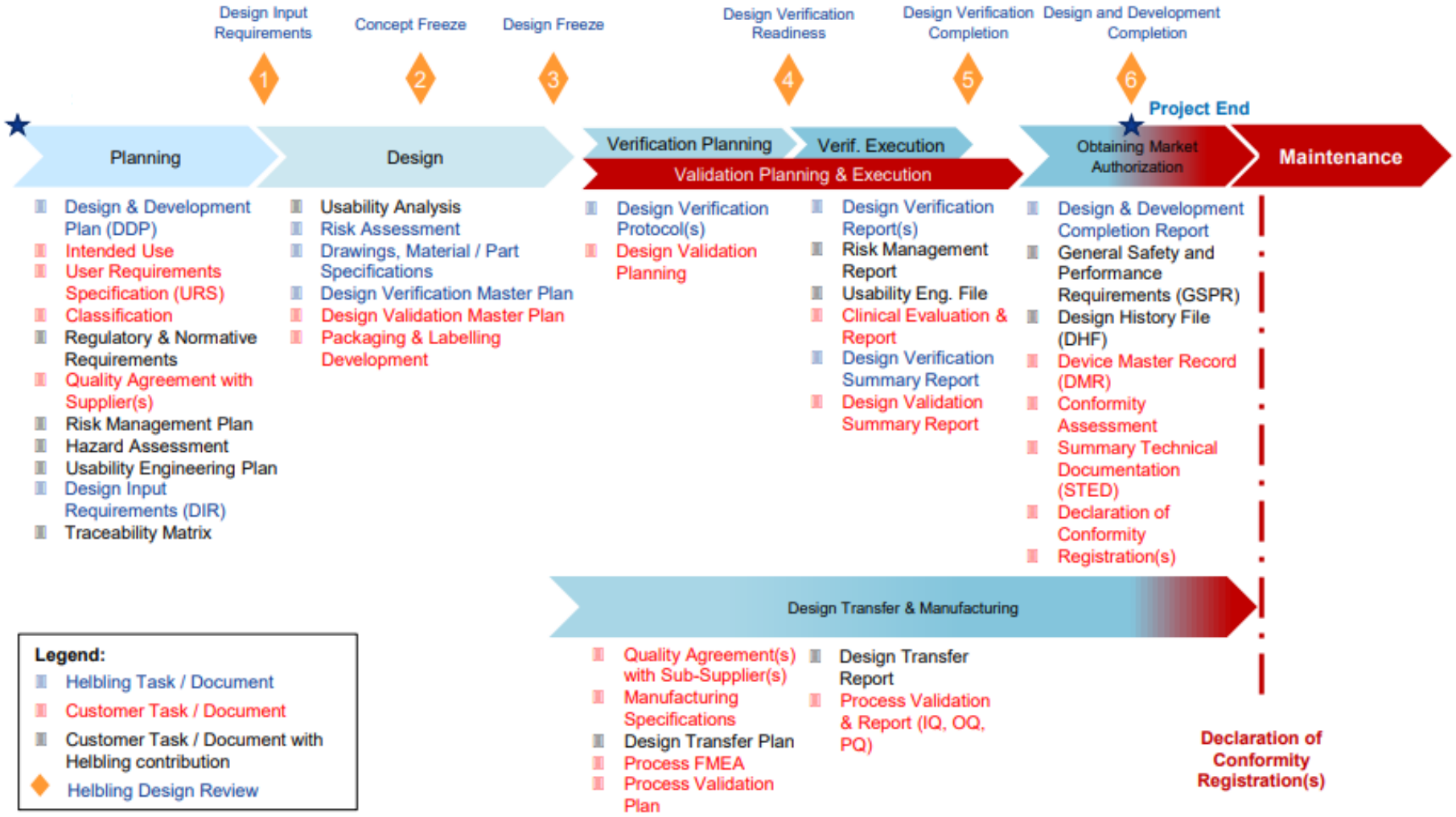
**Engineering Prototype**

- Testing performance
- Preparing Design Input Requirements

Maturity of System Requirements and Architecture evolves in the Exploratory Phase, Thanks to hands-on experience

# The Design Control at Helbling

## Support of the Design and Development lifecycle, covering the needed technical documentation for Market Approval



# Helbling MedTech Development Process

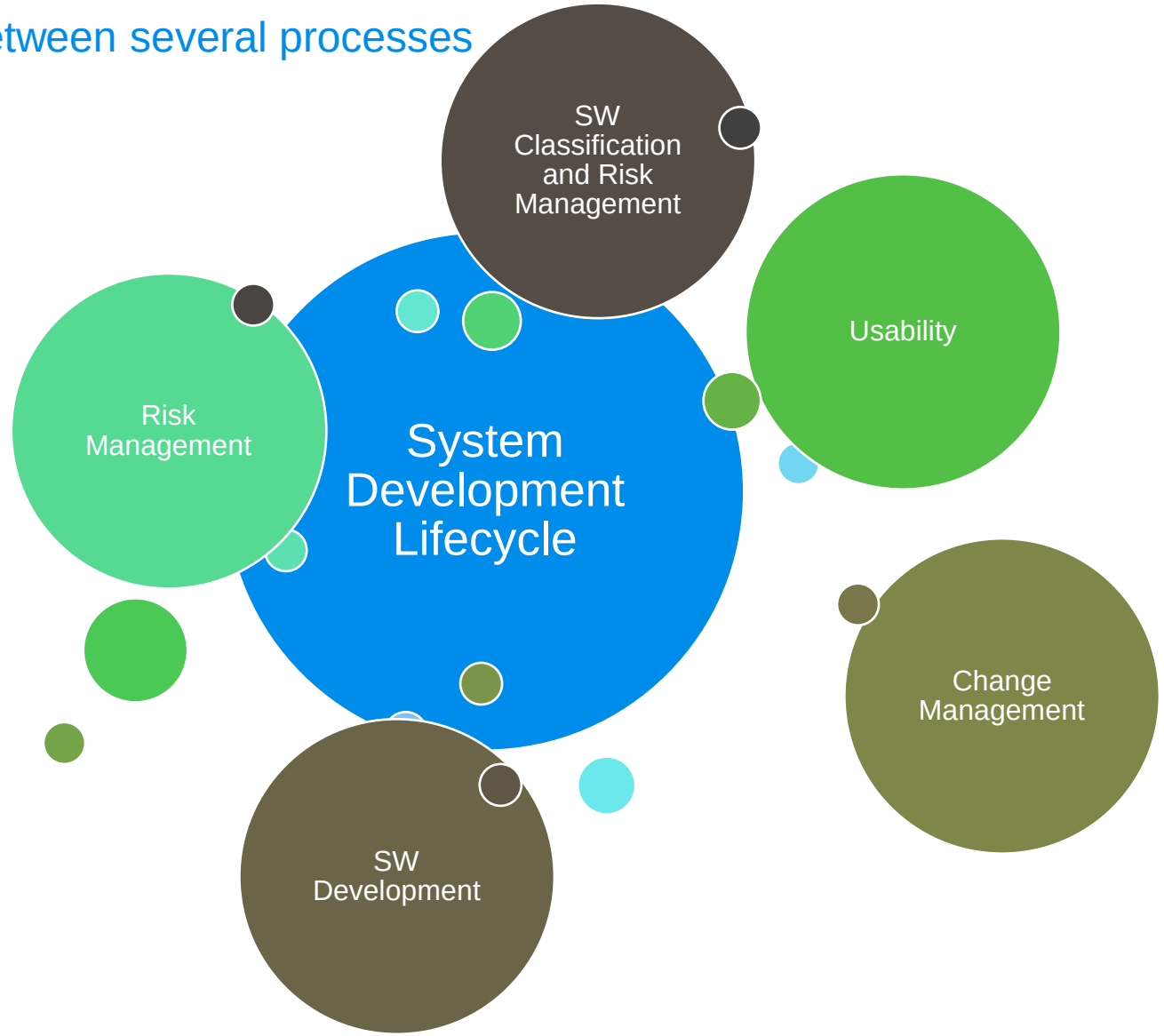
## System development is a link between several processes

ISO 13485 — Medical Device Development

ISO 14971 — Risk Management

IEC 62366 — Usability

IEC 62304 — SW development



# Inputs required for Medical Equipment Accreditation

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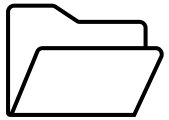
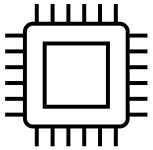
### Risk Management File



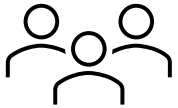
- *Risk Management Plan*
- *Risk Analysis*

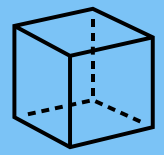
### Design Input

### Critical components data



### Usability File

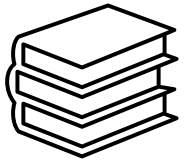




Medical Equipment

### Test documentation

### Accompanying Documents



- *Instruction for use (IFU) §7.9.2)*
- *Technical Description §7.9.3*

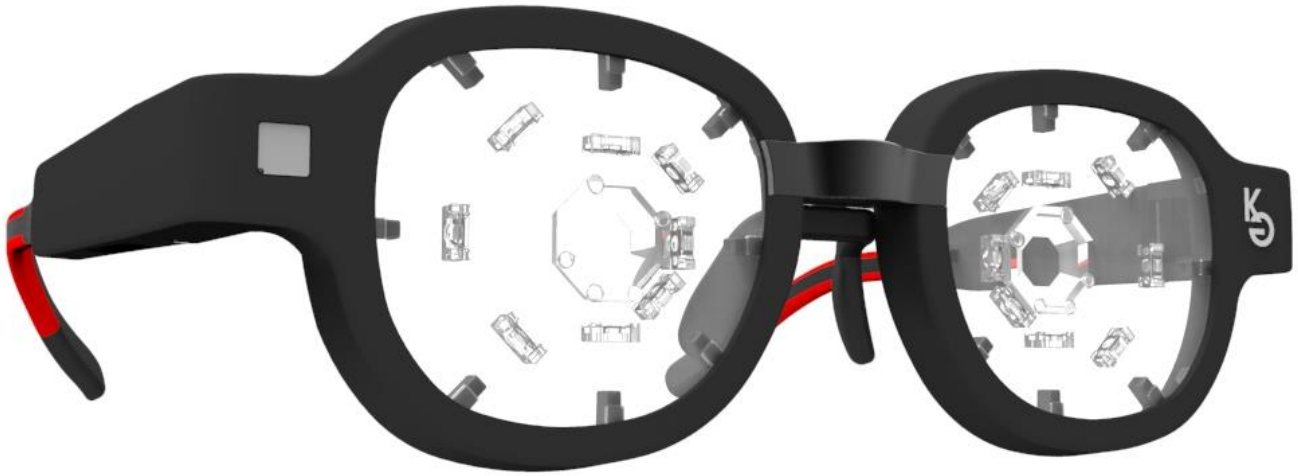
### Labelling (Marking)

### SW documentation

# Example: Electronic Spectacles for Treatment of Eye Diseases

## Prevention of myopia progression in children

Kubota Vision **demonstrated** during first clinical studies **a decrease of the axial length** of the eye with the application of **projected myopically-defocused images**



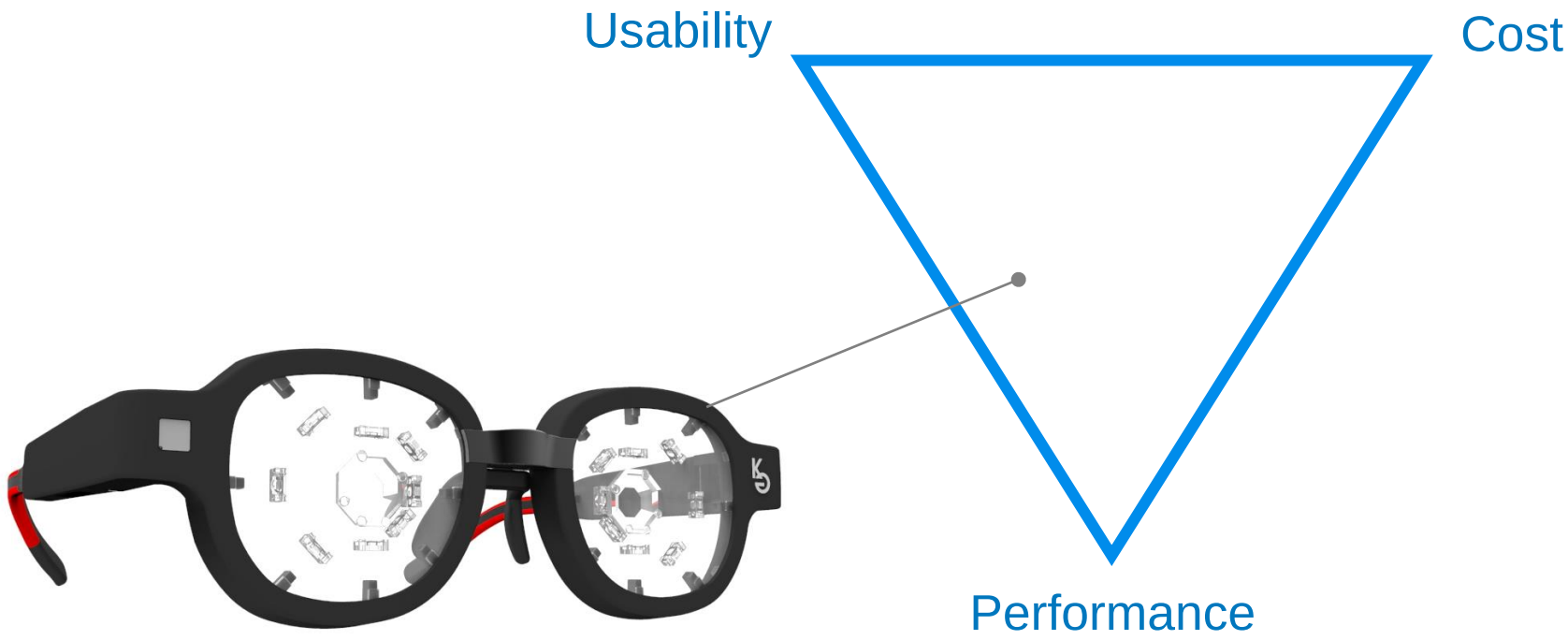
Generation of an active visual stimulus pattern with lens-induced defocus

# Helbling development methodology

## Define development priorities

*The task*

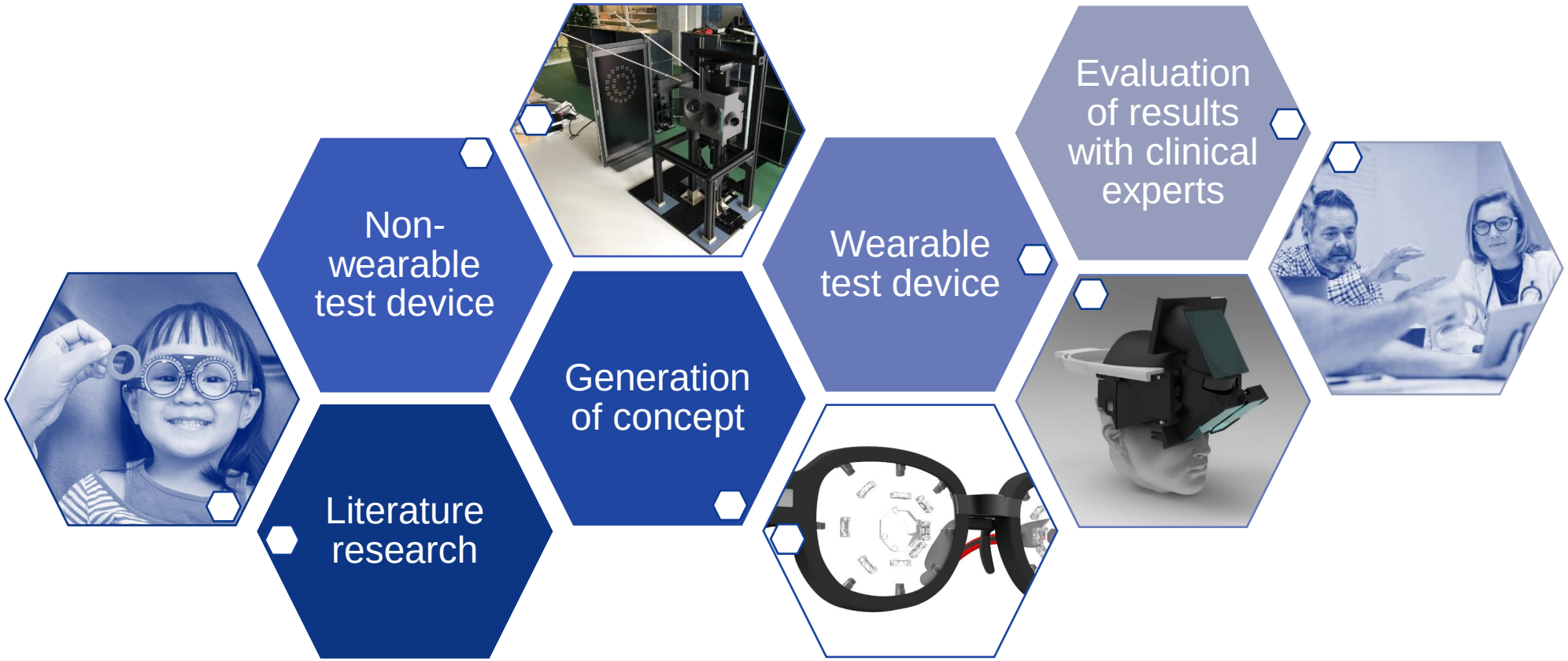
Helbling shall bring the vision of an innovative product following the principle of myopically-defocused images to reality with focus on performance and usability.



# Helbling development methodology (1/2)

## Investigating scientific evidence with clinical studies

Demonstrating feasibility of the approach was a key-factor.
Helbling supported early prototype demonstrator to be used in clinical validation




Contribution to clinical studies demonstrating a sustainable, physiological effect with regard to reduction in myopia [1]
developing and realising test devices to proof treatment efficacy of active lens-induced myopic defocus based on augmented reality principle

[1] Biometric and refractive changes following the monocular application of peripheral myopic defocus using a novel augmented-reality optical system in adults | Scientific Reports (nature.com)

# Helbling development methodology (2/2)

## Complete development from Ideation to Design Transfer

Once clinical validation was executed, Helbling supported the project throughout the entire development process

# The product is now on the market

https://kubotaglass.com/


KUBOTA GLASS™

Kubota Glass® - an ophthalmic product for the prevention of myopia progression

# Conclusion: a *Systems Engineering* approach added tremendous value to the development project

A *Systems Engineering* approach allows us to

- choose an established platform as carrier
- develop platform optimizing requirements effort and costs
- document rationales for design decisions along the way
- re-use established and tested items as system elements to reduce risks
- develop the system in record time
- verify and test the system in a reproducible and documented way

**→ *Systems Engineering* is the basis for an efficient creation of the technical file according to ISO 13485 for submission to regulatory bodies**