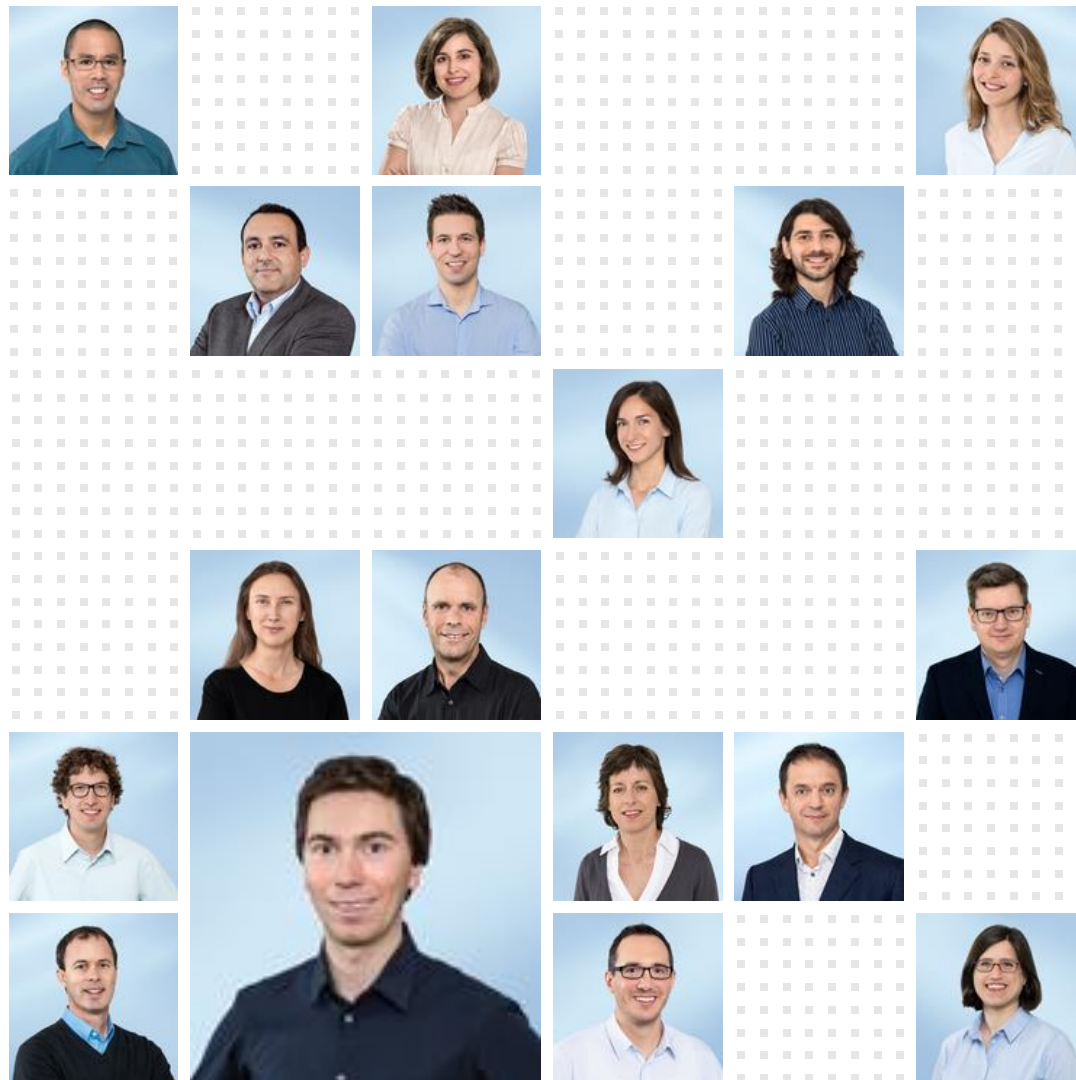# helbling

Systems Engineering for Medical Device Development

Example of an Eye Implant

SAQ Qualicon
QQ-Impuls, 2024-01-25

Dr. Stefan Bauer
Certified Systems Engineering Professional (INCOSE)

Agenda

1. About Helbling

2. Product Vision

3. Systems Engineering

   WHY – HOW – WHAT

4. Discussion

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.
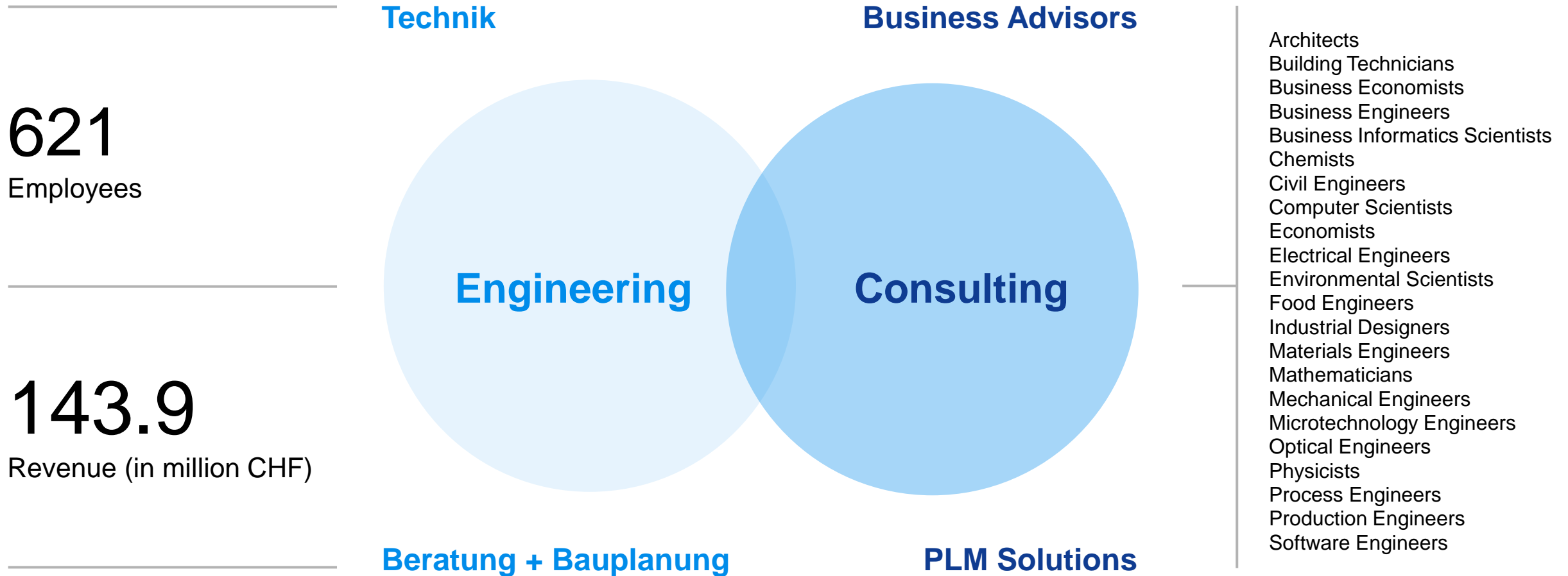
Helbling PLM Solutions

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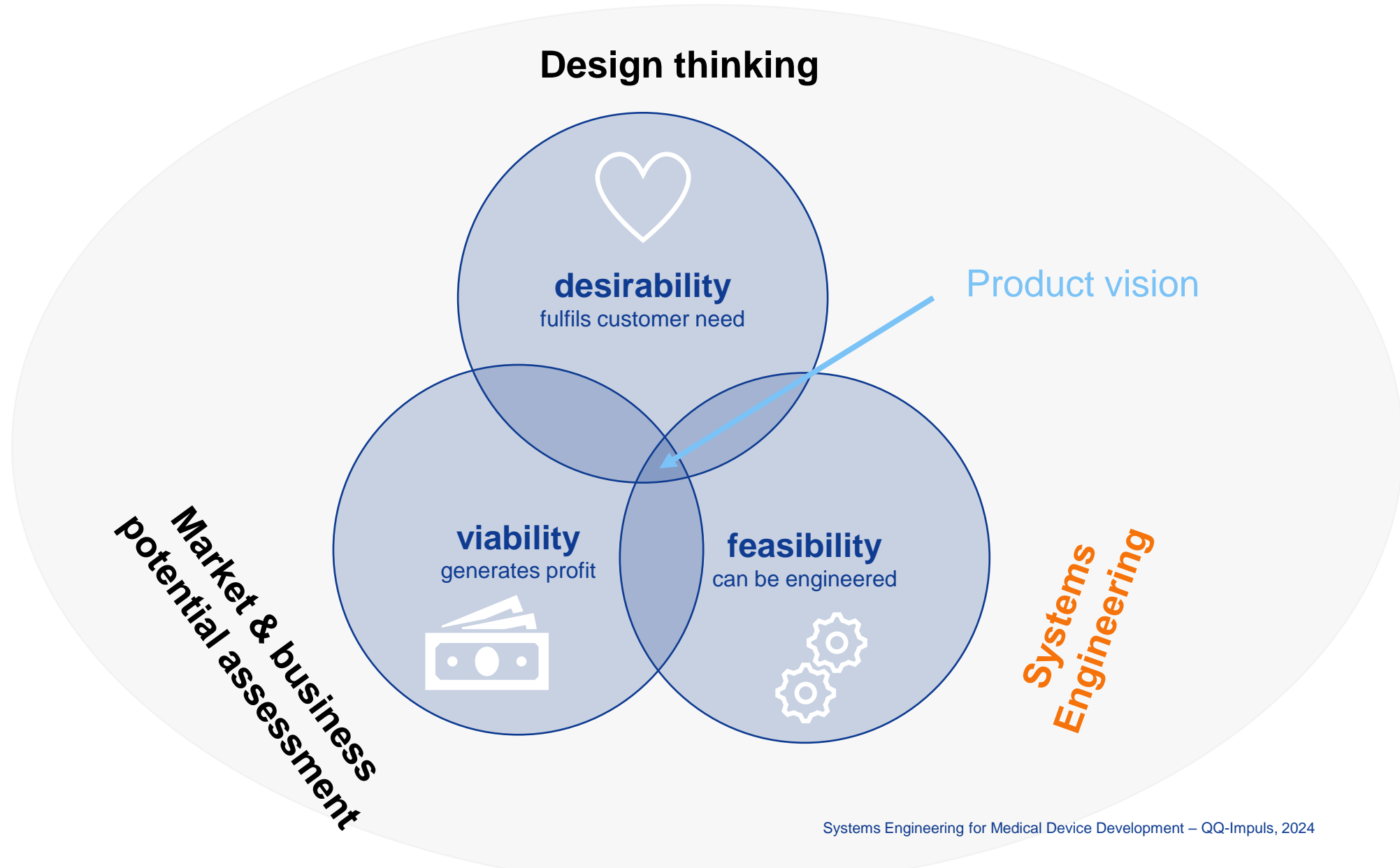
Overview Helbling Group

621
Employees

143.9
Revenue (in million CHF)

Technik

Business Advisors

Engineering

Consulting

Beratung + Bauplanung

PLM Solutions

Architects
Building Technicians
Business Economists
Business Engineers
Business Informatics Scientists
Chemists
Civil Engineers
Computer Scientists
Economists
Electrical Engineers
Environmental Scientists
Food Engineers
Industrial Designers
Materials Engineers
Mathematicians
Mechanical Engineers
Microtechnology Engineers
Optical Engineers
Physicists
Process Engineers
Production Engineers
Software Engineers

Founded 1963 ▪ Headquartered in Zurich ▪ 36 Partners ▪ Professionals from 22 disciplines ▪ Locations in Switzerland, Germany, Poland, the USA and China

A Product Vision has to fulfil 3 main aspects

Design thinking

desirability
fulfils customer need

Product vision

viability
generates profit

feasibility
can be engineered

Market & business
potential assessment
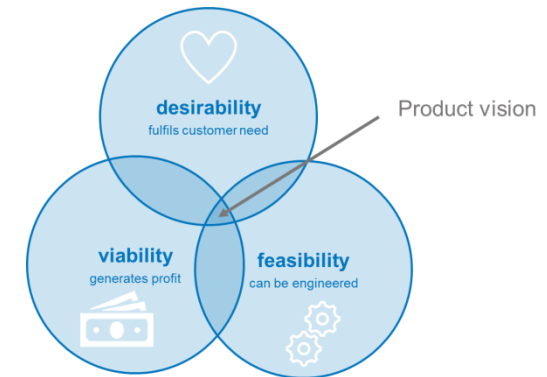
Systems
Engineering
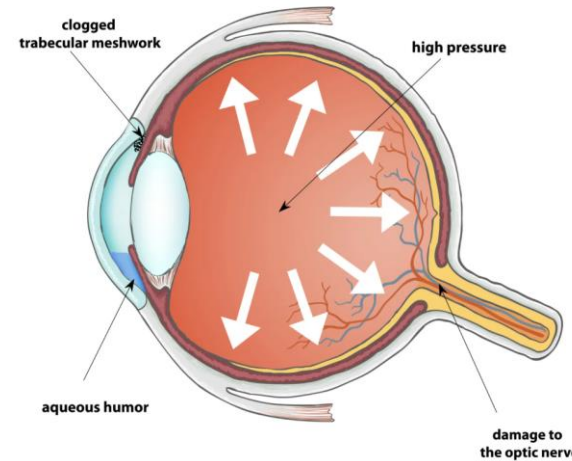
The Challenge
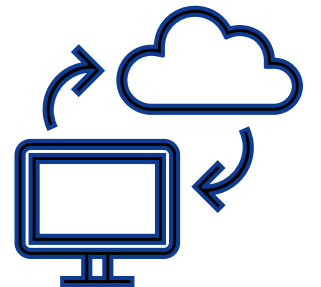from one of our clients

Challenge offered:
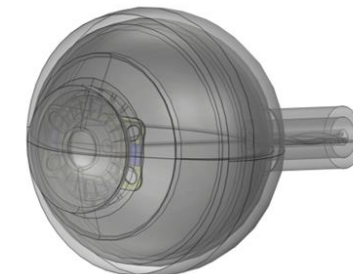
Continuous monitoring for glaucoma patients
Development of a medical device

Challenge accepted:

Development of an implantable intra-ocular pressure
sensor with cloud connectivity for glaucoma patients
using a *Systems Engineering* approach

WHY – HOW – WHAT
of *Systems Engineering*
for Medical Device Development

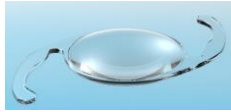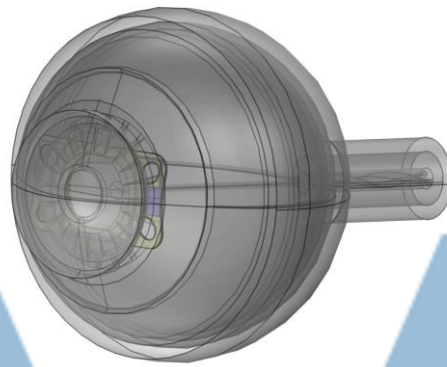# WHY do we need *Systems Engineering*

The tree swing illustration panels:
- How the customer explained it
- How the project leader understood it
- How the engineer designed it
- How the programmer wrote it
- How the sales executive described it
- How the project was documented
- What operations installed
- How the customer was billed
- How the helpdesk supported it
- What the customer really needed

Effort / Time graph:
- The "usual" approach to realize a project
- "Targeted" approach constraining project scope
- Architectural Design / Development
- The "ideal" approach to realize a project

WHAT is *Systems Engineering*

- Is an overarching discipline to **manage complexity** of engineering projects
- Covers the complete product **lifecycle**
- **Manages all (engineering) disciplines**, e.g.,
  - Electrical engineering, mechanical engineering, software engineering, etc.
  - Project management, quality management
- **Ensures that stakeholder needs are satisfied** in a cost-efficient and schedule-compliant way, with high quality
  - **Balancing risks and complexity**
  - Performs **optimization at a holistic level**, instead of optimizing system elements separately

HOW is *Systems Engineering* done

User requirements

System requirements

Architecture definition

Design specification

Implementation
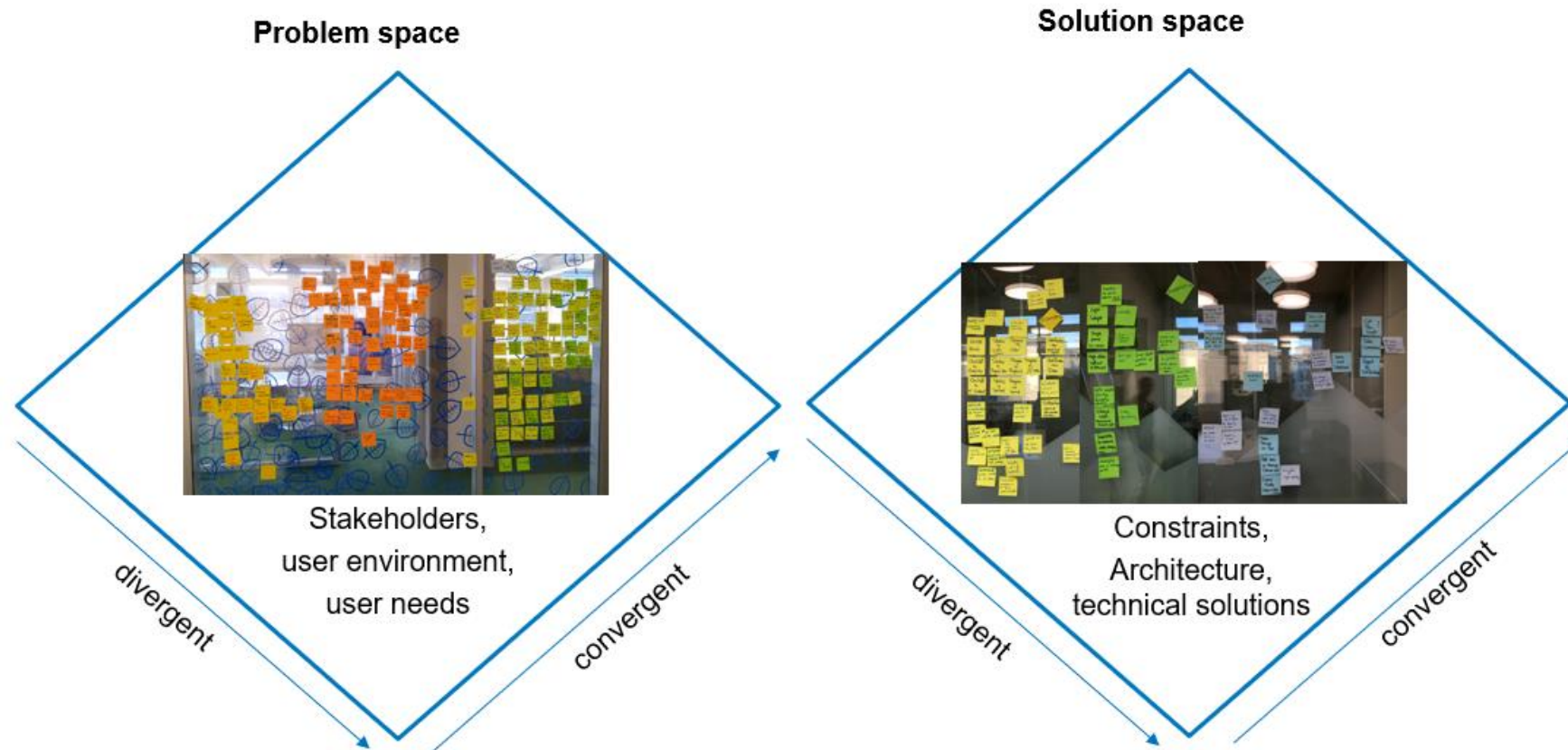
System Validation

Verification

Integration

helbling

HOW is *Systems Engineering* done
Systems Engineering starts with requirements management …
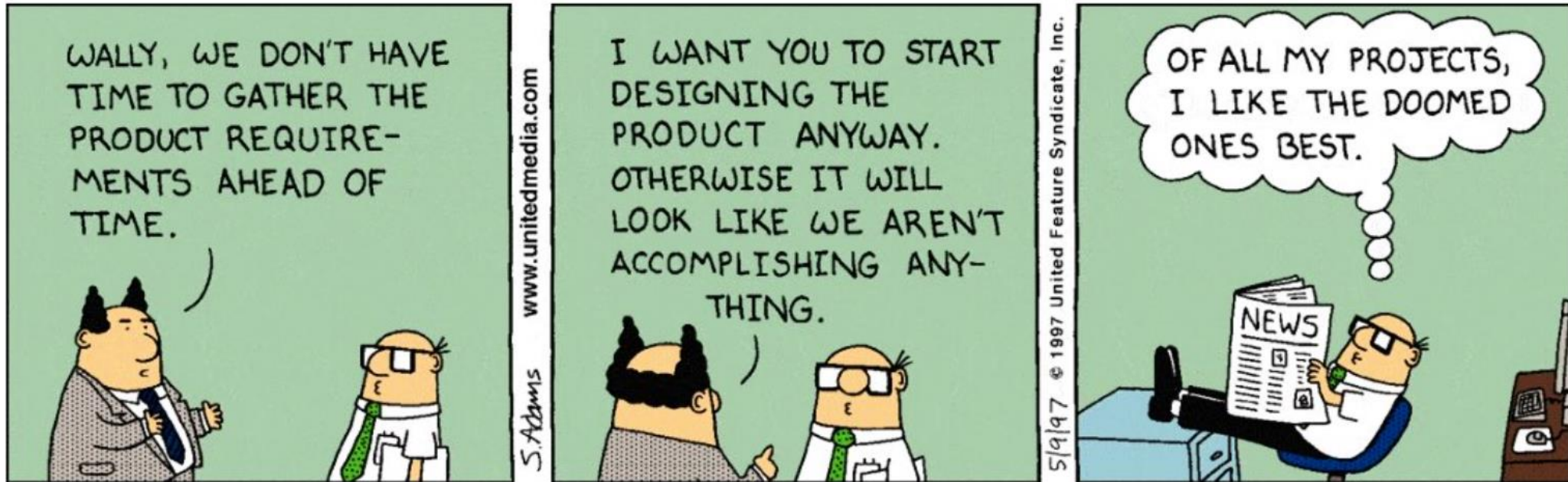
HOW is *Systems Engineering* done
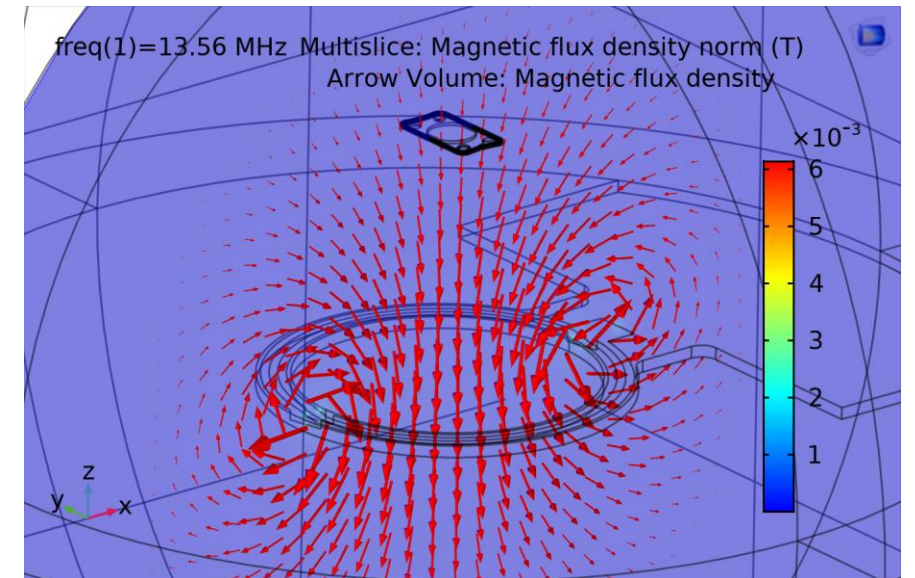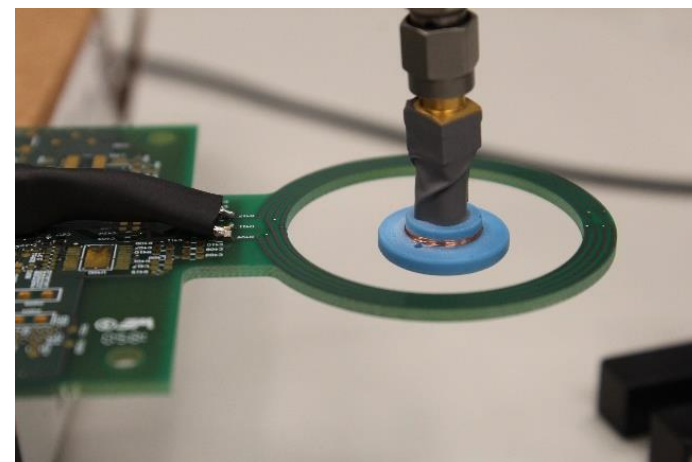… and here we can integrate design thinking aspects for exploring the *design space* …

Problem space

Stakeholders, user environment, user needs

divergent / convergent

Solution space

Constraints, Architecture, technical solutions

divergent / convergent

HOW is *Systems Engineering* done
… and only then comes the engineering implementation …

freq(1)=13.56 MHz Multislice: Magnetic flux density norm (T)
Arrow Volume: Magnetic flux density

HOW is *Systems Engineering* done
 … do not underestimate the testing effort at the end
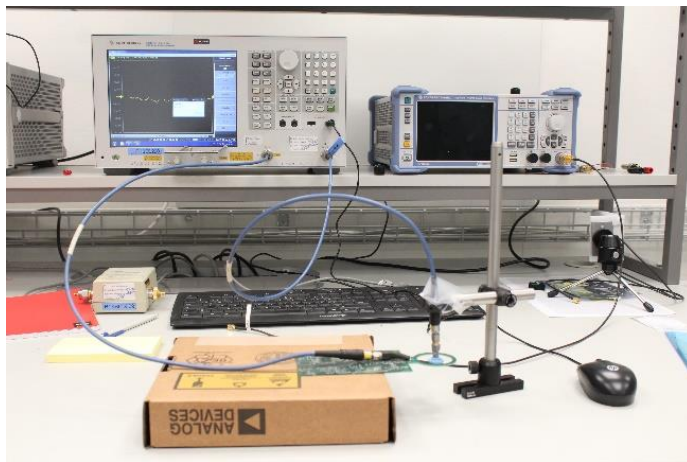
Conclusion: a *Systems Engineering* approach added tremendous value to the development project

A *Systems Engineering* approach allowed us to
- choose an **established platform** as carrier
- develop platform with minimum requirements and therefore **minimum 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**
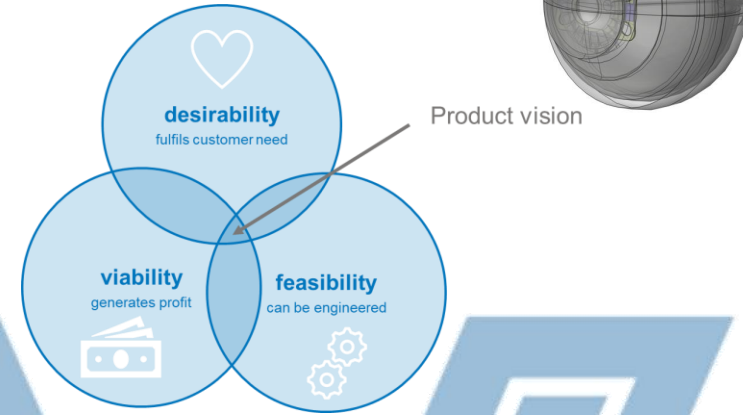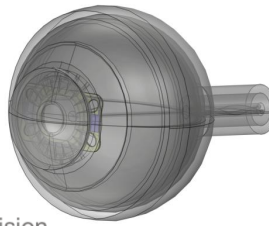
helbling

Innovation,
together
we do it !

Your Contact

Dr. Stefan Bauer
Head of *Sensors & Medical Electronics*
T +41 979 16 63
stefan.bauer@helbling.ch

Helbling Technik Bern AG
Stationsstrasse 12
CH-3097 Liebefeld-Bern
www.helbling.ch