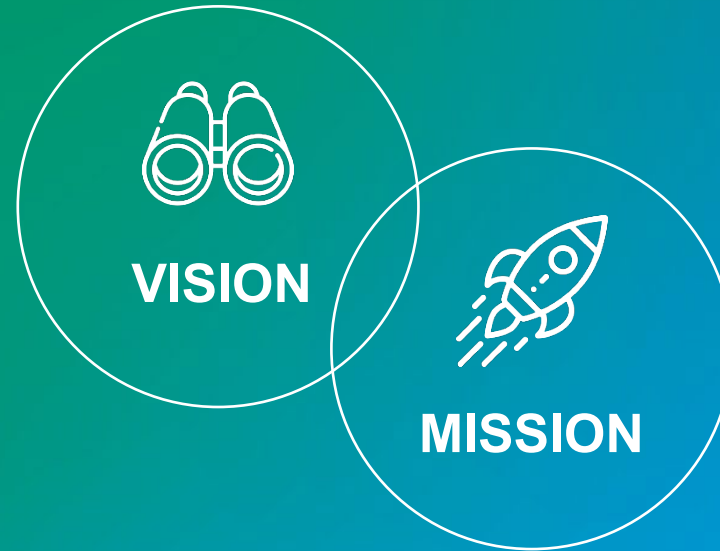




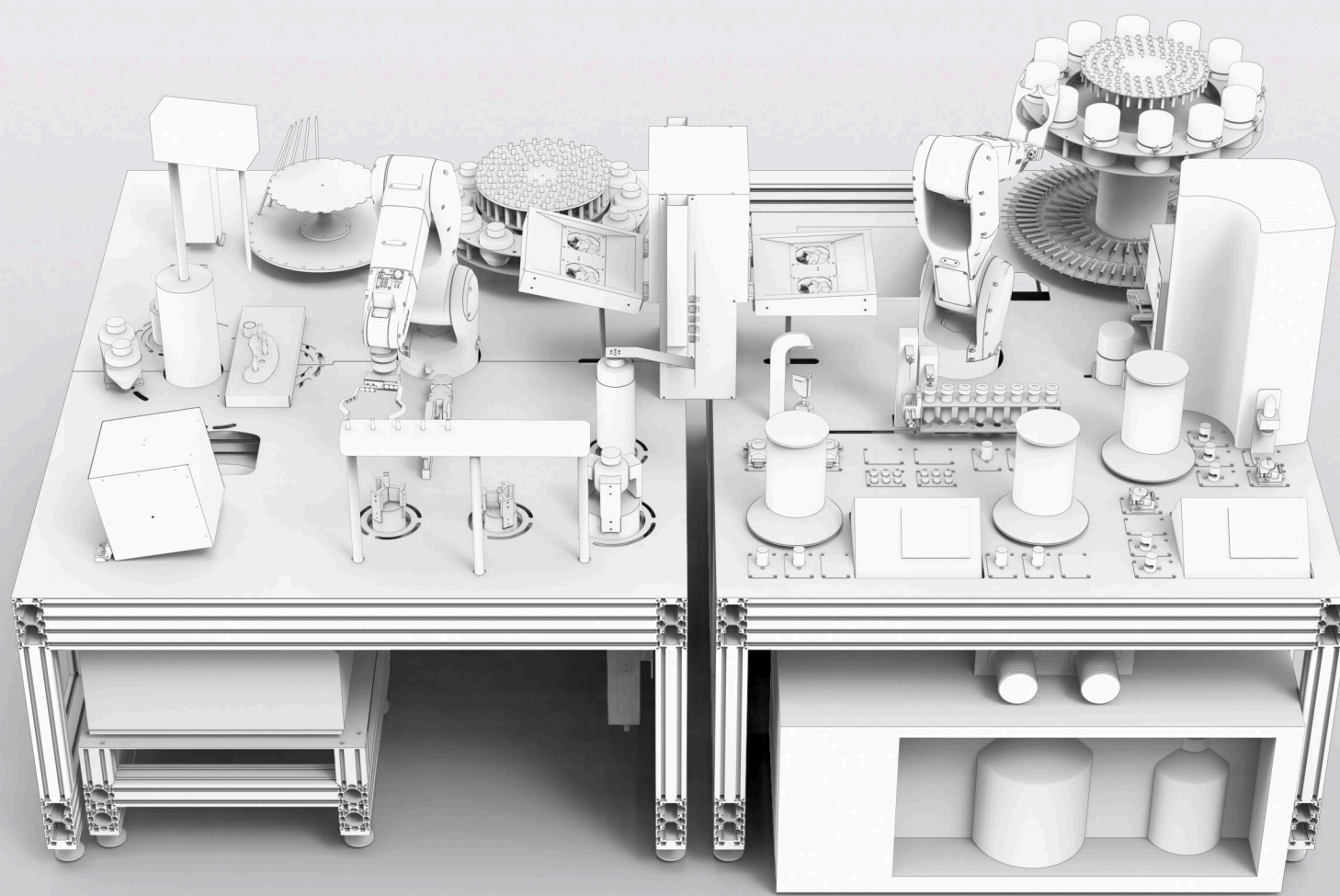
Fraunhofer IPT & Harro Höfliger

From lab-scale to industrial production:
We automate your life science processes

**Transformation of your
manufacturing process for
medical and biological products
from the laboratory to
professional industrial production**



**We support you in the design of
your system, taking into account
product relevant design
requirements and bring your
setting up to industrial standards**

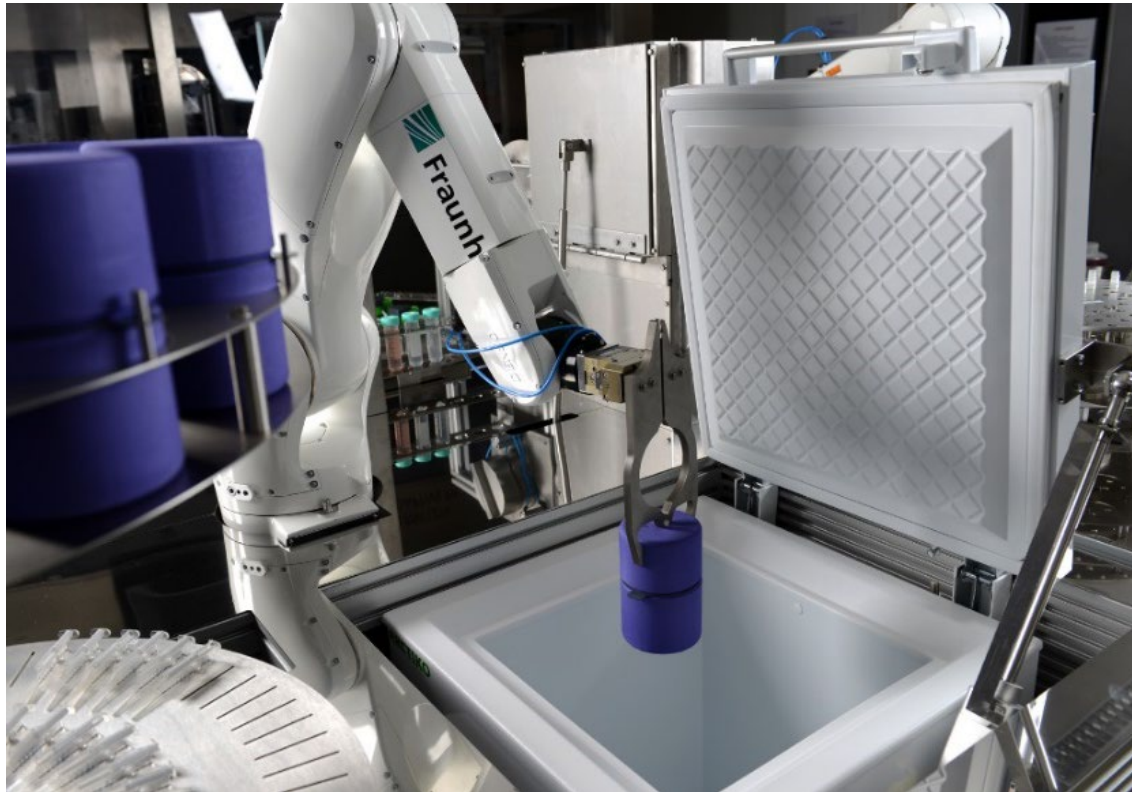


New therapies driven by a fusion of science and industry

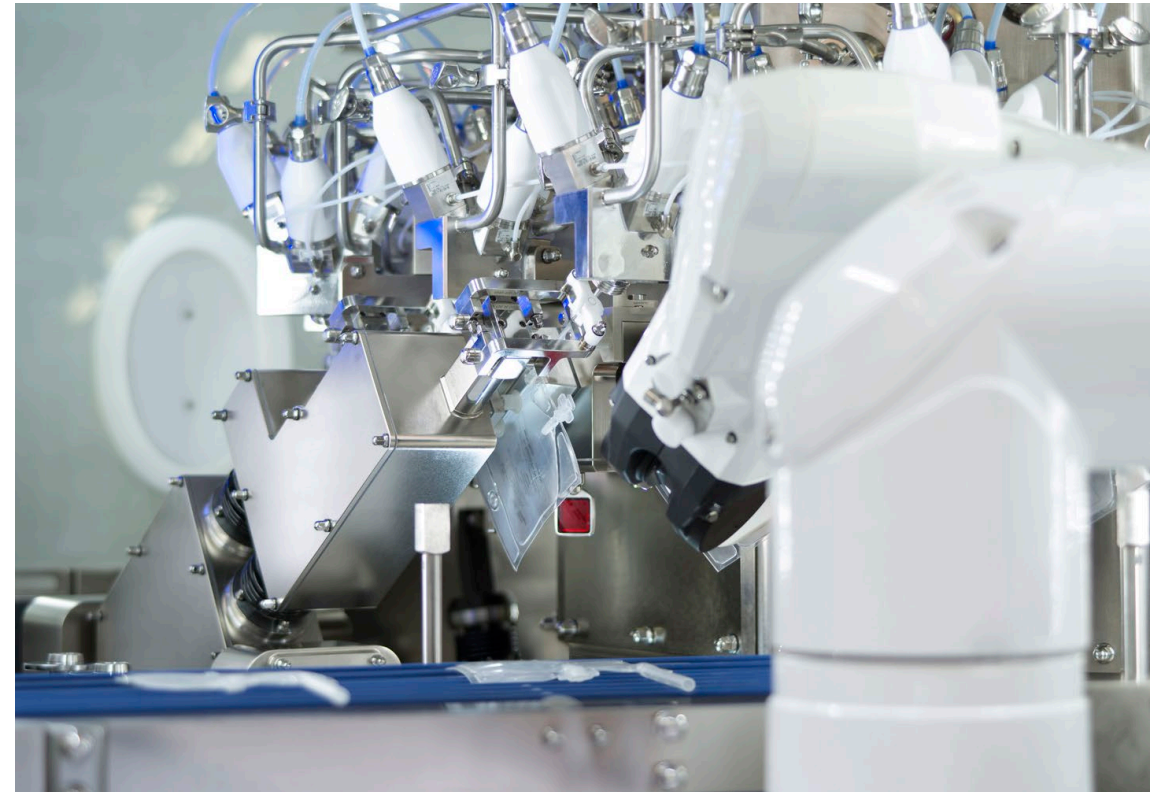
The combination of the Fraunhofer IPT's research capabilities and Harro Höfliger's industrial expertise will revolutionize life science production!

The best of both worlds

We know how to keep your cells happy!



Fraunhofer IPT



Harro Höfliger

Valley of tears in the ATMP development process

When should I automate my production?

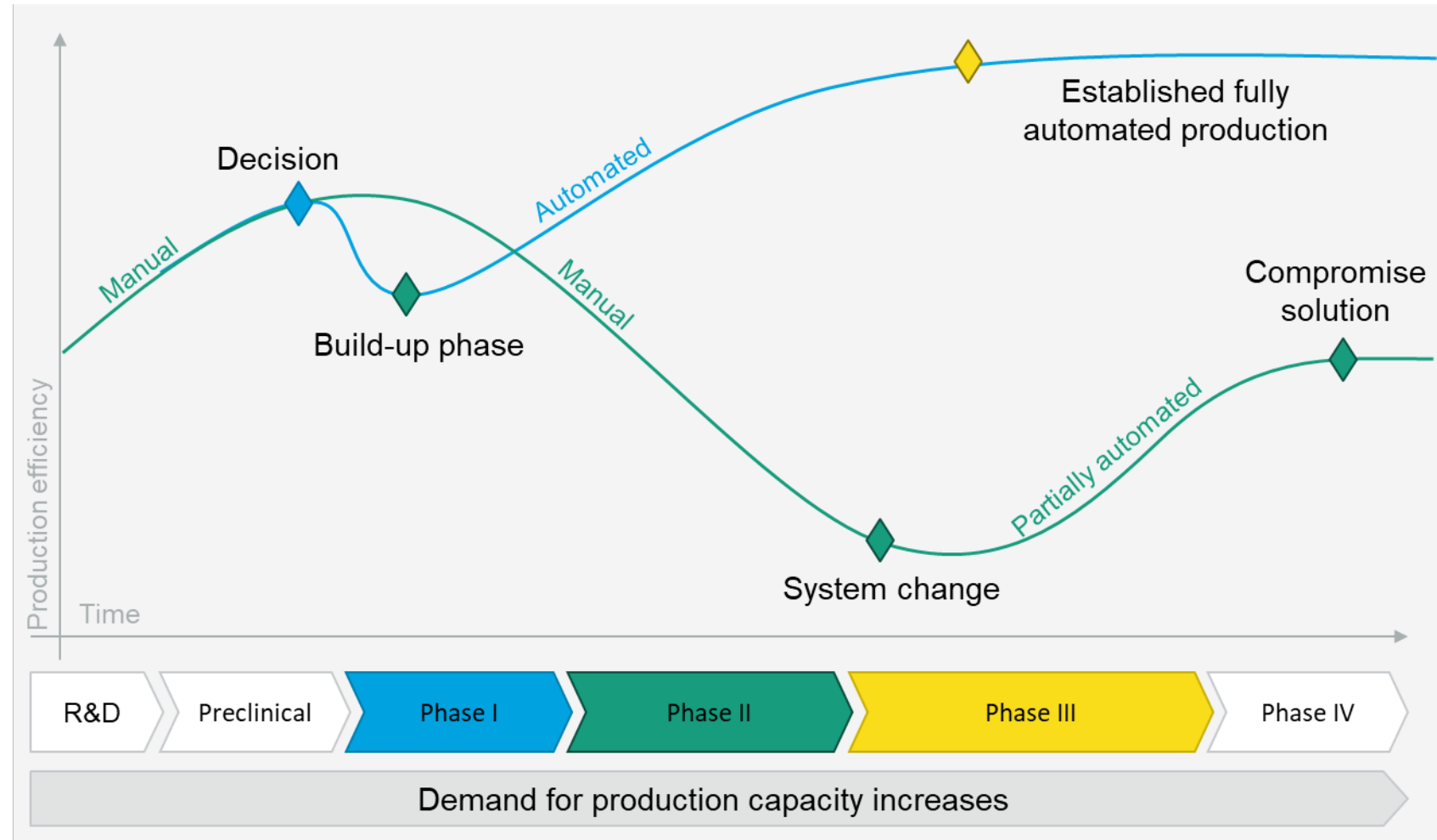
- At the end of the preclinical phase, when clinical trials are to begin, all ATMP manufacturing processes must be established

➡ Design Freeze

- From Phase II onwards, manual production is no longer cost-efficient due to the increased throughput and is later no longer feasible. The process must be changed at great regulatory expense

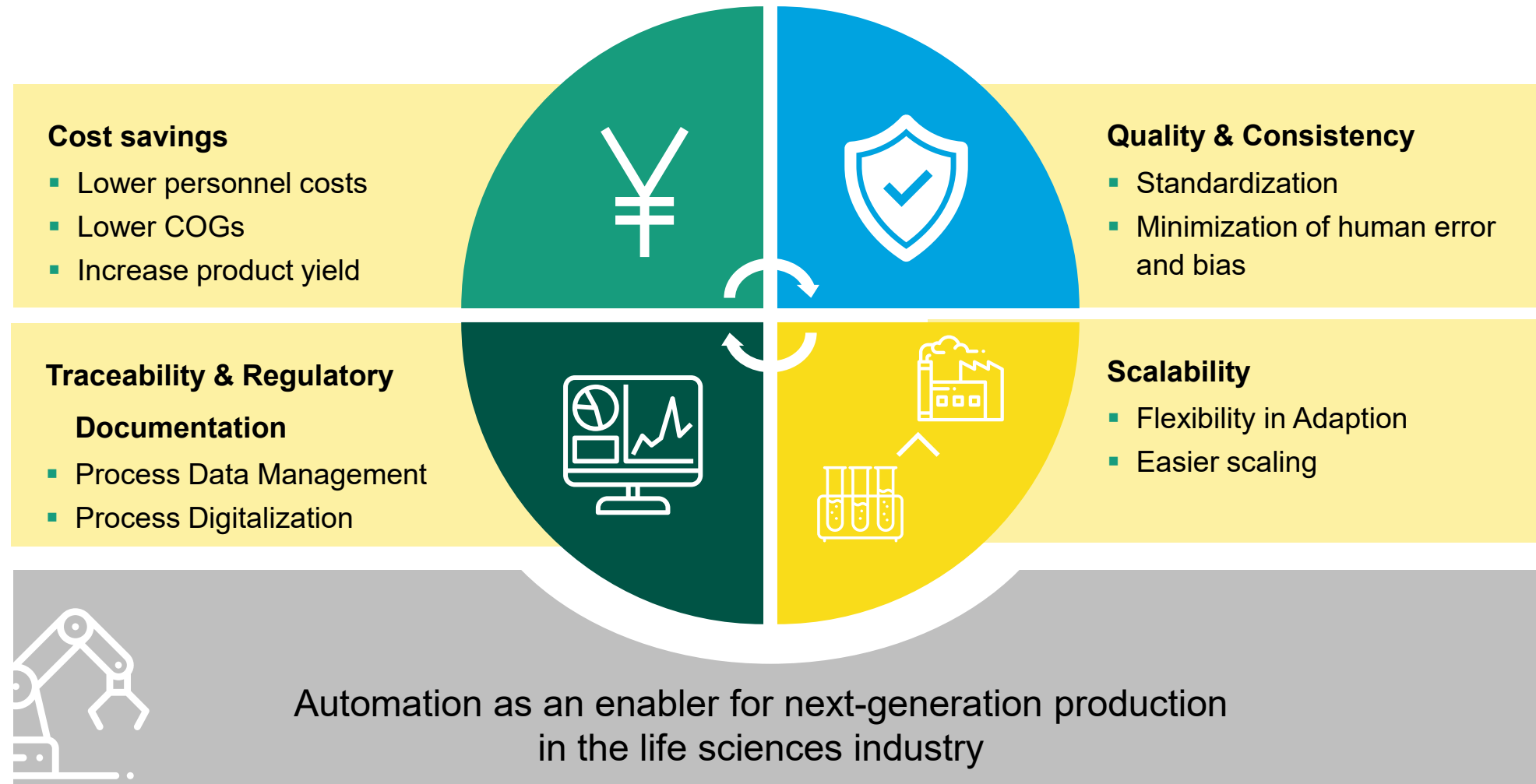
➡ Valley of Tears

- In the long term, even a subsequently partially automated process does not achieve the productivity of a production plant that has been fully automated from the start



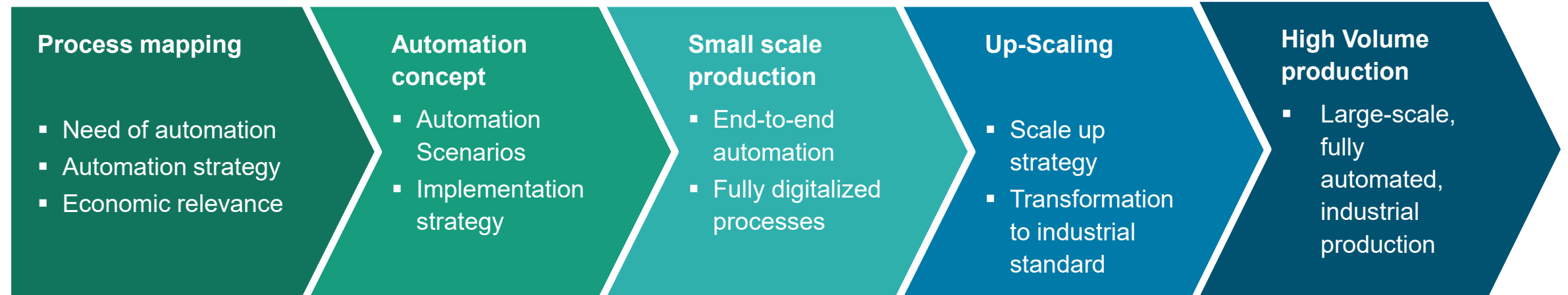
Transforming Efficiency and Quality in Life Sciences Production

Increasing innovative strength and competitiveness



Your journey with us, get on board!

New therapies driven by a fusion of science and industry



Fraunhofer IPT

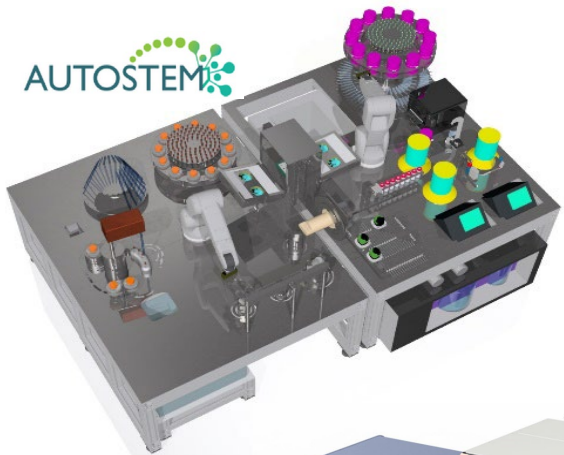
Wherever you are, we help along the entire process
and production chain



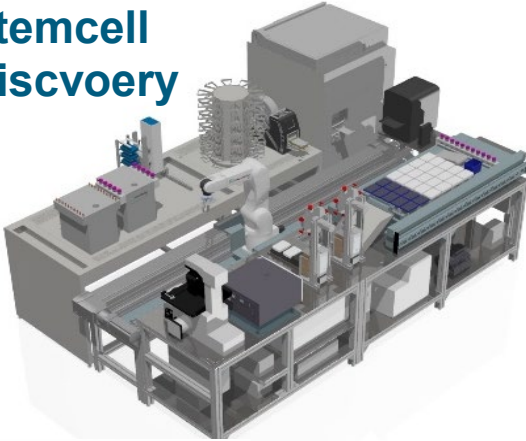
Fraunhofer IPT - Research manufacturing platforms

Our current Projects

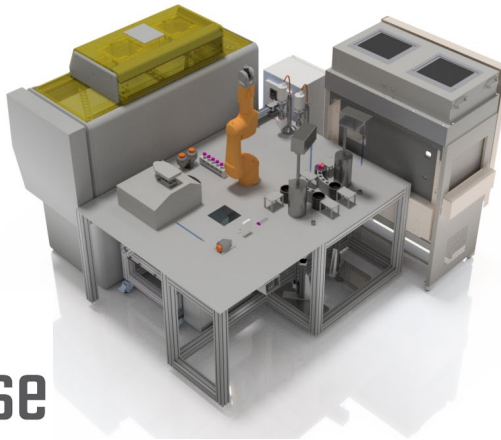
AUTOSTEM



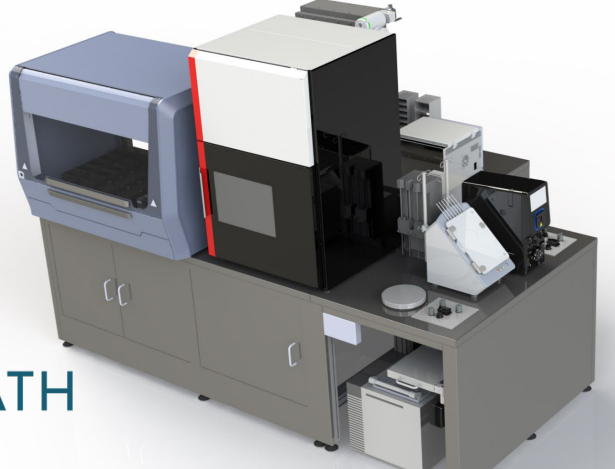
Stemcell
Discovery



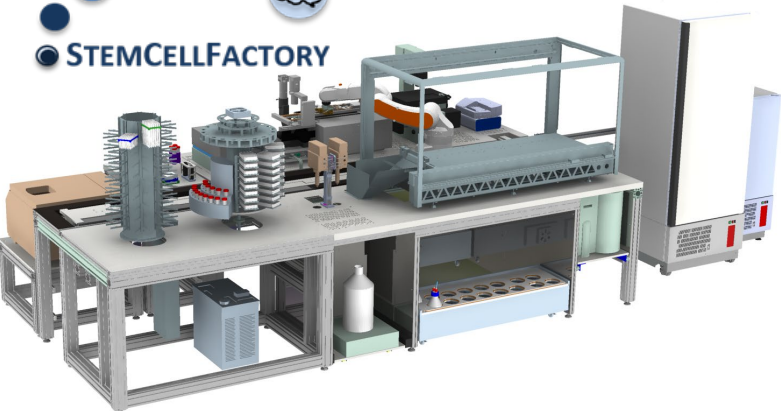
Joint
Promise



AIDPATH



STEMCELLFACTORY



Let's shape the future of your production together!

Provided by Fraunhofer IPT Research and Harro Höfliger Production Design Consulting

Engineering

You are provided with schemes and scaled 2D (or 3D) drawings of the designed production system including a parts list of all components. This forms the technical basis for commissioning the construction of a fully automated production system.

Economics

Our profitability analysis comparing manual and automated production processes provides you with well-founded data proving the lucrativeness of an investment into an automated production system compared to the manual production.

Roadmap

At the end of our consulting, we develop a detailed roadmap for you, which recommends the next steps to be taken in order to lead your production to full automation.

Set up & Scale


We build your fully automated production system, or help you to scale your current system, using the latest technologies and experts from more than ten specialist areas.

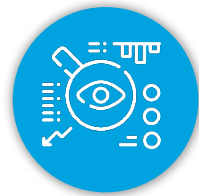
Fraunhofer IPT Automation Consulting

Five building blocks for successful laboratory automation




EXPERIENCE DAY (ONSITE AT IPT)

 Introduction to the automation solutions for stem cell production developed at the Fraunhofer IPT




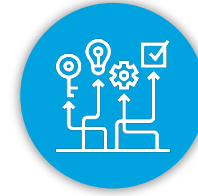
QUICK SCAN & PARTNER'S VISION

 SOP analysis and automation feasibility assessment




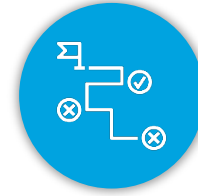
CURRENT STATE ANALYSIS

 Economic and technological analysis of the current manufacturing process




POTENTIAL & GAP ANALYSIS

 Derivation of the potential regarding the automation of the considered process



ROADMAPPING & IMPLEMENTATION STRATEGY

 Concrete implementation strategies for an automated production process

Strike price for automation consulting: 90.000 €

Harro Höfliger

Offering from lab to production

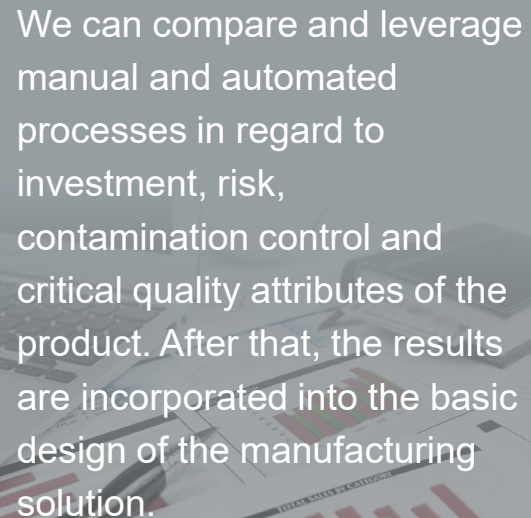
Engineering

We have a three step design approach from basic design, concept design including packaging design and user requirements development and detailed design. Finalizing the steps lead to manufacturing of the machines and executing the built of the equipment.



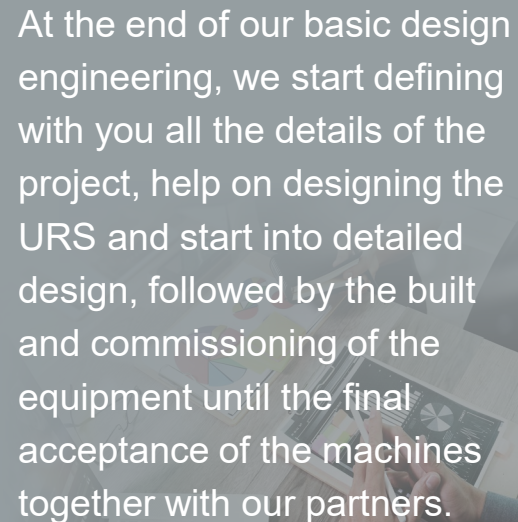
Economics

We can compare and leverage manual and automated processes in regard to investment, risk, contamination control and critical quality attributes of the product. After that, the results are incorporated into the basic design of the manufacturing solution.



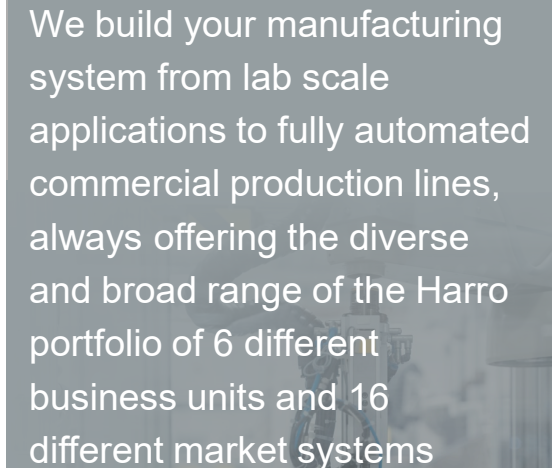
Roadmap

At the end of our basic design engineering, we start defining with you all the details of the project, help on designing the URS and start into detailed design, followed by the built and commissioning of the equipment until the final acceptance of the machines together with our partners.



Set up & Scale

We build your manufacturing system from lab scale applications to fully automated commercial production lines, always offering the diverse and broad range of the Harro portfolio of 6 different business units and 16 different market systems



Harro Höfliger Portfolio Overview

Your product – our focus

PHARMACEUTICAL TECHNOLOGIES



Inhalation



Capsule Filling & Weighing



Aseptic Processing



Microneedles



Combination Products

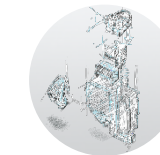
ASSEMBLY TECHNOLOGIES



Parenteral Device Assembly



Medical Device Assembly

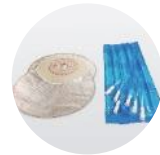


New Technologies

WEB TECHNOLOGIES



Wound & Skin Care



Ostomy & Continence Care



Transdermals & Oral Films



Eye Care



Portion Packs

PACKAGING TECHNOLOGIES



Packaging



Surgical Sutures



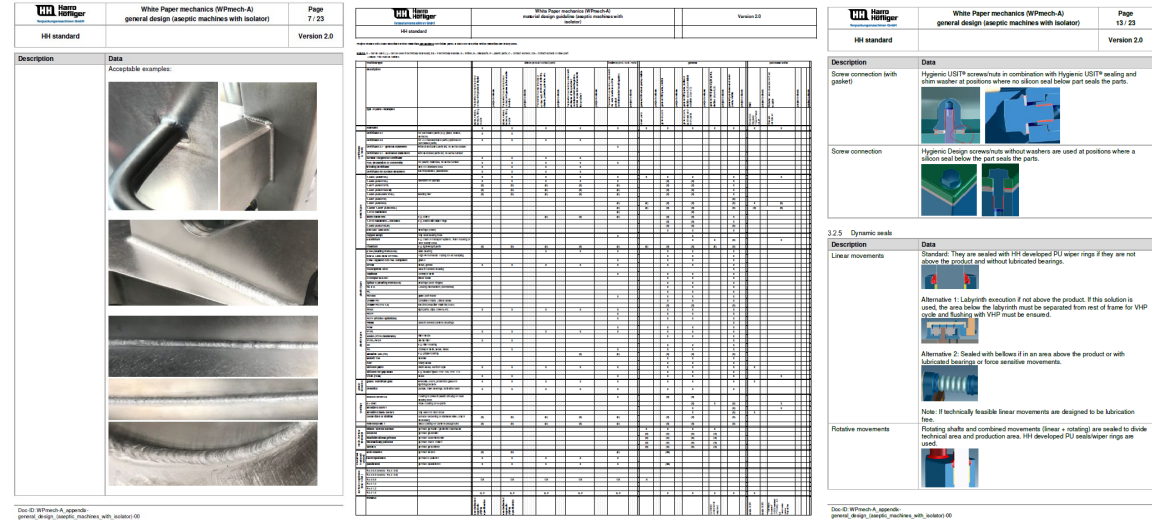
Diagnostics

Aseptic Processing

Basic Information and Philosophies

Aseptic Technology Design Standards

- Driven by GMP Annex 1
- Harro Höfliger Aseptic Whitepaper – The design specification for aseptic machines
 - Hygienic design standards
 - Covers, sealings, product contacts parts
 - Materials, certificates, surface finishes
 - Compatibility with cleaning & disinfection agents



Pharma Service & Engineering and Innovation Services

- Proof of concepts
- Filling, assembly and sealing trials
- Active product analysis, lab and cleanrooms available
- Product handling and packaging for aseptic infeed (VHP / NTT...)

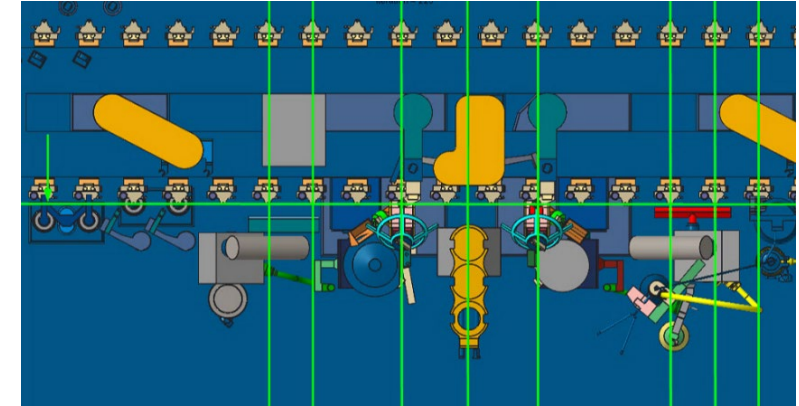
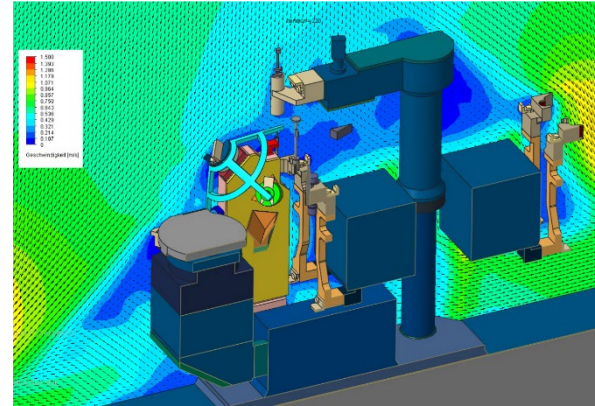


Aseptic Processing

Basic Information and Philosophies

CFD Simulations

- Laminar airflow & turbulences
- First air contact
- Air velocities
- Pressure cascades & overflow into surrounding areas



Mock-up Sessions

- Aseptic set-up and preparation for VHP-Deco. & production
- Glove port positions, door sizes & hinge positions
- Environmental monitoring
- Reachability, Accessibility, Cleanability & Ergonomics



Get in touch with us!



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