Fraunhofer Group for Life Sciences

Applied Science Dedicated to Life

Cooperation on Pharmaceutical R&D between industry-public authorities-universities: Importance of effective collaboration

Istanbul, October 23rd

Fraunhofer
LIFE SCIENCES

Joseph von Fraunhofer (1787-1826)

Researcher – inventor – entrepreneur

An early pioneer with visions

Researcher

- Discovery of »Fraunhofer Lines« in the sun spectrum

Inventor

- new methods of lens processing

Entrepreneur

- Head of royal glass factory

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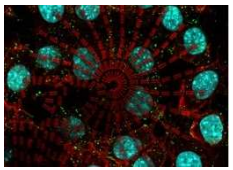
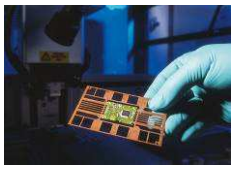
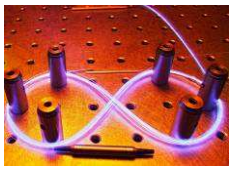
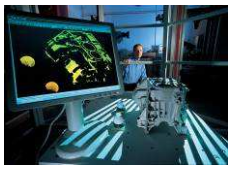
Profile of Fraunhofer-Gesellschaft

- 66 institutes
- over 22,000 employees
- Budget of 2 billion euros

Seven Fraunhofer Groups

- Information and Communication Technology ICT
- Life Sciences
- Microelectronics
- Light & Surfaces
- Production
- Materials and Components – MATERIALS
- Defense and Security VVS

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Creating Innovation at Fraunhofer

Taking the Role of the Other:

- **Complementarity**
- **Gender and Diversity**
- **Intercultural Cooperation**

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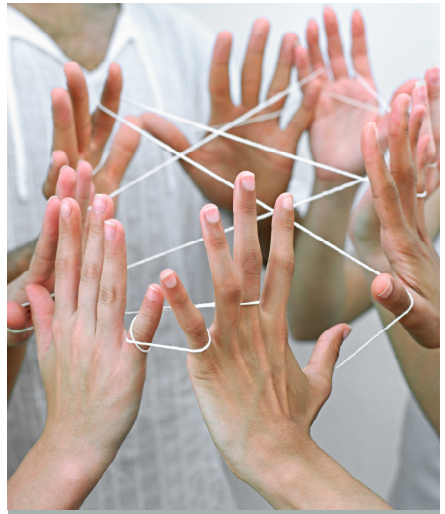
Positioning – Fraunhofer Group for Life Sciences

Research for human health and the environment

- Six strongly performing Fraunhofer institutes and a Fraunhofer research institution are collaborating in the Group
- 1707 employees
- Budget of 124 million euros (2013)
- Scientists, physicians, and engineers in close cooperation
- Synergies from cross-disciplinary cooperation
- applied research aimed at market-oriented solutions



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Increase the Potential:

Systematic recording, evaluation of synergy potential, identification of overlapping developmental topics and involved players

Pharmacogenetics, Pharmacogenomics

Stratification of clinical studies

In vitro diagnostics up to *in vivo* diagnostics (preventive medicine)

Body-area-networks

Biomarkers

Autologous tissue engineering

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Automated Tissue Engineering on Demand

AUTOMATED TISSUE ENGINEERING ON DEMAND

Values

In-vitro-test systems

- Reduction of experiments with animals
  as part of REACH, cosmetic testing, and drug development
- Fulfillment of high quality standards
  standardization and automation of quality control for optimized clients' test results
- Sustainable use of resources
  non-destroying quality control methods

Skin-transplants

- Quick and sufficient availability of high quality transplants

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Custom-Made Tissue Models – Tissue Engineering on Demand

Goal

- Automation of a manually established tissue-engineering-method
- Increase production of human skin test models for in-vitro chemical, drug, and cosmetics tests

Methods

- Re-engineering of every step of the laboratory procedure to automate the complete process
  → **Knowledge transfer and intensive dialogue between biologists and engineers**
- Construction and development of the complete facility including new processing methods and new tissue dissociation and bioreactor systems

Results

- Optimized production of in-vitro-skin test models currently 5,000 units per months possible

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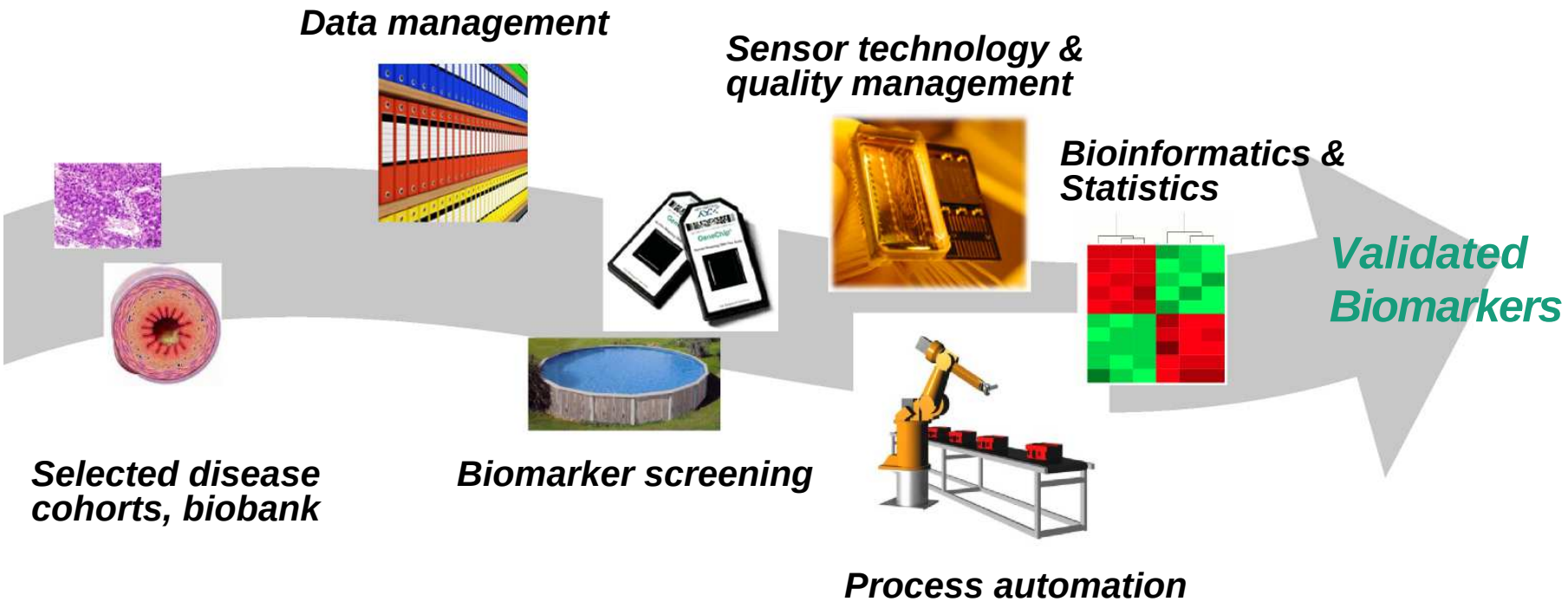
Biomarker Screening – Fraunhofer Foundation
Project RIBOLUTION

Innovative Ribonucleic Acid-based
Diagnostic Solutions for Personalized Medicine



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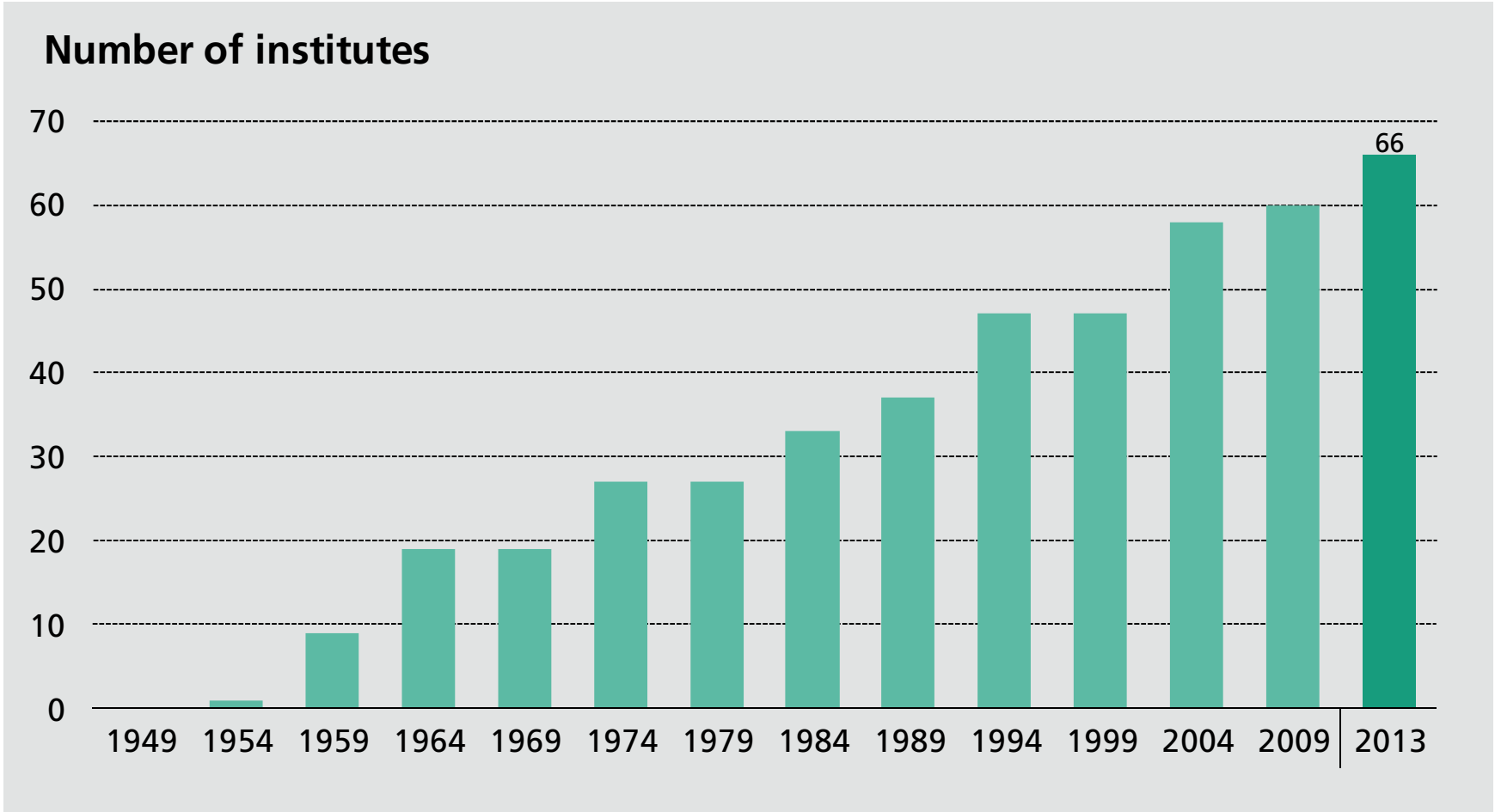
From a Small Association to the Leading Organization for Applied Research in Europe



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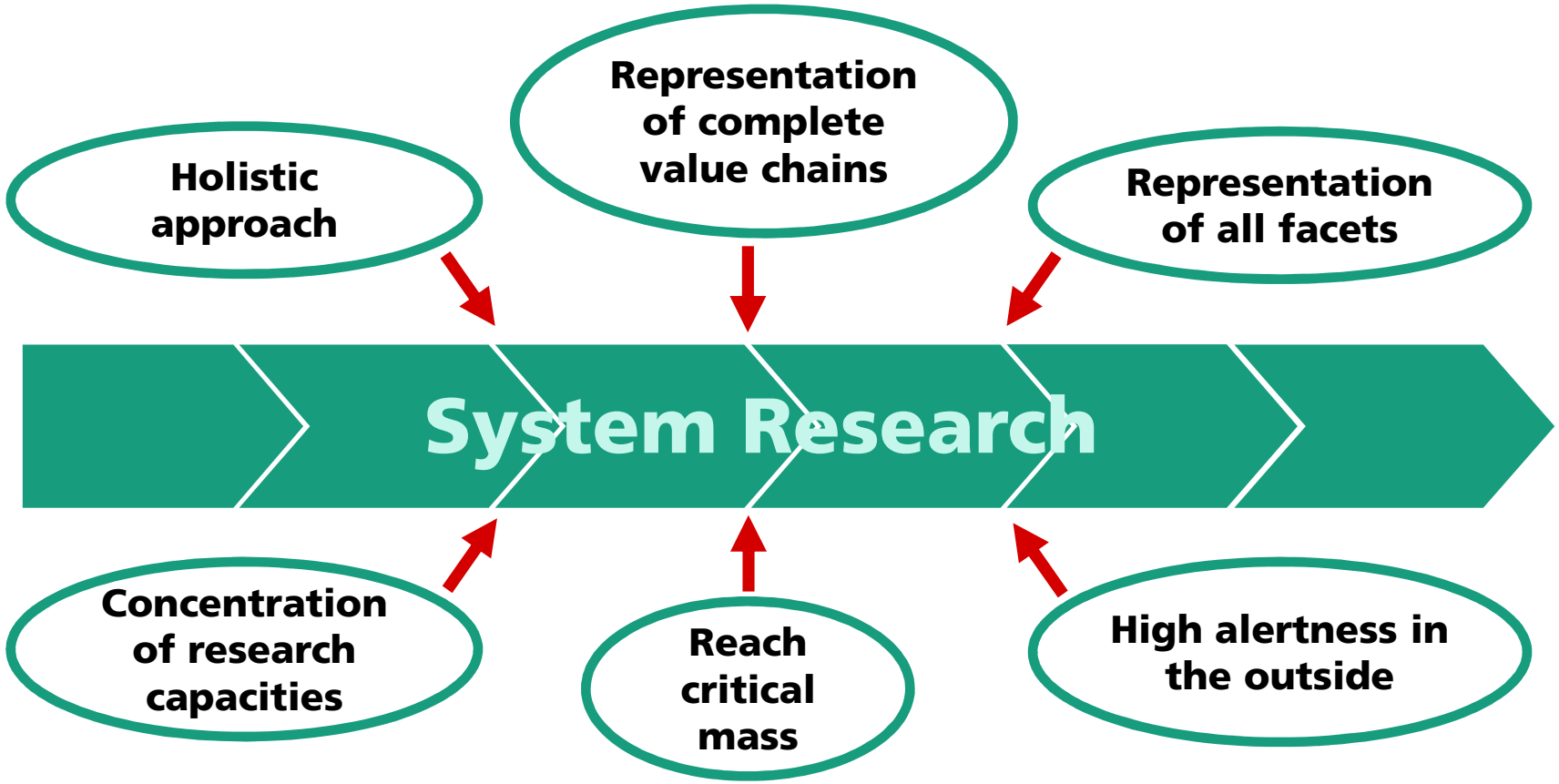
Networking of Players and Collaboration through System Research, e.g. Electromobility



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Business Units and Highlights

BU 1

Medical Translational Research and Biomedical Technology:

The Challenge of Innovative Diagnostics and Personalized Therapy

BU 2

Regenerative Medicine:

The Challenge of Qualified Biobanking and Controlled Self-Healing

BU 3

Healthy Foods:

The Challenge of High Consumer Acceptance and Disease Prevention

BU 5

Process, Chemical, and Herbicide Safety:

The Challenge of Environmental and Consumer Protection

BU 4

The New Potential of Biotechnology:

The Challenge to Learn from Nature for Industrial Exploitation

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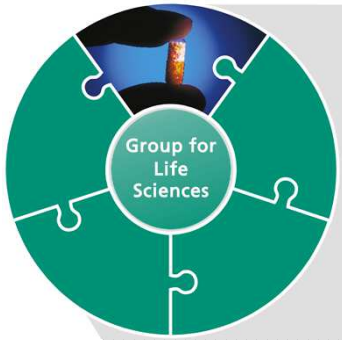
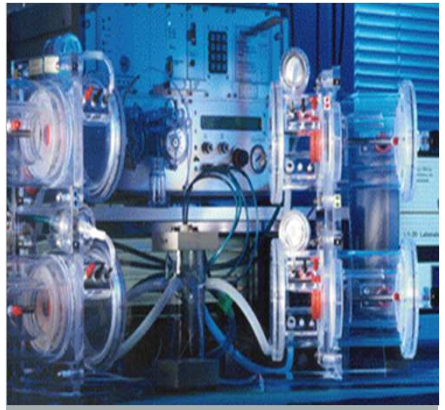
BU 1 **Medical Translational Research and Biomedical Technology:** The Challenge of Innovative Diagnostics and Personalized Therapy

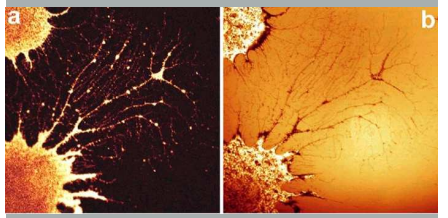


Our responses

- innovative biomarkers for prognosis and therapy control
- wide variety of chip systems for in-vitro diagnostics – one component on the road to personalized therapy
- highly effective antibiotics from new sources such as insects
- improved imaging technology
- GMP platform with a wide range of expression systems
- ecological product design of pharmaceuticals

Successful treatment through optimally tailored, personalized therapy





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Translational Medicine: From Molecule to Patient

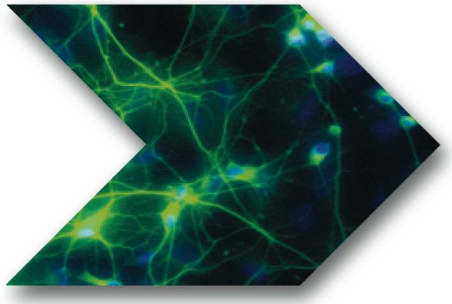
Bio-Hybrid and Cell-Based Tests – Early Go/No-Go Decisions

Target and drug discovery

- Databases: gene expression profiles
- High-throughput screening
- Array technologies
- Biochips: DNA chips, protein chips
- Cell-based assays and chips

Target validation

- Animal transgenic and in-vitro 3-D human disease models
- Large-animal models
- Behavioral animal models
- Cardiovascular and neuronal organotypic models and disease models



Lead optimization

- Structure optimization and humanization
- Aerosol generation
- High-content screening
- Human cell models
- Organotypic cell culture models

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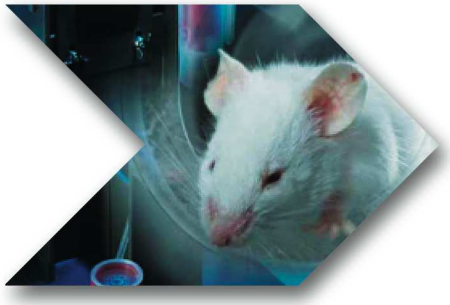
GXP Platform: GLP – GMP – GCP

APIs/Vaccines/Cell Therapeutics – System-independent Solutions – Clinical Studies Airways

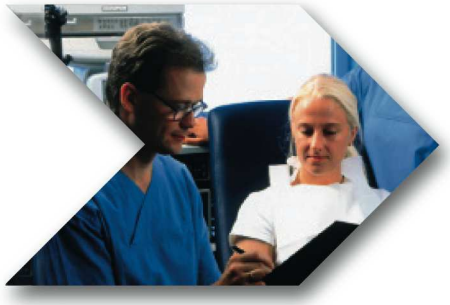


Safety pharmacology and toxicology

- GLP
- In-silico prediction ADME
- Molecular and functional imaging
- Nano- and microparticle systems
- Biomarkers of disease

Manufacture of clinical investigational products

- Consulting on regulatory and economic aspects
- Evaluation of customer processes
- GMP facilities
- Compound libraries and high-throughput systems
- Expression systems



Clinical trials of phases I and II

- GCP-compliant protocol development
- Toxicology and pharmacology
- Dose escalation studies in patients with malignant diseases
- Segmental lung challenge

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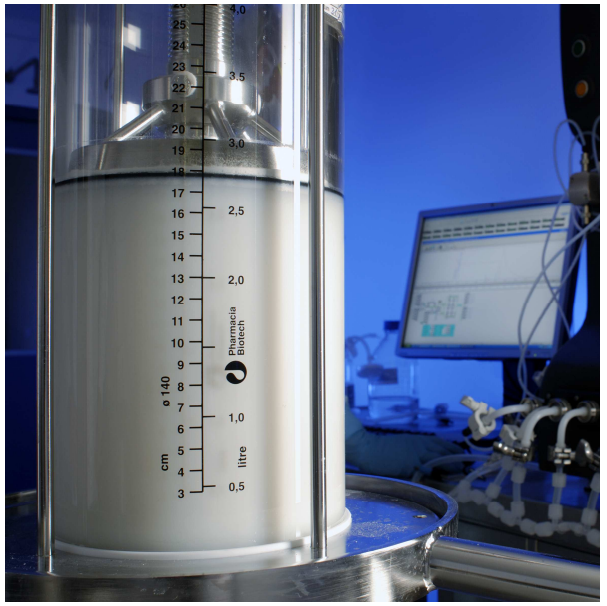
Pharmaceutical Biotechnology

- GMP- und non-GMP manufacturing of APIs
- Development of manufacturing processes
- Stability testing
- Validation of the manufacturing and purification process
- Aseptic filling of small quantities (Fill & Finish)



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Highlights GMP Services

- Development of robust and standardized production cell lines and manufacturing processes
- Manufacturing of active pharmaceutical ingredients (APIs) for pre-clinical and early-phase clinical trials
- Manufacturing of APIs, tissue engineering products, organoid test systemens and cellular therapeutics for clinical studies
- Expression systems: mammalian cell cultures, yeasts, *E. coli*, plant cell cultures

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Manufacturing Processes for Biosimilar Drug Substances Developed at Fraunhofer

e.g.

EPO √

G-CSF √

ß-INF √

Individual molecules ↔ individual manufacturing process

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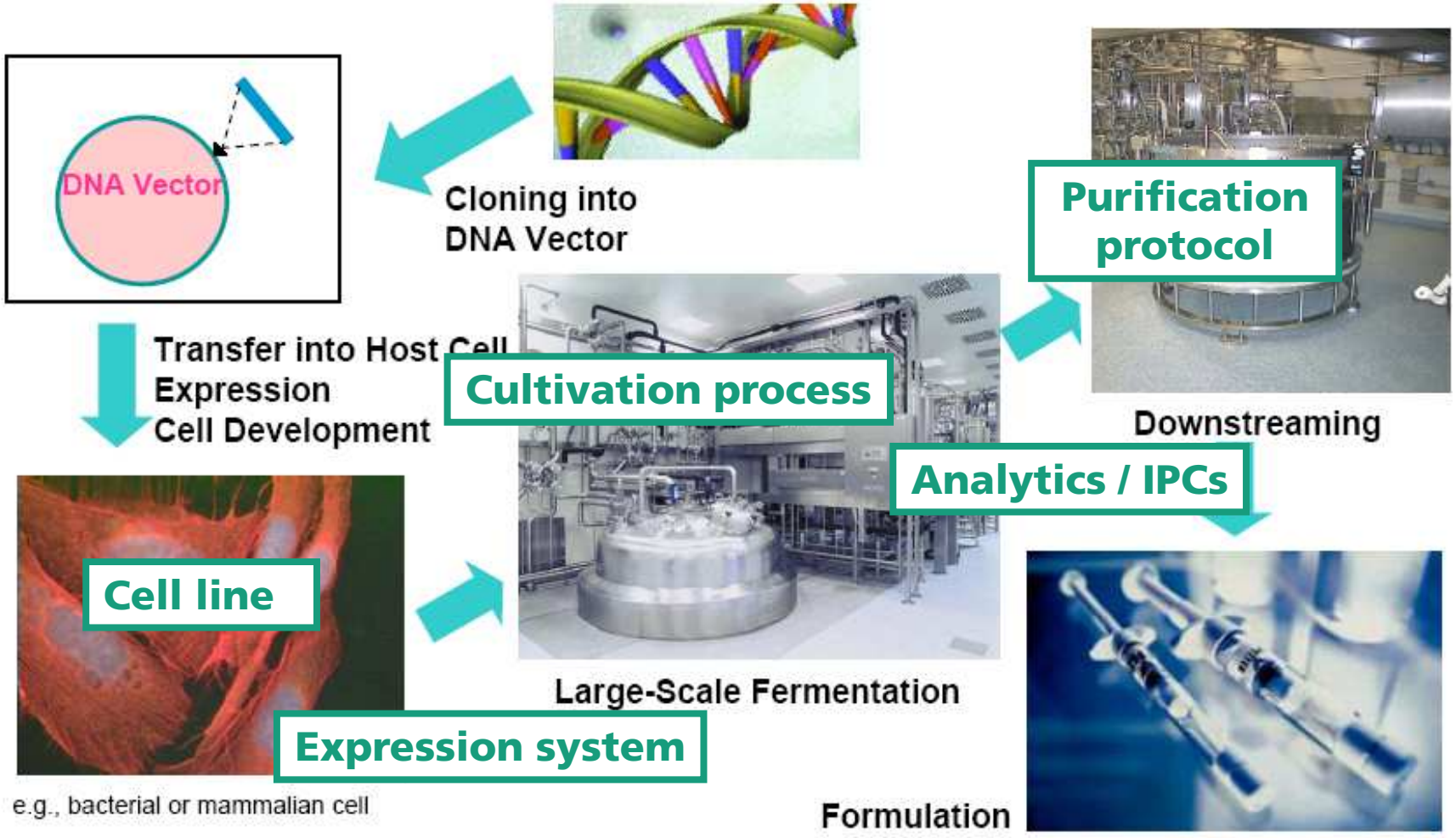
Access Points for the Standardization of Antibody Manufacturing Processes



Modified from GB Kresse, Roche Diagnostics GmbH, 2009

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Elements of Fast Antibody Manufacturing Process Development at Fraunhofer

1. Standard cell line for the expression of different antibodies
2. Generic high cell density cultivation process
3. Robust and generic purification sequence
4. State of the art spectrum of analytical procedures

Implementation of generic elements in the antibody manufacturing process make process development independent from

- the target antibody and
- the starting materials

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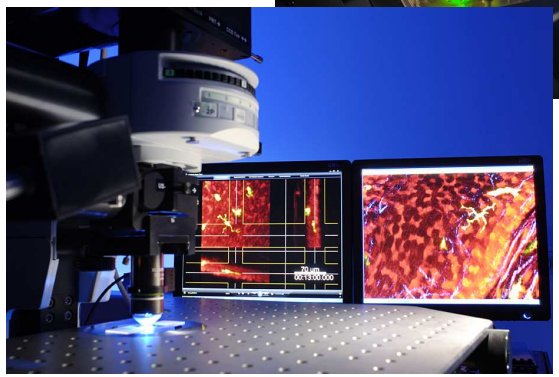
Pre-clinical Studies

- Toxicity studies in rodents and non-rodents
- Reproduction toxicity studies
- Genetic and *In-vitro*-toxikology
- Inhalation toxikology/Pharmacology
- Immunology and immunotoxicity tests



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Clinical Trials Airways

- Clinical trials phase I and IIa
- Bronchoskopy with isolation of test samples
- Spirometry
- Fraunhofer Environmental Challenge Chambers ECC

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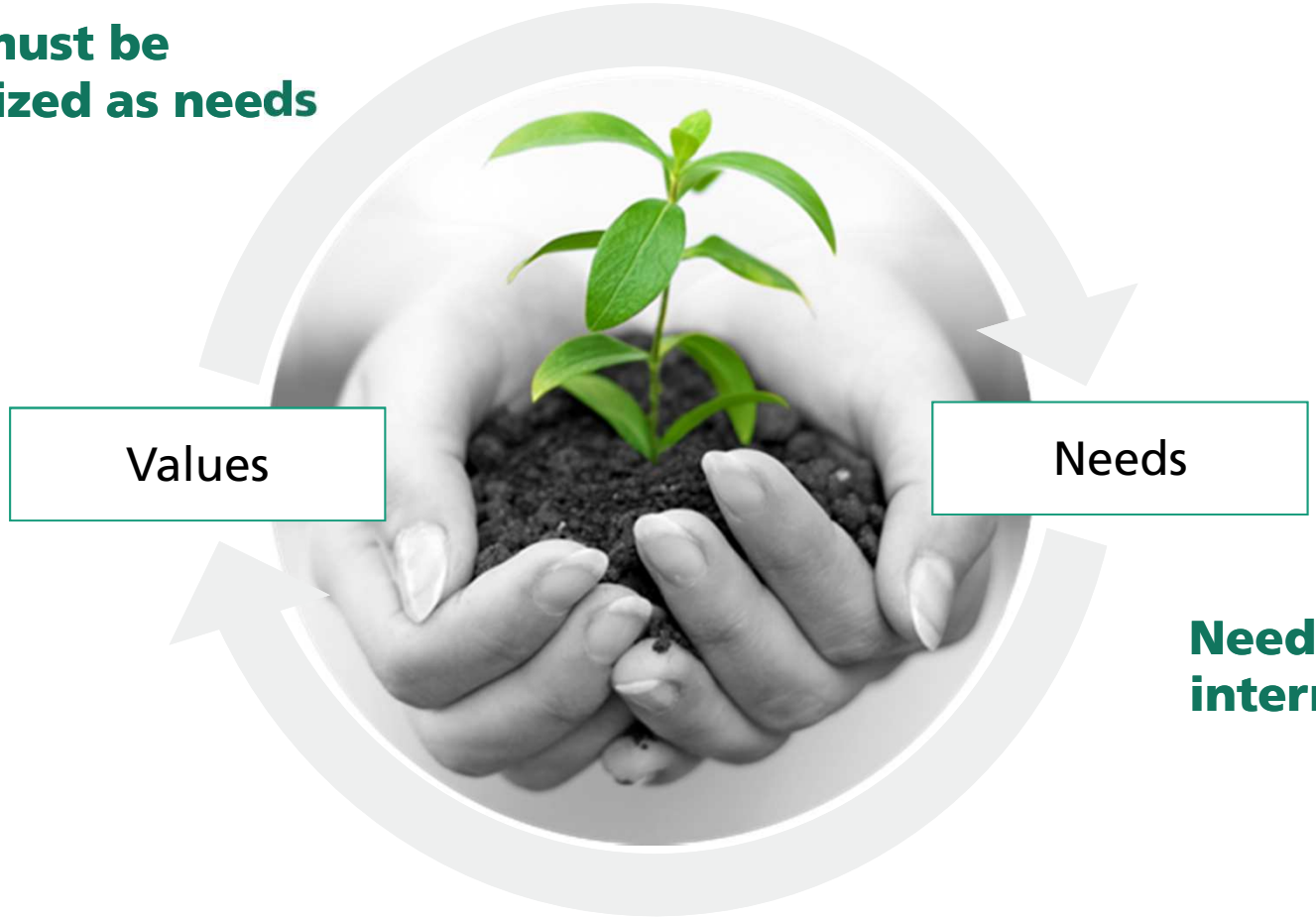
Balance, Harmony, and Empathy Research for Mankind

Values must be internalized as needs



Needs must be internalized as values

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Do not hesitate to contact us

We are pleased to help you find answers to any questions you might have or solutions you are looking for.

Please contact our Central Office:

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