

SWOT-Analysis of Needs

„TUC closes Gap (Valley of Death) for Product Innovations towards Industrialization at optimized COGs for Global Competitiveness by Sustainable Manufacturing Technologies“

**Historic Claim
Key-Technology Portfolio**

**5 WW-Mega-Trends
Contribution**

**Products
for Social Needs**

Universities

**Manufacturing Technology
TUs**

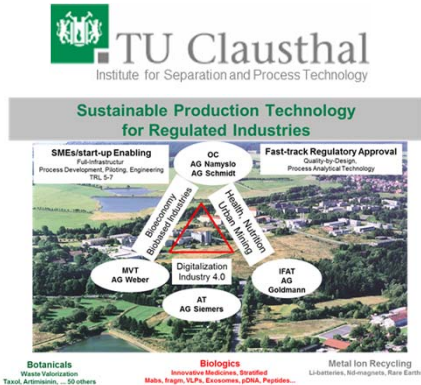
**Global Markets
/No-Niche**

**COGs Optimization
@ D/EU**

Competition

Made in China 2025
USA-first
BRIC etc.

**Globalization
Domination/Coexistence Claim**



**1775 Metal Ion Processing,
High Value Products Manufacturing**

**Urban Mining,
Resource Efficiency**

**Manufacturing Technology/
Industrialization**

- 3. Energy <- Nd-magnets etc.
- 4. Mobility <- Li-battery etc.
- 5. IT <- Rare Earth elements etc.

- 1. Health
 - 2. Nutrition
- CLZ**

**Sustainable, Green
Waste Valorization, Recycling
Closed Cycles, Zero-Waste/Emission
„Traceless Plans Traceless Productions“**

**Strictly
Regulated Industries
High Value Products**

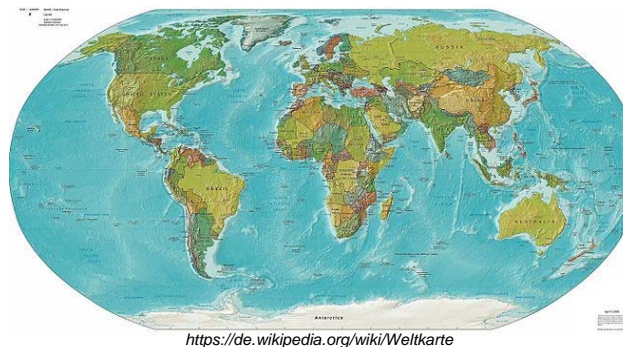
**antinfektiva, antibiotics,
MRSA, Mabs, fragms,
cell therapies, VLPs,
exosomes etc.**



**Industrialization,
Manufacturing
Technologies**

- 1. Health
 - 2. Nutrition
 - 3. Energy
 - 4. Automotive
 - 5. IT
- MHH, HZI, BRICS, PVZ, UMG, MPI etc.
agricultural area, KWS, Symrise etc.
VW, ...
...

Nds.



D/EU

World Wide

TUC-ITVP Fit for the Future in Nds.

1. Health

Innovative Medicines, Stratified

MHH, HZI, BRICS, PVZ, UMG, MPI ...

2. Nutrition

OS, OD, UGö, ..

3. Energy

Growth

4. Mobility

5. IT

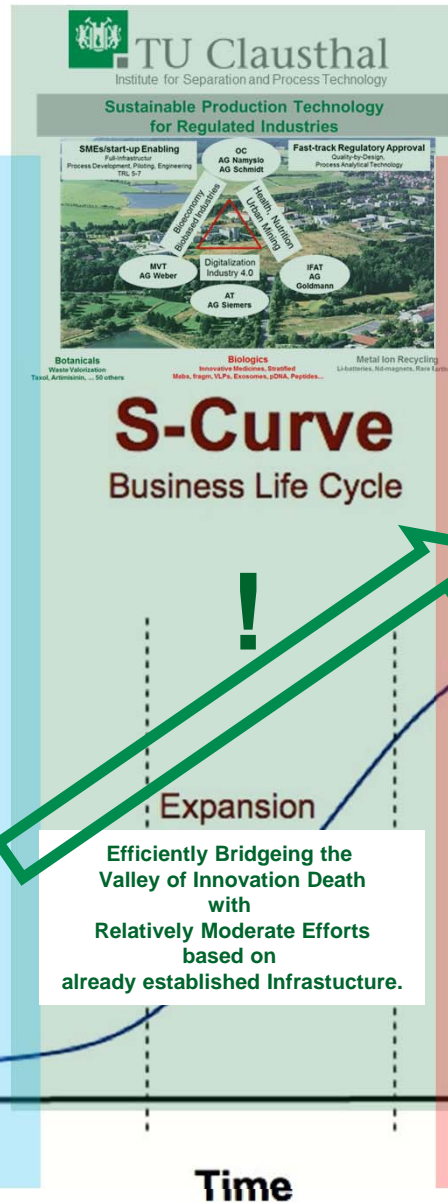
Many good activities and funding

Product Innovation

Strong Activities

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Infancy



Industrial Manufacturing

Hidden Champions
SMEs, Startups

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Maturity

Efficiently Bridging the Valley of Innovation Death with Relatively Moderate Efforts based on already established Infrastructure.

Projects Needs

1. Piloting

- Final Feasibility Proove and Regulatory Approval Acceptance
- 6 months x 10 employees = 0,5-1 Mio. €projects

2. Prototyping

- e.g. Agricultural Cultivation Cooperative + Container Plant @ fully integratrd manufacturer = 1- 5 Mio. €projects



3. Technology Park

- Start-up Infrastructure
- Improve Region
- 10 – 100 Mio. €

Many industrial activites

Lectures, Training & Education

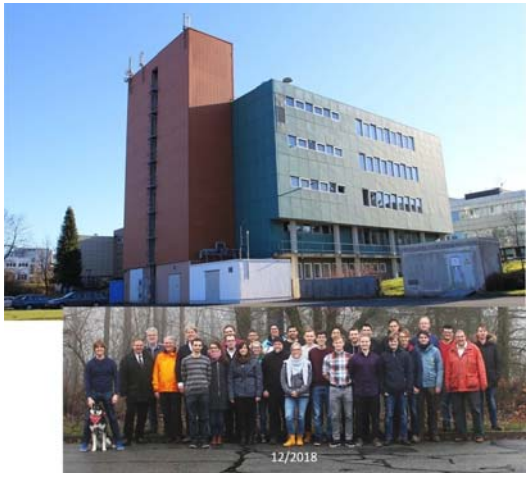
- Separation and Process Technology
- Biotechnology and Bioanalytics for USP and DSP
- Pharmaceutical Engineering
- Process Modelling and Simulation
- Innovative Manufacturing Technologies

- Phytoextraction – Products and Processes organized by

Forschungsvereinigung der Arzneimittel-Hersteller e.V.



Bachelor			Master			
1. WS	5. WS	6. SS	1. WS	2. SS	3. WS	4. SS
Ref. I. & II	TV1	TV2 (MSc)	BioVT1	BioVT2	Gemeinlich-Therm (Gobelt-Roes)	Jan./Feb.
	Stoff-/Wärmetransport Thermodynamik Spezielle Grundoperationen Extraktion SL-Extraktion Chromatographie KrySTALLISATION / Fällung Membranverfahren Trocknung Membranverfahren	Stofftransport Thermodynamik Spezielle Grundoperationen SL-Extraktion Chromatographie KrySTALLISATION / Fällung Membranverfahren Trocknung Membranverfahren	Molekularbiol. Grd. USP Biochemie Grd. USP/DSP Bioanalytik Biotechnologie Regulatorien	USP Bioanalytik Labordiagnostik Techn. Chrom. (Ditz)	Phyto Nth. Tilo (Papenbock, Hansch, Strube)	März
	Stat. Sim. (MSc)	Pharm. Sim. (MSc)	BioVT4 (Tegmeier)	BioVT3 (Tegmeier)	Pharm. Nth. Tilo (Papenbock, Hansch, Strube)	Masterarbeit
	Stat. Sim. (MSc)	Pharm. Sim. (MSc)	ModuSimVTS Pharmazie Blanzen COSE/PCPE Numerik Prozesssimulation	Pharma VT Pharmazie Virtuelle Modellierung COSE/PCPE Apparate/Anlagen Regulatory / GMP	Einf. i.d. Biochem. (Schmitz) Makromoleküle (Schmitz)	Februar
	Anst.-Praktikum TV1	Anst.-Praktikum TV2	Prozesstechnik Prozesssynthese Fisch-Technologie Mini-Plant K.u.W. - Rechnung Pharmazie u. Biochem. Chemstrand (Koster, Prohaska)	Prozessintens. Biochem. Lab. (Ditz, Strube) # TV4 Proz. Appl. d. SUIIT Chem. Ind. Wandel	Analytik (Namyso)	
	Praktikum Dest.		Praktikum Chrom/Krist./LE/SE, Bioanalytik Gruppenarbeit			



- Process Chromatography
- Downstream Processing
- Continuous Bioprocessing
- Accelerating Biomanufacturing by Modelling



Results

- Ready-to-Project and Research Portfolio, Fast Track Regulatory Approval
- Education & Trainings Courses
- Prototyping with TÜV and FDA/EMA approval
- Piloting-Studies for Model Validation Botanicals and Biologics ~ 6months*10 employees
- Accelerating Biomanufacturing by Modelling, Model Validation Studies
- **H-factor 23 (~ 10 publications/a), 0,5-1 Mio. € grants/projects, 25-40 employees**

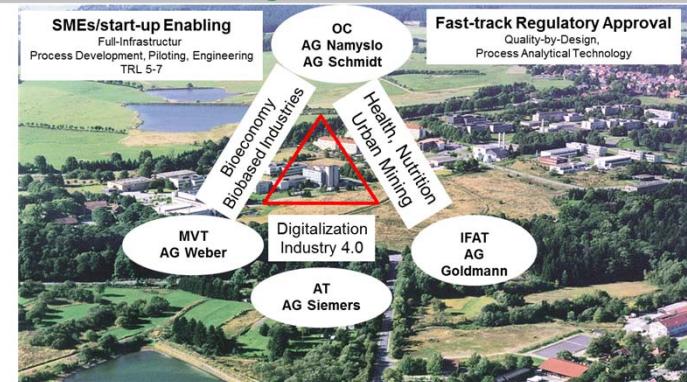


Institute for Separation and Process Technology
Prof. Dr.-Ing. habil. Jochen Strube

TASK

- SME/Start-up supporting Infrastructure TRL (EU technical readiness level) 5-7 to become fully integrated Sustainable Manufacturers
- Chemical-Pharmaceutical Industry is 3rd largest Branche in D/EU, Products fulfill elementary Social Needs, but Global Competition causes the need for innovative method for sophisticated Process Optimization without unnecessary overdimensioning to keep Manufacturing in D/EU at acceptable COGs
- Only Sustainable Production Technology generates Jobs & added value/social needs in D/EU

Sustainable Production Technology for Regulated Industries



Botanicals
Waste Valorization
Taxol, Artemisinin, ... 50 others

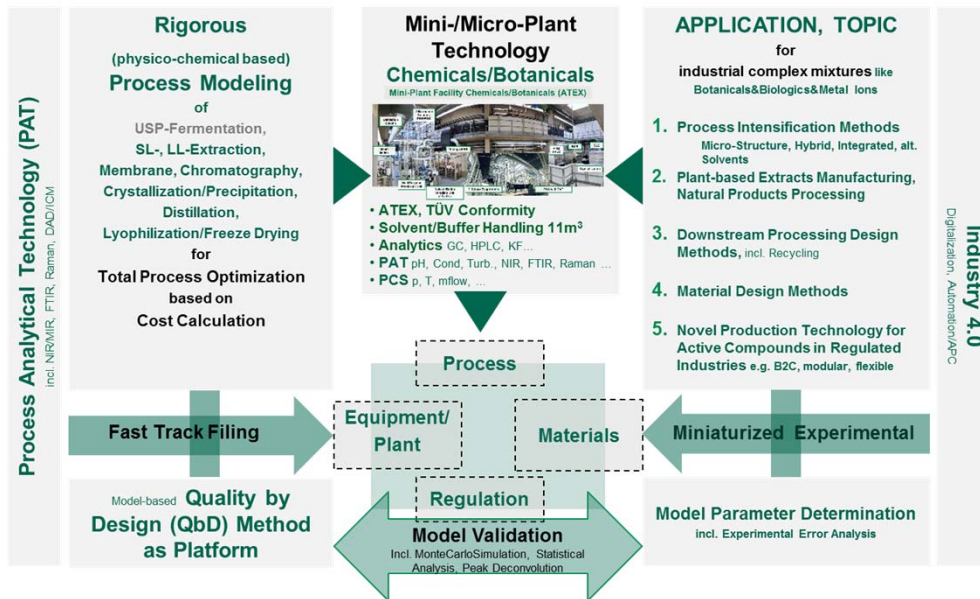
Biologics
Innovative Medicines, Stratified
Mabs, fragm, VLPs, Exosomes, pDNA, Peptides...

Metal Ion Recycling
Li-batteries, Nd-magnets, Rare Earths ...

Solution Approach

- Develop Scientific Engineering Methods for Regulated Industries
- to Industrialize innovative Product Ideas from Medicine, Nutrition, Agro, Urban Mining
- Operate full Infrastructure and Portfolio for SMEs/Startup support/projects
- Focus on Regulated Industries Bioeconomy, Digitalisation/Ind4.0
- Botanicals/NaWaRos/Chemicals, Biologics, Metal Ions/Urban Mining
- **Total Process Modelling**
- **combined with exp. Model Parameter Determination in laboratory scale**
- **Integrate Process Analytical Technology for Quality by Design Approach**
- **DOE/Statistical Modelling, Rigorous physical-chemical Process Modelling, Cost Modelling**
- **PCA/PLS, Chemometrics, Metabolomics, Data-Analysis**
- **Batch2Conti and Accelerating Biomanufacturing by Modeling**

ITVP Research Concept Overview



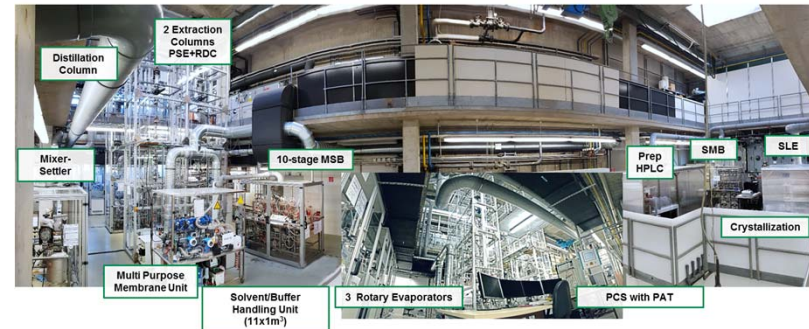
Infrastructure

- Mini-Plant Chemicals/ATEX 1-2 l/h and Biologics S1/S2, g-kg lab, **TRL 5- 7**
- Chemical and Biotechnology Laboratories incl. Analytics,
- Inline DAD, FTIR, NIR, Raman, DAD, Fluorescence, pH, Cond, Turb. etc.
- PLT/PCS and fine-mechanics work-shops
- Software Tools and PC/Laptop Network
- QbD and PAT approach tools
- Strategic Cooperations Automation AG Siemens, Particle Technology AG Weber
Analytics/NMR/MS AG Namyslo/Schmidt, Recycling AG Goldmann

Mini-Plant Biologics S1/S2 Laboratory



Mini-Plant Facility Chemicals/Botanicals (ATEX)



Portfolio

- **Ready-to-Project:** Process Development, Prototyping, Piloting, Production Analysis
- **Research Portfolio:** Sustainability, Batch2Conti, Modular Plants
- **Botanicals** – water-based processing, waste valorization, MRSA/antibiotics, diabetes, immunology support
- **Biologics** – MABs, Fragm. VLPS, Exosomes, ...
- **Urban Mining** – Nd-magnets Li-batteries, Rare Earth elements, ...

Future Projects, Demands

- Piloting Studies for SMEs, startups, etc.
- Digitalization, Ind40 industrialization with prototyping
- **Botanicals** - cultivation cooperative with container plant as fully integratd manufacturer - efficacy studies with optimal products quality/reprod.
- **Biologics** - MABs/Fragm, peptides, VLPS, Exosomes - b2c, stratified medicines
- Urban Mining/Recycling – Green Technologies/Manufacturing
- SMEs, Startup projects support