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-Nische

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,
Ressource Efficiency

Manufacturing Technology/Industrialization

1. Health
2. Nutrition

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

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

Strictly Regulated Industries
High Value Products

CLZ
Nds.

D/EU

World Wide

www.niedersachsen.de
1. Health
   Innovative Medicines, Stratified
   MHH, HZI, BRICS, PVZ, UMG, MPI ...

2. Nutrition
   OS, OD, UGö, ...

3. Energy

4. Mobility

5. IT

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 integratd manufacturer
   - = 1- 5 Mio. €/projects

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

Many good activities and funding

Many industrial activites

©ITVP
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 Forschungsverband der Arzneimittelhersteller e.V.

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

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. €/a grants/projects, 25-40 employees

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 Branch 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

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 Biotechnology, Digitalisation/4.0
- Botanicals/NaWalRos/Chemicals, Biologics, Metal Ions/Urban Mining
- Ready-to-Project and Research Portfolio, Fast Track Regulatory Approval
- Education & Trainings Courses
- Prototyping with TÜV and FDA/EMA approval
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Sustainable Production Technology for Regulated Industries

- DOE/Statistical Modelling, Rigorous physcial-chemical Process Modelling, Cost Modelling
- PCA/PLS, Chemometrics, Metabolomics, Data-Analysis
- Batch2Conti and Accelerating Biomanufacturing by Modelling
**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**

- Cultivation
- ATPE
- SPTFF
- IPC, PCS
- ICCC
- UF/DF
- Lyophilization

**Future Projects, Demands**

- **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, ...

**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, ...

- **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**