

# TRANSLATIONAL CENTER REGENERATIVE THERAPIES TLC-RT



# INTERDISCIPLINARY



## BIOMEDICINE

*Isolation and handling of human primary and induced pluripotent stem cells | generation of three dimensional tissue models as an alternative to animal testing | pre-clinical testing | development, validation and production of ATMPs for applications in regenerative medicine*

## ENGINEERING

*Lab automation | robotics | in silico simulation of fluid dynamics | scale up of cell culture processes | bioreactor design | rapid prototyping*



## MATERIAL SCIENCES

*Development, characterisation and biomedical application of synthetic as well as biologically-based materials including particles, fibers, and coatings*



# ... MISSION

The Translational Center Regenerative Therapies TLC-RT, part of the Fraunhofer Institute for Silicate Research ISC in Wuerzburg, develops medical devices and medicinal products based on novel biomaterials, novel human cell-based 3D tissue models and test systems, scalable automated production processes, and biological vascularized implants up to the prototype level. Besides accelerating cost efficient drug development, TLC-RT promotes the 3R principles. The main goal is the fast application and implementation of current material research and tissue engineering for pre-clinical and clinical usage. By cooperating closely with partners in medical technology, biotechnology, academia and the pharmaceutical industry, we conduct research on behalf

of companies, diagnostic laboratories and research facilities. Creativity and interdisciplinarity allow us pursuing new paths leading up new high-tech products for the healthcare sector. As application oriented research facility we are able to tackle new topics by initiating publicly funded projects and/or collaborating with industrial partners, renowned research institutes and universities.

The TLC-RT is proud of offering its partners and clients an exceptionally broad variety of services, from risk assessment through development of cell based implants and medicinal products up to preclinical studies and meeting demands for receiving manufacturers permission.

## TEAM

*48 Permanent staff  
20 Scientists | 11 Graduates | 4 Technicians*



## TOPICS

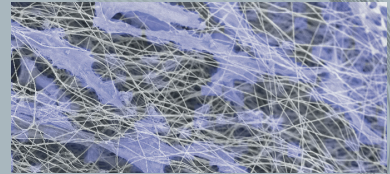
- *Biomaterials*
- *Lab automation | bioreactors*
- *In-vitro test systems*
- *Clinical development*

# ... TOPICS

LAB AUTOMATION | BIOREACTORS



BIOMATERIALS



IN VITRO TEST SYSTEMS



CLINICAL  
DEVELOPMENT





# LAB AUTOMATION | BIOREACTORS

For tissue engineering of biological tissues or even whole organs it is essential to maintain the function of the tissue-specific cells in vitro. Therefore, the microenvironment of the cells in vivo must be mimicked. In addition to a sufficient nutrients supply, tissue-specific cues must be applied. For instance, conditions like media flow, rotational, strain and pulsatile forces are important factors during tissue development.

The Lab Automation and Bioreactor Group of the TLC-RT is specialized on the development and design of synthetic environments and the technologi-

cal implementation of variable environment control for tissue engineering and cell culture.

In order to enable standardized processing and to reduce costs, the group develops an automated, robot-assisted lab that facilitates production, in vitro testing and furthermore the affordable manufacturing of implants under the applicable guidelines.

## EXPERTISE

- Application-specific bioreactor technologies for 3D tissue engineering
- Lab 4.0 – lab automation for cell-based therapies

- Device development
- Dynamic cell culture | tissue engineering
- Simulation
- Digitalization

## APPLICATIONS

- Bioreactors
- Incubator technologies
- Process automation | robotics
- ArtCut® – device for controlled wounding of in vitro tissue models

## CONTACT

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# BIOMATERIALS

The Biomaterials Group develops synthetic as well as biologically based materials, e. g. particles, fibers, coatings for regenerative medicine, tissue engineering and diagnostics. One of the core tasks is to cover the entire value chain, starting from R&D-development tasks over process up-scaling, pre-clinic evaluation to the clinical phases. Current activities are focused on biohybrid and biodegradable materials with biofunctionalization, biologized surfaces or controlled drug release properties. We provide both the infrastructure for and the experience in processing and manufacturing biomaterials on

a pilot scale. Expertise in implementing automated processes for the material synthesis under GMP-compliant conditions and down-stream services as material testing of biocompatibility according to DIN EN ISO 10993 standards and – more advanced – in complex human 3D in vitro tissue models completes the supply.

## EXPERTISE

- Biodegradable fiber, membrane and coating systems
- Biological scaffolds
- Theranostic (nano)particles
- Encapsulation
- GMP-compliant manufacturing

- Automated material production and testing

## APPLICATIONS

- Materials for regenerative medicine
- Wound management
- Tissue engineering
- Drug delivery systems
- Tumor therapy
- In vitro and in vivo diagnostics

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# IN VITRO TEST SYSTEMS

Preclinical risk and efficacy testing and the development of new products in the chemical industry are currently dependent on animal experiments. The TLC-RT develops ethically accepted 3D Tissue Models that are often more predictive compared to animal testing. These models are very close to the morphological and functional properties of human tissues. Also, we are developing new technologies such as non-invasive assessment methods or automated tissue production to improve the quality and availability of the tissues. By creating new tissue models and technologies, innovative test procedures can be established

to ensure the effectiveness and safety of new products. Especially if no standardized assay is available, TLC-RT is a unique partner for the development of customized test procedures.

## AVAILABLE TISSUE MODELS

- Skin models (epidermal, epidermal-dermal, vascularized and ex vivo)
- Cutaneous wound healing model
- Cornea
- hiPSC based blood-brain barrier model
- 3D intestinal models based on human primary organoid cultures
- Airway models
- Oncological models

## SERVICES

- Efficacy testing to support regulatory acceptance
- Preformulation testing of topically applied compounds
- Risk assessment of substances
- Development of healthy and diseased tissue models
- Gene expression and (histo-) morphological analyses
- Infection studies
- Analyses of cell-cell and cell-material interactions

## CONTACT

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# CLINICAL DEVELOPMENT

Bridging the gap between clinical research and advanced clinical therapies is our mission in the Clinical Development group at TLC-RT.

We are cooperating closely with partners in medical technology, biotechnology and the pharmaceutical industry and we conduct research on behalf of companies, diagnostic laboratories and research facilities.

Clinical research often lacks on regulatory expertise to bring your promising products and innovative treatment strategies to the patients.

Our experts in the clinical development group support your product development from very early non-clinical stages up to GMP-compliant manufacturing and up to clinical application.

Our competences in the field of Advanced Therapy Medicinal Product (ATMPs) and Medical Devices bring your therapeutic visions fast-track to the patient and to the market.

## EXPERTISE AND SERVICES

- Quality assurance measurements (set up and qualifying on material and devices, staff, process, documentation, audits)

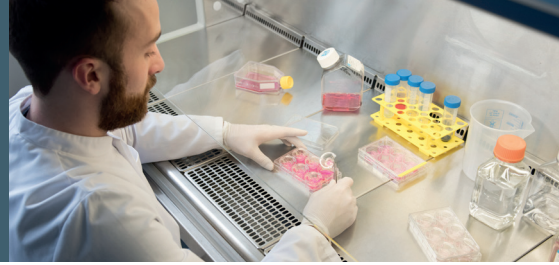
- Pre-clinical safety development (genotoxicity, cytotoxicity, tumorigenicity and biodistribution, validation of analytic procedures acc. to current regulatory guidelines)
- Manufacturing under GMP (process development, clinical GMP manufacturing)
- Regulatory guidance (GMP-compliance, risk assessment, authority guidance)

## CONTACT

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# SERVICES



## BIOACTIVE MATERIALS

- Materials development and manufacture on a pilot scale for implants, wound care, regenerative medicine, dental restoration, regeneration
- Particle development and manufacturer for diagnostics/theranostics
- Biofunctionalization, 2D and 3D structuring
- Additive manufacturing

## MATERIALS AND DEVICES

- Evaluation of material and medical device – cell/tissue interactions
- Custom-based bioreactor and incubator development for 3D tissue engineering
- Support in laboratory and process automation

- Development of therapy supporting diagnostics (theranostics)

## CHARACTERIZATION

- Product development accompanying analysis and characterization
- Production monitoring and failure analysis
- In-vitro testing
- Cell-based assays
- Live cell imaging
- Material-based consulting

## TISSUE MODELS

- Risk assessment and efficacy testing of biological, synthetic or pharmaceutical substances
- Infection studies with bacteria and viruses

- Support of regulatory acceptance
- Mode of action of new drugs and immune therapies
- Validation of new endpoints in risk assessment

## REGENERATIVE THERAPIES

- Cell therapy development and GMP manufacturing for advanced therapeutic medicinal products (ATMPs)
- Implant development and GLP safety assessment for ATMPs
- Regulatory guidance for pre-clinical and clinical development using ATMPs and medical devices

## CONTACT

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# CLIENT-SPECIFIC TEST DEVELOPMENT

For the development of new drugs or medicinal products, standard assays are often not sufficient. Especially to prove the efficacy of novel drug candidates, customized test methods are needed.

The TLC-RT is expert in the development of client-specific test procedures that are tailored for individual scientific aspects and requirements. Based on our expertise in the development of tissue models and the establishment and standardization of novel test procedures a broad range of issues can be addressed. Interdisciplinary teams of biologists, engineers,

material scientists and regulatory experts contribute to the customer specific solutions and can be consulted for individual requirements. Thereby, complex projects can be executed with a broad range of professional expertise.

## CONTACT

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## WE OFFER

- Consultancy in regard to possible in-vitro testing strategies
- Development of customized assays based on a unique portfolio of available in-vitro models and established test methods
- Established clinical and industrial network
- Support in pre-formulation development including the generation of model formulations for topical applied drugs and cosmeceuticals
- Long standing experience in the execution of industrial projects

# CONTACT

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