VSB TECHNICAL UNIVERSITY OF OSTRAVA | FACULTY OF MATERIALS SCIENCE AND TECHNOLOGY

Medical device – materials and technologies

The Faculty of Materials Science and Technology (FMT) at VSB-TUO is committed to driving innovation in medical device development, regulatory compliance, and advanced materials research. Our expertise aligns with the objectives of Horizon Europe's HORIZON-HLTH-2025-01-TOOL-05 and HORIZON-HLTH-2025-01-IND-01 calls, particularly in accelerating the translation of biotech research into innovative health therapies and optimizing the manufacturing of Advanced Therapy Medicinal Products (ATMPs).

Boosting the translation of biotech research into innovative health therapies

FMT provides specialized support in bridging the gap between biotechnology research and clinical application by offering:

- Regulatory and clinical translation support: Expertise in ensuring compliance with MDR and FDA for biotechnology-derived therapies.
- Preclinical material testing & Biocompatibility assessments: In vitro screening using advanced biological models (cell cultures, drosophila, daphnia) to evaluate toxicity and safety.
- Surface and biochemical characterization: Advanced spectroscopy and imaging techniques (Raman, FTIR, LC-MS, SEM, TEM) to analyze biomaterial interactions and degradation products.
- Predictive assessment for therapy durability: Simulating long-term performance and wear effects of biotechnology-based therapeutics.
- Integration with risk management frameworks: Ensuring alignment with regulatory strategies for smooth clinical transition and market deployment.

Our expertise supports early clinical trials by validating materials, optimizing delivery mechanisms, and ensuring that biotech-derived therapies meet stringent safety and quality requirements.

Optimizing the manufacturing of Advanced Therapy Medicinal Products (ATMPs)

FMT offers advanced research and technological support for ATMP manufacturing, addressing key challenges such as process optimization, scalability, and regulatory compliance:

- Biocompatibility & Toxicity studies: Supporting ATMP developers with biological evaluation and compliance strategies.
- Additive manufacturing & Smart automation: Enhancing precision in ATMP production through 3D printing, robotics, and AI-driven process control.
- In-process quality control & Validation: Development of standardized, regulatory-compliant assays and predictive models for batch-to-batch consistency.
- Electrochemical & Corrosion testing: Ensuring long-term stability of ATMPs under real-world conditions.
- Sustainable & Green manufacturing strategies: Implementing eco-friendly processes to reduce waste and energy consumption in ATMP production.

FMT collaborates with industry partners, healthcare providers, and regulatory bodies to streamline the pathway from ATMP development to clinical implementation, aligning with Horizon Europe's goal of strengthening the EU's health biotech sector.

FMT possesses vast expertise in preclinical assessments, guaranteeing that medical devices meet safety and regulatory standards.

- **Mechanical testing under clinical conditions** – Performing tensile, fatigue, tribological, and impact testing to simulate real-world use.
- **Validation of testing protocols** – Designing standardized, regulatory-aligned procedures in compliance with standards.
- **Predictive assessment for medical device longevity** – Evaluating material durability and failure mechanisms to support long-term clinical performance.
- **Integration with risk management frameworks** – Ensuring that testing aligns with risk-based approaches required for regulatory approvals.

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