



BRINGING MEDICAL INNOVATIONS MORE SWIFTLY TO THE PATIENT

Translation in medicine, i.e. the transfer of results from preclinical research into clinical development, is fraught with considerable hurdles. The financial costs associated with special technologies, which arise during the long period of conformity evaluation (CE) prior to the market entry of a medical product, often hinder - particularly in the case of start-up companies which are still less strong financially - the entrepreneurial decision to introduce medical technology innovations onto the market and therefore to the patient. The joint project "Translationale Fertigungsplattform Medizininnovation" (translational production platform for medical innovation), funded by the State of Lower Saxony via the NBank, aims at breaking down this barrier by means of a new structural approach for accelerating the transfer of innovation. For the first time, this provides SMEs and start-ups with simple access to existing special technologies for the manufacture of innovative medical products.

Production process validation

Within the framework of the funding project, a total of five partners, the Institute for Microtechnology at the TU Braunschweig, the Lower Saxony Centre for Biomedical Engineering, Implant Research and Development (NIFE), the HAWK University of Applied Sciences and Arts, the Fraunhofer Institute for Toxicology and Experimental Medicine ITEM and the Fraunhofer IST, are exemplarily developing a process for the efficient establishment of a production platform for a medical product. The example product is a flexible electrode, the so-called "Flextrode", which is used to identify epileptogenic tissue, i.e. nerve tissue in the brain which can trigger epilepsy.

Atomic layer deposition for medical applications

Within the framework of the project, the Fraunhofer IST is developing the coating technology on the basis of the so-called atomic layer deposition (ALD) for the production of nanometer-thick diffusion barrier layers for implants with deep-set micro-undercuts or vertical material interfaces. ALD technology is characterized in particular by the fact that highly

conformant and uniform coating systems can be deposited on geometrically complex surfaces with excellent reproducibility. The validation of the manufacturing process is performed in accordance with the DIN EN ISO 13485:2016 standard, in order to prove the conformity with the fundamental safety and performance requirements pursuant to the "Medical Device Regulation" and is divided into installation, function and performance qualification of the production lines.

Our service

The Fraunhofer IST offers both companies and universities that do not have their own corresponding infrastructure the use of the facility for atomic layer deposition—which is qualified for medical technology—within the framework of joint projects. This is of particular interest for small companies and spin-offs or start-ups, as it provides them with access to a facility approved for the manufacture of medical products, without the need for large investments. In this way, the IST contributes towards both the reduction of obstacles to innovation and the acceleration of medical innovations being brought to the patient.

1 *The ALD process is capable of coating three-dimensional objects and complex geometries with high conformity and homogeneity.*

2 *Demonstrator for neuro-transplants for the identification of epileptogenic tissue.*

The project

The described results were achieved within the “TransPlaMed” project, funded by the European Regional Development Fund (ERDF) and the Lower Saxony program area “Stärker entwickelte Region” (Stronger developed region, SER).

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