

Pressemitteilung**Fraunhofer-Institut für Biomedizinische Technik IBMT****Dipl.-Phys. Annette Maurer-von der Gathen**

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<http://idw-online.de/de/news755690>Forschungsprojekte, Kooperationen
Biologie, Ernährung / Gesundheit / Pflege, Informationstechnik, Medizin, Werkstoffwissenschaften
überregional**Strengthening innovative power of German medical technology industry:
In-vitro diagnostics, medical devices, implants****Fraunhofer Institute for Biomedical Engineering IBMT as partner in the BMB joint project
"EUREKA-AMeLie: Advanced Systems Engineering aims to reduce production costs for SMEs and increase design flexibility - Exemplary testing on application cases from the fields of in-vitro diagnostics, medical devices and implants**

The medical technology industry is facing major challenges due to digitalization, new manufacturing technologies and changes in the regulatory framework. In order to strengthen the innovative power of the SME-driven German medical technology industry, the BMBF joint project "EUREKA-AMeLie: New Advanced Systems Engineering Methods for Development Processes Using Product Examples from Medical Technology and Lifesciences", launched in October 2020, aims to create new opportunities for a structure for networked product development. Classical approaches and methods of systems engineering along the V-model will be tested for their applicability with regard to new challenges and are interpreted and redeveloped in a contemporary way, taking into account work-science aspects.

Nowadays products are becoming more and more complex - different disciplines with networked applications must work together during product development. This is especially true for new products in medical technology. In particular, small and medium-sized enterprises (SMEs) are often not sufficiently prepared for this increasing complexity. The new European Medical Device Regulation (MDR) increases the challenge of SMEs with regard to the certification of new and existing products. For example, existing medical devices have to be recertified, modified and verified or validated at great expense. Even materials that already have been certified for use in the human body must now go through the certification process again. This increases the development times and costs for individual products. New possibilities and paths for a structure for networked product development are therefore necessary to strengthen the innovative power and competitiveness of the SME-driven German medical technology industry.

Architecture framework for SMEs in the field of Advanced Systems Engineering

Over the next three years, a European consortium in the new BMBF joint project "EUREKA-AMeLie" will develop an architecture framework for medical technology SMEs and develop or revise concepts, guidelines and directives for the introduction and implementation of Advanced Systems Engineering (ASE). Classical approaches and methods of systems engineering along the V-model will be tested for their applicability and will be interpreted and redeveloped in a contemporary way by means of occupational science aspects. The developed concepts will be implemented in the form of software-based application tools and will be tested, demonstrated and validated in four real-life application cases from the fields of in-vitro diagnostics, medical devices and implants together with the participating medical technology companies. The products of all application cases have in common that previous production processes are to be replaced by printing methods in order to reduce production costs and achieve greater design flexibility. A further technical goal is to develop more robust solutions for the electrical connection of flexible thin-film electrode structures to low-resistance and less flexible supply lines.

Over 20 years of Fraunhofer IBMT expertise in use

The Fraunhofer Institute for Biomedical Engineering IBMT has been developing medical products for more than 20 years, including active implants and implant components such as electrodes based on thin polymer films. A decisive advantage over other substrate materials is their high flexibility, which corresponds very well to the mechanical properties of biological tissue.

The Fraunhofer IBMT expects that the "EUREKA-AMeLie" research project will provide new methods and tools that can be used advantageously in future bilateral projects with industry to better master the complex development of medical technology products.

In the "EUREKA-AMeLie" project, the Fraunhofer IBMT is researching processes for printing electrodes on polyurethane substrates using conductive polymers. Furthermore, a process for printing a polyimide substrate and the electrodes, leads and insulation layers is to be developed. In addition to that, the focus is on the development methodology using the example of microfluidics and its combination with printed electrodes as well as the development of an assembly and interconnection technology compatible with this system for modern cell diagnostics.

The Fraunhofer IBMT utilizes its previous experience in various projects in printing electrodes, for example for applications on the skin or for sensors in well plate format. The research group "Cell Models & Toxicology" contributes its experience in the development of customized microfluidic systems for in vitro diagnostic products, in printing electrodes for biomedical applications as well as in assembly and packaging technology.

As a research institute, the Fraunhofer IBMT supports the industrial partners of the project in developing methods of printing technology and packaging technology for the four sample products. Furthermore, it will be investigated to what extent the developed methods of ASE are suitable for this purpose and which further adaptations are necessary. The Fraunhofer IBMT forms the interface between medical applications and systems engineering, coordinates the technological development between the partners with a focus on additive manufacturing technologies (e. g. inkjet printing) and supports the adaptation of production processes to the requirements of the sample applications.

Six transnational research groups cooperate for success

In the transnational funding project "EUREKA-AMeLie", six research groups from Germany (five companies, one research institute) will work together with four research groups from Israel (two SMEs, one university, one research institute). The participating German SMEs benefit from the European cooperation with the EUREKA partners through their international business relations and access to foreign markets. Especially in the field of medical technology, Israeli companies and universities are known for their high innovative strength.

BMBF joint project: "New ASE methods for development processes using product examples from medical technology and life sciences"; Acronym: EUREKA-AMeLie

Support measure: "Mastering the complexity of socio-technical systems - A contribution to advanced systems engineering for tomorrow's value creation (PDA_ASE)" in the "Innovations for tomorrow's production, services and work" program of the Federal Ministry of Education and REsearch (BMBF)

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Multi-well plate with printed electrodes.

Bernd Müller.

Fraunhofer IBMT.