MIMEDI

Microtechniques pour les médicaments innovants

NEW TECHNOLOGICAL SOLUTIONS FOR OPTIMIZING THE PRODUCTION OF "DRUG CELLS"

COLLABORATIVE PROJECT IN THE FRAME OF THE SMART SPECIALIZATION PROGRAM (RIS3)

CONTEXT

Advanced Therapy Medical Products (ATMPs) recently emerged in order to provide new therapy solutions for patients in therapeutic impasse or for new therapies. These ATMPs rely on the use of "drug cells" exhibiting new physiological functions, biological characteristics or reconstitution properties directly inspired from natural processes occurring in the human organism.

However, fabricating these products implies using complex technologies of cell sorting, amplification, gene transduction, division and/or activation. These requirements should be met throughout the fabrication process in specific clean-room like facilities.

Due to these fabrication constraints, producing such ATMPs is extremely expensive. For an easier access to ATMPs, a new production concept is required.

PROJECT PRESENTATION

The MiMédi project aims at proposing such new fabrication concepts (MiMédi: French acronym for "Microtechniques pour les médicaments innovants"). The goal is to associate competences in microfabrication (microfluidics, acoustics, optics, automation, micro and nano technologies) and know-how in tomorrow's personalized medicine in a freestanding enclosure which can be placed at the patient's bed.

The idea is to automate the fabrication in a closed system which integrates the different fabrication steps. This should ensure reproducible processes at a much lower cost, in a fully secure way.

Practically in this bioreactor, cells samples from a patient will be treated, modified and multiplied before being re-injected to this particular patient.

Fabricating ATMPs involves developing complex protocols in order to produce biological medicines.

Based on current laboratory protocols of cell culture, sorting and selection, the fabrication requires inventing new processes to characterize not only the fabrication process but also the final medical product.

ATMPs production process analysis conducted recently established the list of every constraint related to such a production.

The first constraint concerns the absence of contamination of processed products. This implies working in an ideally closed and controlled environment. This is particularly difficult due to the lack of containers, reagents or equipment adapted to the fabrication protocol or to the sample volume. Usually, such a contamination control requires regularly sampling products in order to conduct external quality controls. This increases the control duration, contamination probability and therefore traceability requirements. Because these controls are time consuming, production continues in parallel to the controls. Consequently, the production may be stopped several days after a contamination occurred, hence increasing the production costs, delaying (and possibly stopping) the product delivery.

The second constraint concerns the complexity of the protocols and/or reagent manipulations. A large number fabrication steps must be perfectly performed according to very strict guidelines, including long, difficult and repetitive operations, which is a source of potential problems.

Also, ATMPs production is not without new and original challenges. For example, we can mention the need for more specific cell sorting (from global centrifugation to cell by cell sorting) or the combination of real-time characterization, quantification and detection of physical-chemical factors or contamination using innovative proteomic approaches throughout the fabrication.

This is why the research, the development and the placing on the market of ATMPs must be completely rethought. With this ulterior motive we propose what follows.

- Method point of view

To develop innovative and modular production methods adaptable for the wide range of ATMPs, to propose a closed system in order to avoid contamination and to increase the compactness in a cost lowering approach.

- Product point of view

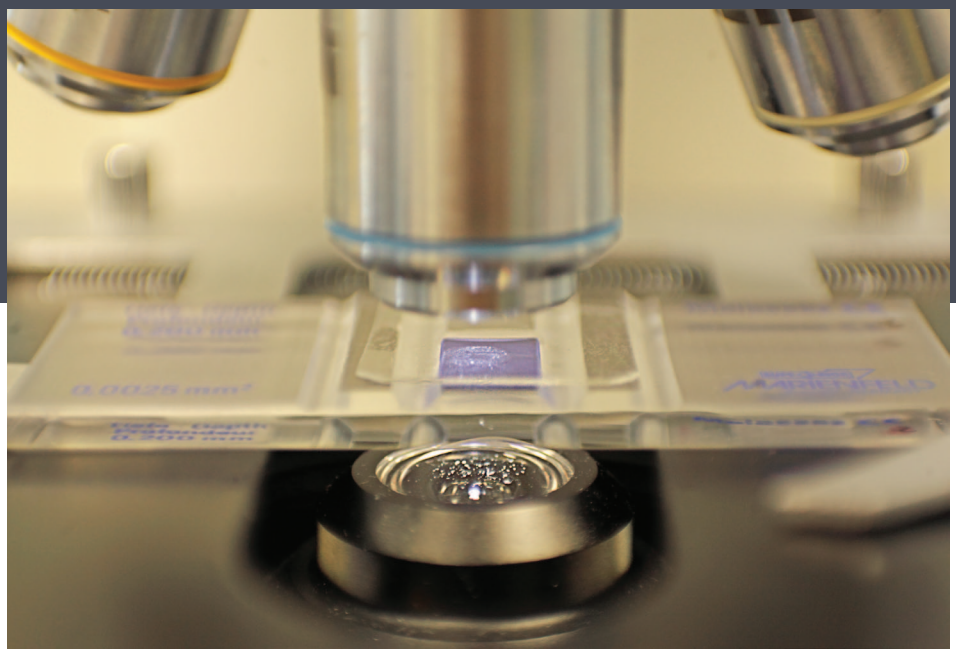
To place on the market ATMPs issued from these new production methods after pre-clinical validation (proof of concept) and clinical trials (early development).

PERSPECTIVES

This major regional project aims at optimizing the production of ATMPs in order to reduce their price. These new personalized therapies could be proposed as an alternative or in conjunction with current chemical approaches. MiMédi should make ATMPs more easily available for patients. Once placed on the market, they will help more efficiently control serious dangers to public health like cancers, inflammatory diseases or tissue repair by producing them at the patient's bed.

DURATION AND FUNDING

The MiMédi project, which involves 10 regional partners (6 companies, 3 laboratories and 1 transfer body), is part of the Smart Specialization Program and more specifically its "microsystems for health" sub-program. Mimédi was launched in January 2018 for a 4 years duration. The global cost of the project is 13.6 m€ and 75% are provided by the European FEDER program and the Regional Innovation Fund.



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