ICAB – Consortium Study Topics

Four tracks guiding to next generation ATMP production

The ICAB consortium study on "Advanced Biomanufacturing" aims to delve into four crucial tracks, addressing various facets to provide comprehensive insights. The community will also have the opportunity to influence the study by voting on additional topics.

1. Automation

There are numerous machines and devices on the market for processing and analyzing cells or other biological materials. Some of the devices already have interfaces for integration into fully automated systems, other devices are semi-automated closed systems, and some still are stand-alone systems for manual use only. The overwhelming variety often leaves end users grappling with questions such as:

- Which properties are relevant for which requirements?
- Which device is best suited for which tasks?
- How are these devices compatible with others?
- How do the individual manufacturers compare with each other?

We want to provide guidance for answering these questions. Thanks to our many years of experience in the integration of laboratory devices in production environments, we have extensive expertise to answer these questions.

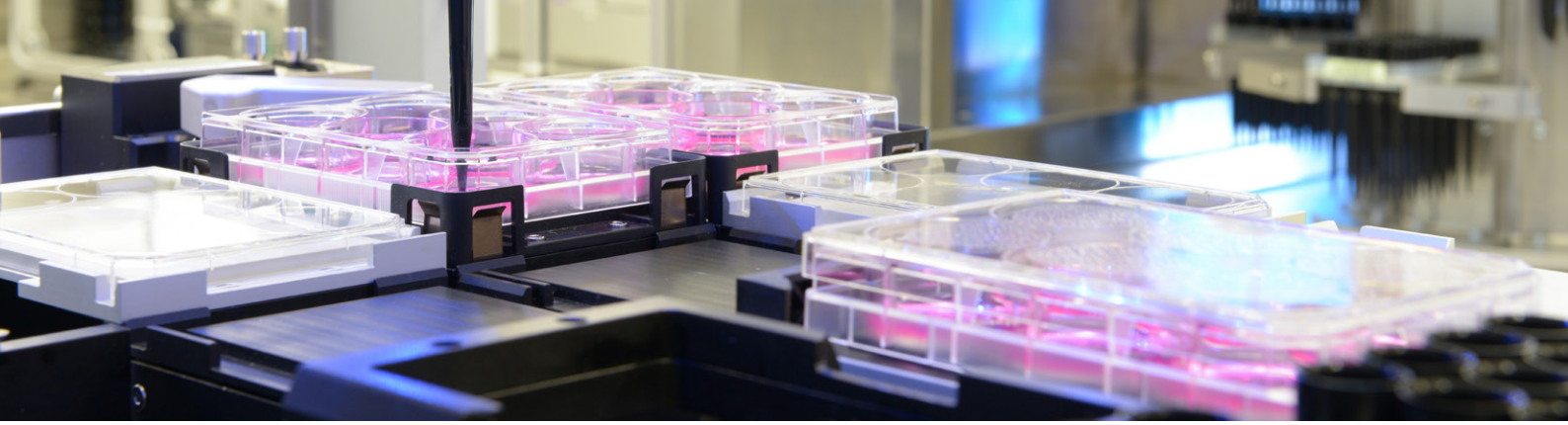
As part of the study, we will carry out a detailed technology analysis, a benchmarking and will develop a Device-Selection-Guide.

2. Digitalization

Digitalization is a fundamental necessity for automated production. Currently, many laboratory devices lack a standardized interface to communicate efficiently with each other and further software solutions.

The new OPC "Laboratory and Analytical Devices Standard (LADS)" is based on OPC UA thus builds on technologies and standards from other industries which have already been tried and tested over many years. LADS provides a solution for plug-and-play interoperability between laboratory and analytical devices. It focuses on use cases in the field of automation and service and asset management like remote monitoring, remote control, results management and condition monitoring. The seamless integration and digitalization of devices has the potential to boost the productivity of all laboratories. Nevertheless, the establishment of OPC LADS is still in its infancy.

We have been following this development for some time and would like to analyze the following points in more detail as part of this consortium study:



- What potential does the technology bring and which problems are being solved specifically?
- What are the current challenges and hurdles for both device manufacturers and users?
- What are the differences to other interface standards such as SILA?

3. Resilience

The development of new ATMPs starts in the laboratory in small quantities. As clinical trials are entered, more and more products are needed for testing purposes. By Clinical Phase 3, companies must seriously consider scaling up their manufacturing process. In general, the earlier scalability is considered in the development process, the more economically it can be implemented. In addition to scalability, there are several other aspects that need to be considered in product and production planning to ensure resilient manufacturing. These will be examined in this study using real-world use cases to answer questions such as:

- How do I plan the scaling of my production?
- How do I continuously monitor the economic potential of my product during development?
- What strategies and best practices are established?

4. Sustainability

Currently, sustainability factors play a minor role in the development and production of pharmaceuticals. Single-use products and energy-intensive processes are the norm in bioproduction. However, stricter regulatory requirements will change this in the near future. The desire to minimize the ecological footprint is becoming increasingly important. In the field of bioproduction, conflicts with medical regulations pose challenges to sustainable production practices. Another problem is the difficulty in obtaining relevant data about the product and its production for determining for example the emission of CO_2 equivalents.

In our consortium study, we will approach this topic with three main questions:

- What do the regulatory authorities in the EU and the USA currently and in the future require for the production of pharmaceuticals?
- Which sustainability-related Key Performance Indicators (GreenKPI) exist and how can they be accurately determined for individual products?
- What are the approaches to transform a company so that GreenKPIs are continuously monitored and documented in a compliant manner? And how can this data be used to optimize product development?

Within the scope of our consortium study, all these topics will be examined and comprehensive results will be generated, which will be made available to the study participants exclusively. In addition, a community voting will allow the participants to vote for the topics which are for them of the highest relevance and should be prioritized within the study.

If the brief introduction of these topics has piqued your interest, we look forward to your registration and the upcoming start of the consortium study. We also welcome any additional ideas and impulses you may have.

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