// **The changing face of process** requirements: challenges, **opportunities** and risks for **new** product classes. ///

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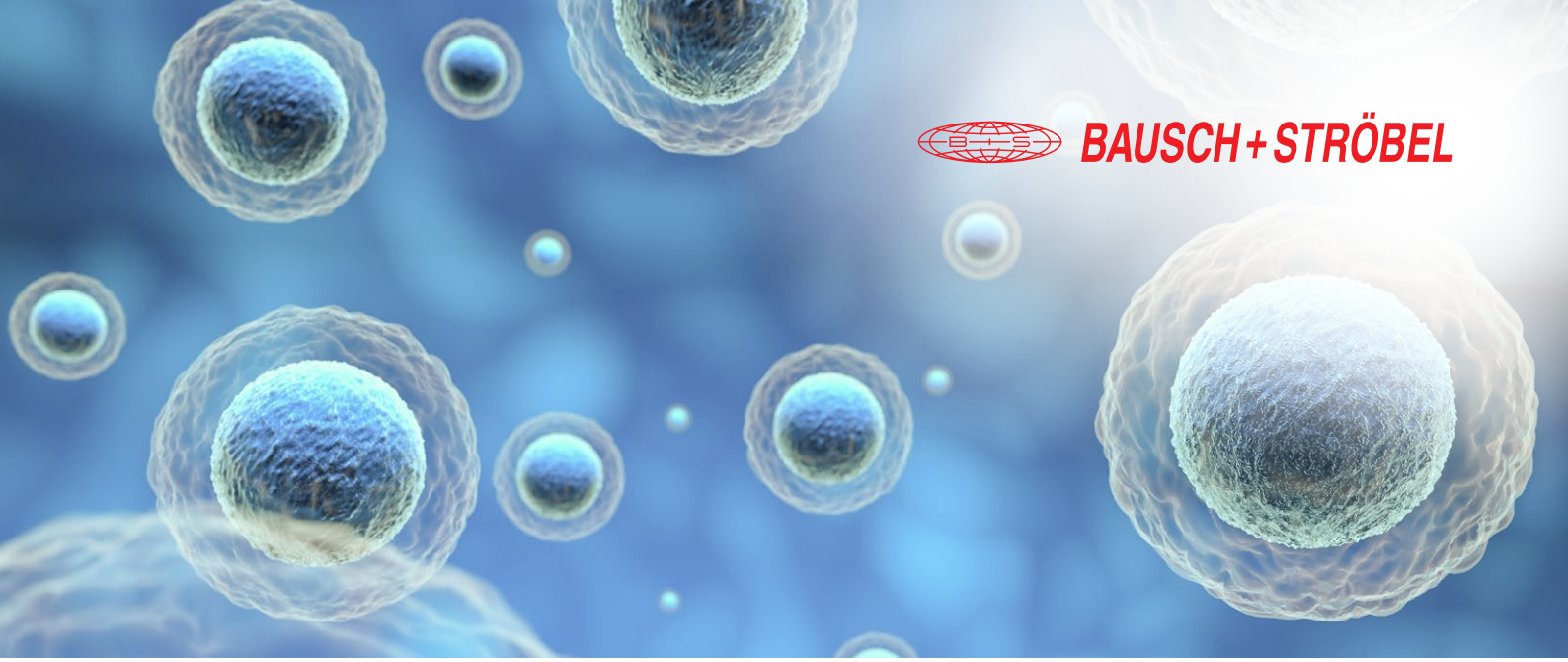
The changing faces of process requirements: challenges, opportunities and risks for new product classes.

They can help where conventional drugs cannot: Advanced Therapy Medicinal Products (ATMPs) have the potential to make previously incurable diseases treatable. To deliver these heterogeneous drugs to patients as quickly and safely as possible, flexible and modular processing platforms are needed more than ever before.

Across Europe, there are currently only ten approved ATMPs. Gene and cell therapies as well as bioengineered tissue products are classed as ATMPs. Despite its small share of the market at present, this new class of drugs is very exciting because it promises cures for rare, often life-threatening diseases[1,2]. The high level of interest in this class of drugs is also reflected in its projected CAGR (Compound Annual Growth Rate) of up to 25 %[3] and in the large number of clinical trials that have been conducted worldwide (over 1,000[4]).

It is worth noting that around 48 % of all new developments today originate from academic research.[5] The production of ATMPs at research institute level is a complex process often involving a number of laborious manual operations and open processes. The high complexity of the production process means that cell therapies and cell-based gene therapies come with a high manufacturing cost. The cost of a single course of treatment often runs to six or seven figures.



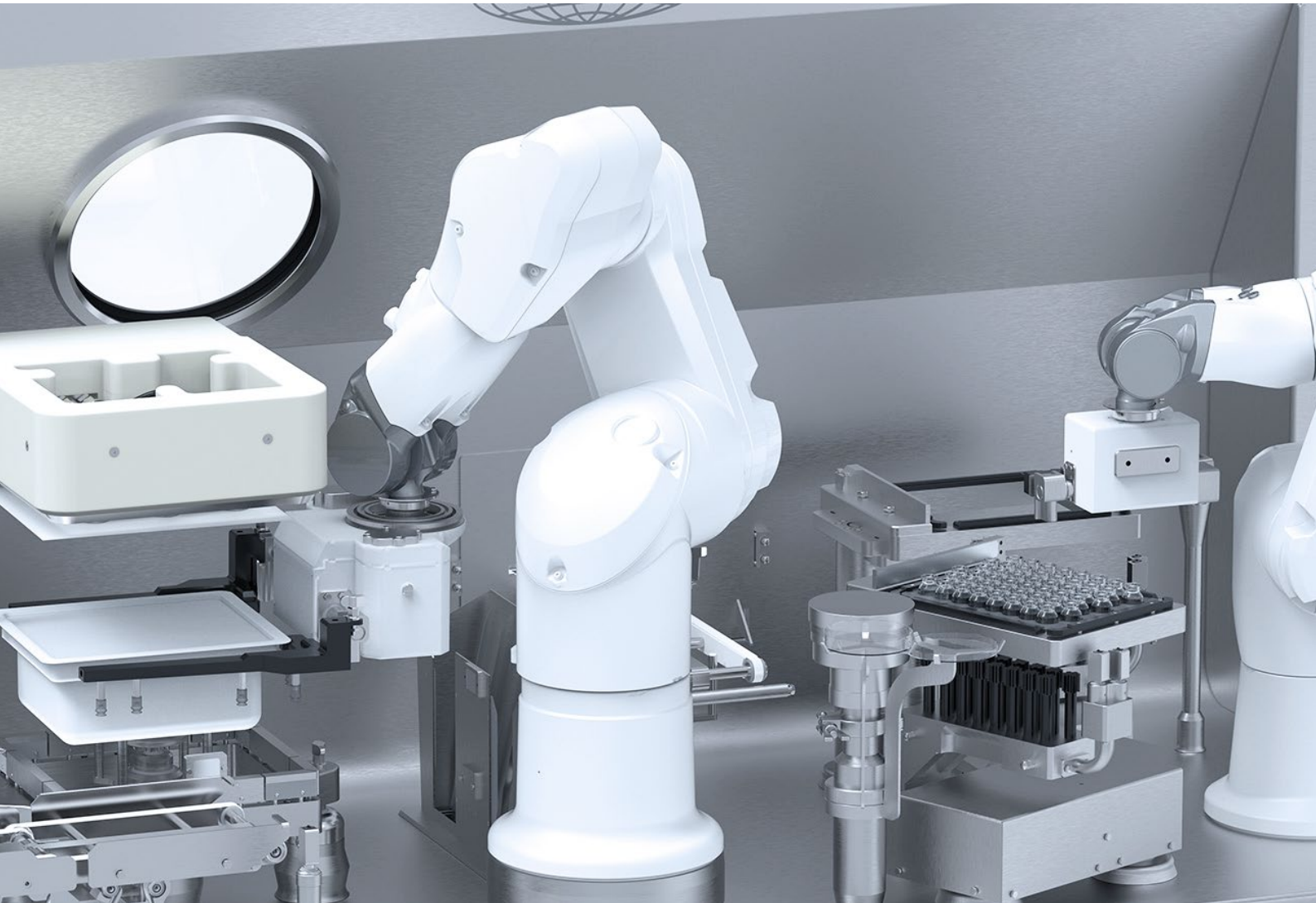
To unlock the full potential of these therapies and to quickly make them available to as many patients as possible, alternative and innovative production solutions are needed. The object is to process as many products as possible from this highly heterogeneous class of drugs in one and the same setting. That is why processing platforms need to be both modular and flexible. Ideally, such platform solutions will already be in use in clinical trials so that “time to market” is not unduly delayed by process transfer between academic research and industrial manufacturing. Standardized production solutions built upon adaptable platforms would provide maximum flexibility and shorter delivery times. However, there are several challenges that would need to be addressed when implementing such production solutions:

+ Complex product composition and input material heterogeneity
+ Complex production processes involving critical process parameters (cPPs) that are not fully understood
+ The extremely high demands this class of drug places on the process environment (process duration, cooling, shear forces, material interactions, etc.)

Advanced Therapy Medicinal Products (ATMPs) have the potential to make previously **incurable diseases treatable**.

Automation is the key to the **future**

Automation caters to the special demands of these therapies, as it allows individual work steps and even entire processes to be implemented within a closed system, maximizing reproducibility and minimizing contamination risks. As the production of therapies often requires lengthy incubation phases without operator intervention, closed production processes could also be parallelized. From a biological standpoint, there is a case for focusing on specific subproduct classes of ATMPs to expeditiously yield insights into the actual process-product interactions. Allogeneic cell therapies reduce the challenge of input material heterogeneity because, although they are not patient-specific, they accurately reflect the complexity of the process and the final product. Looking ahead, these therapies will also become available as off-the-shelf therapies when production is scaled up. It is anticipated that even allogeneic CAR-T-Cell therapies will come onto the market in the foreseeable future. The production of allogeneic therapies could, in turn, open up new opportunities for the production of even more complex therapies.



In-line acquisition and evaluation of critical process parameters could be achieved in the future with the aid of (deep) machine learning. All the data collected could then be used to flexibly optimize the production of ATMPs, thus mitigating the complexity of both the process and the product.

At Bausch+Ströbel, we create reliable machine concepts with a high degree of automation for you. Would you like to discuss this topic with us? Contact Andreas Bühler to find out more about our automation solutions.
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Questions? Let's talk!

If you would like more information about this topic please feel free to contact us.

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