// **Automation** in pharmaceuticals manufacturing: **new technology** still has much to **offer**. ///

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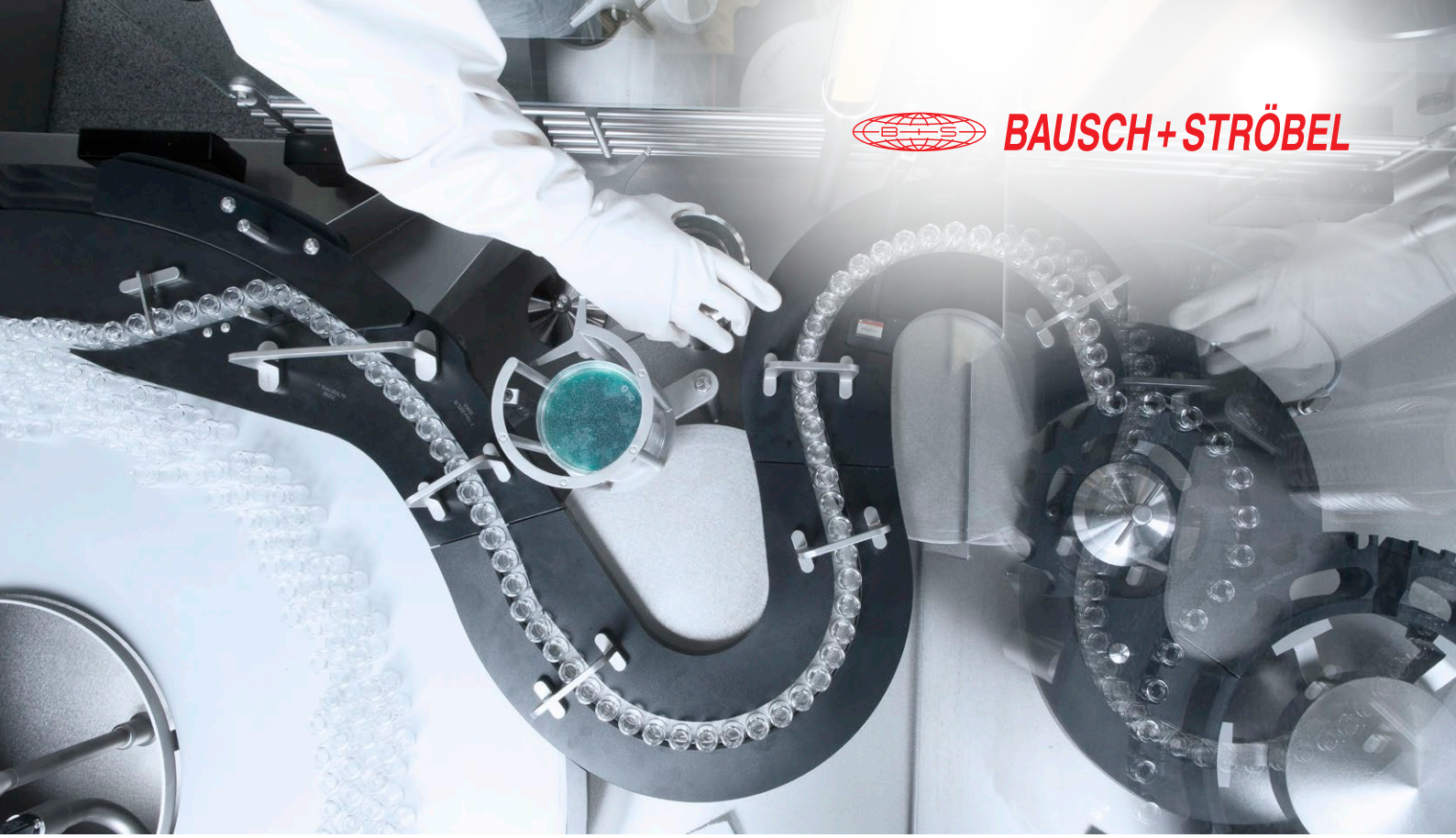
The human factor as a source of error

Thanks to an already high level of automation in the aseptic filling and packaging systems used in pharmaceutical production, it has been possible in recent decades to produce medicines in large quantities quickly, safely and at affordable prices. However, new technology and new methods still have considerable potential to make processes safer, faster and more efficient in the future.
This applies equally to large and small scale production - although the challenges in both areas differ to some extent.

The latest generation of biotech drugs - pharmaceuticals for gene and cell therapy - presents new challenges for production technology and especially the automation of specific types of cell culture.

The framework conditions for the production of biotech drugs (pharmaceuticals derived from gene and cell therapy) are very different to those for conventional drugs. The most striking difference is the low production volumes and the resulting high frequency of batch changes. In research and development, there is a clear trend towards customized products, which in extreme cases can be manufactured in batch sizes as small as 1 (autologous products). Even today, these drugs are still mainly produced and filled on manual or semi-automatic systems, with all the associated drawbacks.

Automation in pharmaceuticals manufacturing: new technology still has **much to offer**. Today, there are still some operations that have to be performed by machine operators.



Machine manufacturers working to increase automation levels

Right now, machine manufacturers are collaborating with experts across industry in a concerted effort to increase automation levels and find technical solutions to the unique challenges facing the production of gene and cell therapies. Special platforms are currently being developed to make drug processing safer, faster and more cost-effective.
In this case, speed is the key: to process the cell material sourced from the patient into a drug for therapeutic use as quickly as possible (vein to vein).

Whether it is large-scale production (e.g. vaccines or insulin) or small batches, process reliability always takes precedence over efficiency and speed when manufacturing pharmaceuticals.
That is because the manufacture of pharmaceuticals is subject to strict compliance with exacting requirements and guidelines. Errors, be it the contamination of drugs, incorrect filling quantities, or even an incorrectly applied label, can have grave consequences for patients' health, and may even cost lives.

In aseptic production processes, pharmaceutical equipment is usually separated from the operators by containment systems such as isolators. An operator can intervene manually in the aseptic production process by using integrated glove ports or by opening the containment system. The idea, though, is to keep operator intervention to an absolute minimum. Manual intervention not only slows down the production process, e.g. because the equipment has to be cleaned and sterilized again before it can be put back into operation. It can also necessitate discarding any containers that have not yet been sealed (e.g. if the glass has been damaged or the operator had to reach over the open vials).
In general, it increases the risk of contamination.

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Unlocking the untapped potential of robotics

With the use of improved testing and monitoring technology, and not least robotics, automation has already made pharmaceutical production safer and more reliable in many ways. Before robots can actually be deployed in the pharmaceutical sector, they have to meet a whole host of additional requirements designed to ensure that they also work under cleanroom conditions. These range from the right surface coating and the development of suitable grippers to the sealing of certain areas. Even the programming has to meet certain criteria, e.g. movements have to be executed in such a way that as few particles as possible are released and, above all, do not contaminate the containers to be filled.

At present, the applications of cleanroom robots are mainly confined to handling and provision or transport of packaging materials. It is safe to say, however, that cleanroom robots will have many more potential applications in the future, including biomonitoring, cleaning and changing size parts. One of the key challenges in this regard is the fixing of problems such as jammed containers. Even today, such problems, due to their mostly unpredictable nature, are exclusively handled by machine operators. But here, too, solutions are already under development.

The goal: to separate the operator from the process

There are several advantages to separating the operator from the process: firstly, as explained, it further reduces the risk of contamination; secondly, it enables automated processes to be documented more reliably than the manual actions of operators. For instance, causes of error can be traced and eliminated more quickly and processes reproduced more easily.
And last but not least, it protects the operator by minimizing exposure to the cleanroom atmosphere and prevents people from coming into contact with highly potent substances.

Eliminating the need for operator intervention is also to the advantage of machine design. There is no need for glove ports and thus also for cleaning and inspection. When configuring individual stations, even more attention can be paid to hygienic design, i.e. optimal air flow and cleanability of the system, as the accessibility of individual stations via the glove ports is no longer a factor to be considered.

In summary, robotics looks set to revolutionize the production of pharmaceuticals in the near future - whether by improved product quality, machine operator safety or process monitoring - not least because it opens up entirely new possibilities for plant design.

Questions? Let's talk!

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

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