**Packaging of medicinal products: Which trends are important for pharmaceutical producers and machine manufacturers post-covid**

*Even after the Corona pandemic has subsided, the demand for pharmaceuticals is increasing. But the requirements are changing - and this has an impact on production equipment. Machines for packaging medicines are not exempt from this. And their manufacturers are only spurred on by this.*

Biopharmaceuticals are the real mimosas: heat, moisture, oxygen ingress or simply just the wrong light can cause the sensitive drugs, which are made from living organisms or cells, to lose their effect. This became particularly clear in the Covid pandemic: the new mRNA vaccines from Biontech-Pfizer and Moderna require sophisticated packaging and logistics concepts to ensure storage temperatures between -60 and -80 °C, for example. And although manufacturers are working feverishly and also successfully on less sensitive active ingredients - packaging remains an essential element in the fight against past and future pandemics.

The example of vaccines only highlights the importance of pharmaceutical packaging. Every second new drug approved in the EU is now produced using genetic engineering, is particularly sensitive to environmental influences and must be packaged accordingly. In addition, there are increasing regulatory requirements for production technology, such as Annex 1 to Good Manufacturing Practice (GMP guidelines), which was finalised in 2022: This will newly regulate the sterile production and the filling and packaging of medicinal products - with the aim of reducing contamination risks for the medicine.

**Pharmaceutical market growing, machine market even stronger**

No wonder, then, that the market for pharmaceutical packaging machines is growing disproportionately - even more strongly than the pharmaceutical market as a whole. Market researchers from Evaluate Pharma, for example, expect the global pharmaceutical industry to grow by 6 % annually to 1.6 trillion US dollars between 2022 and 2028. In parallel, the market for pharmaceutical packaging will grow by 8.24 % and that for pharmaceutical packaging machines by 7.5 % per year - according to the expectations of the market research company Mordor Intelligence.

At the same time, the rising costs for filling, packaging and labelling medicines are being met by declining revenues for pharmaceutical manufacturers. After the vaccine boom of the Corona years, the pharmaceutical industry is not only struggling with declining sales, but also with the cost explosion due to the energy crisis. On the stock exchanges, the market value of biotech companies has halved, while at the same time the prices for inputs - including chemical precursors - have risen significantly in 2022. The pharmaceutical industry has come under particular pressure here because - as in the EU, for example - it has to sell some of its products at a fixed price.

These and other trends are now also reflected in the enquiries and specifications for packaging machines: Whereas in the past, for example, filling and sealing machines with high output and lines designed specifically for one drug were demanded, today the desire for flexible lines that can be quickly - and if possible automatically - converted to new products and other packaging formats dominates. The trend towards smaller batches plays just as much a role here as easier handling. It is noticeable that the desire for flexible production processes is no longer only expressed by contract manufacturers, so-called CMOs, but also by original manufacturers.

**Flexible filling and packaging processes required**

This development is clearly illustrated by the example of injectable preparations, the so-called injectables. Already in the years before the pandemic, machine manufacturers had registered a strongly growing demand for ready-to-fill syringes. The enormous demand for vaccines in the Corona years 2020 to 2022 had recently caused a revival of bulk packaging such as vials, but in the meantime the share of "ready-to-use" (RTU) syringes is rising again significantly. With RTU syringes, for example, the medicine is filled directly into a sterilised syringe. This not only reduces the risk of contamination during preparation and administration, but also avoids dosing errors.

The customer's desire to find better packaging solutions for less money is therefore driving the machine manufacturers. And one keyword runs through the description of most new developments: Flexibility. Syntegon, for example, has developed the Versynta flexible filling system as a platform with which biopharmaceuticals can be filled both in RTU syringes and in bulk packaging in the isolator. To significantly reduce project times, supplier Groninger also relies on flexibility with the Flexfill concept, but combines it with standardised modules that are also housed in the isolator or RABS. Bausch+Ströbel also relies on modularisation and has radically reduced the number of format parts in the new CombiSys line. This makes it comparatively easy to convert the machine from vials to RTU packaging, for example.

**New transport systems and digital technologies**

Bausch+Ströbel kills two birds with one stone with a new magnetic transport system that moves the packaging material through the machine: In contrast to common drives, a fixed cycle time is no longer required, which increases flexibility. At the same time, the magnetic drive makes wipers and bellows seals unnecessary, thus eliminating a cause of contamination in the sterile area. Optima has also addressed the transport of packaging materials in the machine: With the new FillCell formatless transport system, the main aim is to increase product yield. Especially with expensive active ingredients, it is important to avoid losses during machine start-up.

Machine manufacturers are taking this requirement into account with new dosing and filling systems, but also optimised transport, monitoring and labelling solutions. Digital technologies are playing an increasingly important role here: this begins with training operators with virtual reality goggles on digitised equipment, extends to the seamless recording of production parameters in the production process, and ends with the evaluation and visualisation of key figures such as Overall Equipment Effectiveness (OEE), which are becoming more and more important in the growing competition of the pharmaceutical industry.

The Körber Group, for example, has dedicated itself to this topic, using its Manufacturing Execution System (MES) to analyse the operational efficiency of biopharmaceutical manufacturing processes on the basis of different and previously unnetworked data. Among other things, this should enable biopharmaceutical manufacturers to significantly accelerate their time-to-market. Uhlmann Pac-Systeme networks machines and entire plants of any manufacturer via interfaces with a new software (Pexcite), thus enabling centralised monitoring and control. In addition to looking at line efficiency and planning set-up times, this also makes it easier to comply with regulatory obligations.

**Robots in glove-free isolator, scalable parenterals production**

The automation strategy of many manufacturers now includes the use of robots - not only at the end of the line, for example to stack packaged medicines on pallets, but already in the sterile isolator. Machine developers are benefiting from the fact that, on the one hand, the range of cleanroom-suitable robots is steadily growing, while at the same time the costs for robotics are continually falling. In this way, automated solutions are increasingly replacing the otherwise necessary gloved interventions on the isolator. This is because in the demanding sterile production of high-quality medicines, human intervention is increasingly being perceived as a nuisance and is being replaced by technical solutions.

At the machine manufacturer IMA, the gloveless aseptic process in the isolator is being promoted under the name "Injecta". But the machine manufacturers already mentioned are also pursuing the trend towards aseptic filling without human intervention with their own solutions. The development is consistently implementing the requirements of the new GMP Annex 1. In many places, this also includes dispensing with the time-consuming sterilisation of the primary packaging material by using sterile packaging materials.

In general, the packaging of sterile preparations for injection and infusion (parenterals) is very demanding, and the machine technology is expensive. This becomes a problem especially when the success of a drug and its required quantity are not yet known. The folding box manufacturer Faller Packaging has developed a scalable solution to this problem together with the machine manufacturer Schubert-Pharma: This starts with the initially manual loading of pre-prepared folding box packaging. As soon as demand increases, cobots are used until the process is finally switched to a fully automatic top-loading machine.

**Sustainability becomes important**

But it is not only the development of the processes around the primary packaging of medicines that follows the new requirements of the pharmacists. Developments in secondary packaging in folding boxes, trays and cartons are not standing still either. In addition to flexibility and product safety, important trends here are resource optimisation and low CO2 emissions. This is because the topic of sustainability is also increasingly finding its way into companies in the pharmaceutical industry via CSR and ESG criteria.

In order to improve the recyclability of packaging, Uhlmann, for example, is increasingly relying on packaging made of monomaterial. With the Parenteral Tray Center, the manufacturer has recently also introduced a flexible "direct-in-carton" solution that can pack ampoules, vials and syringes both in cardboard trays made of monomaterial and in conventional plastic clamp blisters. Recyclable packaging places new demands on machine manufacturers. Close coordination between machine and packaging supplier is therefore important. At Faller Packaging, for example, the approach is called 3R: Redesign, Reduce, Recycle: in addition to the use of new recyclable mono-materials, this also includes testing existing products and processes with the aim of minimising the use of raw materials and energy.

But labelling technology is also evolving. While in the past decade this was mainly characterised by the fight against counterfeit medicines, other requirements are now coming to the fore with regard to biopharmaceuticals. One trend here is the development of new labelling solutions with sensor functions. The so-called "smart labels" use printable indicators that can be used to monitor the correct storage of a medicine or the correct application temperature. If the heat or UV light exposure of the medicine exceeds a defined value, the indicator on the packaging changes colour. Another piece of the mosaic to be able to safely control biopharmaceutical mimosas in everyday life.

*The author: Armin Scheuermann, chemical engineer and freelance trade journalist*

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