INTERVIEW

5 QUESTIONS FOR CHRISTIAN KOLLECKER

In August, Harro Höfliger's new platform for aseptic bag filling was launched. Christian Kollecker, Director Aseptic Technologies, answers the questions about "baXeptic".

1

Aseptic machine engineering is nothing new at Harro Höfliger. What makes baXeptic special?

The new word mark baXeptic is made up of the words "bags" and "aseptic" and already gives an indication of the two main aspects: The aseptic filling of liquid products into pre-sterilized bags, which must not be contaminated under any circumstances during the filling process. More and more complex pharmaceutical products with large molecules and high filling volumes are administered via infusion. Existing process solutions, however, often do not meet the requirements for flexibility and GMP-compliant hygiene design. With baXeptic, the customer's application determines the technical solution and this is where we come in. We can draw on a wide range of proven technologies and more than 30 years of experience in the design and construction of aseptic production machines.

2

What types of therapy do you have in mind?

Generally speaking, the market for aseptic bag applications is growing worldwide. In particular, we are targeting biopharmaceuticals and new therapies with gene- and cell-based ingredients that have great potential to cure chronic and serious diseases. It is a foregone conclusion that terminal bag sterilization after filling is out of the question for biomolecules and livings cells. Due to the small batch sizes, the production and filling of personalized medicine requires a maximum degree of product and process reliability.

3

Keyword process reliability: How do you ensure it?

First and foremost baXeptic is about meeting customer requirements which are usually determined by the product and the primary packaging material. At the beginning of the technical conception, we are in close contact with the customer, so that we can combine their process experience and knowledge about product and primary packaging material with our expertise in building aseptic bag filling lines. This is the basis for achieving a robust and reliable solution. Not only the filling process itself is important but the overall understanding of processes from bag feeding to handling, filling and sealing, all the way to process analytical testing. This understanding must then be transferred to an aseptic system, taking into account the applicable standards and regulations. In the laboratory of our Pharma Services department, liquid media can be tested in order to find optimal processes at an early stage. Our customers benefit from our philosophy "From lab to production", which means scalable processes. At the same time, baXeptic also enables scaling-out, where multiple small-scale lines lead to increased production capacity.

4

Are there special baXeptic machines?

Invariably, the customer's product determines the design, and the end product of our joint effort is always a tailor-made system. This is also due to the fact that there are hardly any standardized bag applications. baXeptic symbolizes the general method how we develop and implement machines for aseptic bag filling. We use the technology program of Harro Höfliger and integrate aseptic key processes into proven machine platforms that can be flexibly configured. This includes our established rotary and oval motion machines, but also barrier systems with isolators or RABS with glove ports, sophisticated concepts for product and operator protection, the use of robots for bag handling as well as the appropriate processes for cleaning and decontamination.

5

What regulations must be observed in aseptic manufacturing processes?

The manufacture of sterile products is subject to strict requirements which ultimately ensure patient safety. The most important regulations are specified in Annex 1 on sterile production of EUDRALEX Volume 4 of the EU GMP Guide. The revised final version was published in August 2022 and will will come into force on August 25, 2023. Harro Höfliger has already devised a detailed concept for GMP-compliant hygiene design, for example about material and surface requirements, cleanability and sterile environments – which was documented in white papers. Companies that take the initiative now to prepare for the new regulatory framework, can gain an important lead in pharmaceutical engineering.

baXeptic

Helmar Lünig