Emerging Gloveless Robotic Technologies in Aseptic Manufacturing for Personalized Cytotoxic Drugs

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This article discusses trends for the pharmaceutical manufacturing industry in the following years. A robotic solution for the next generation of drugs is introduced and its main advantages are presented. The concepts integrated into this innovative solution are explained and technical details are provided.

Pharmaceutical manufacturing of the future

The blockbuster-model that was driving the pharmaceutical manufacturing industry in the last several decades has almost ended. Massive production, large batches, high speed lines have been designed to supply the patients with "multipurpose" small molecules drugs to cover the huge worldwide demand of health for the most common diseases.

The next generation drugs will focus on the single patient and bespoke to cover the individual health demand. For instance, biotech products and large molecules are the most promising therapeutic means for treatment of different kinds of cancer.

The pharmaceutical blue chip companies are investing most of their R&D budget to develop personalized cytotoxic drugs. This means that pharmaceutical manufacturing leaders must manage smaller batches, shorter runs, greater complexity, more volatile demand and ever increasing quality expectations.

According to this scenario and considering that at least 50% of these new drugs are injectable, many manufacturers, including Fedegari Group, are developing an advanced compact solution for aseptic fill/finish of cytotoxic drugs. The new equipment is a gloveless isolator in which all the operations are handled by a GMP-compliant stainless steel robot arm.

Why a robotic solution?

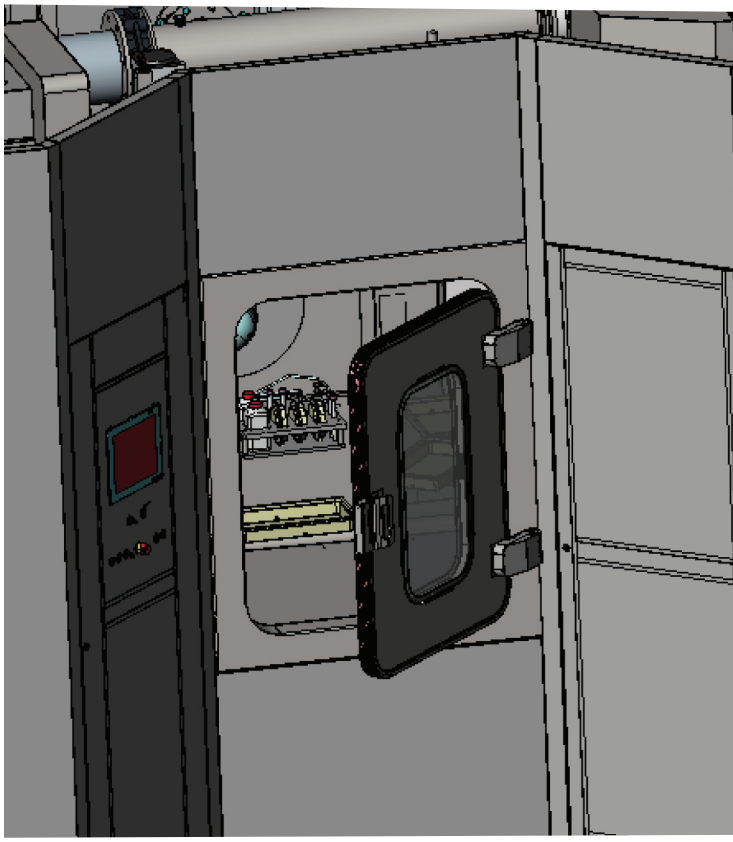
The answer is that an environment free of human presence is expected to be cleaner. Furthermore, considering the dangerousness of handling cytotoxic drugs, a robotic solution increases process safety as the operator is not directly involved in the manufacturing equation. The isolator has been sized for phase II and III clinical trial batches, typically 1.000 vials of 20 ml. The unit is composed of an isolated chamber holding one or more 7 axis hollow wrist GMP robots connected to an autoclave capable of steam sterilizing or decontaminating the primary packaging components. The system foresees the use of pre-sterilized vials or syringes with the relevant closures. All the tubs are treated before entering into the isolator chamber for the fill/finish operations.

A peristaltic pump operates the filling and all the filling line is disposable and can be safely dispensed after the fill/finish operation. At the end of the process, the whole isolator can be washed down to remove all the product residuals.

All the above mentioned operations are possible because of the brilliant capability of the robotic arm. The main features of the robot are:

- AISI 316 L stainless steel construction
- 7 axis arm
- "A" grade design with low particle shedding
- IP67 rating, high pressure and temperature wash down resistant
- fully compatible with H_2O_2 vapors
- hollow wrist design (no external wires).

The concepts integrated into this innovative solution are the handling of pre-treated primary packaging components instead of bulk components; the transfer of all materials operated by the robot therefore replacing a conveyor system; the static material accumulation against a rotary table; stoppering of the vials in static conditions versus a star wheel or in-line arrangement of the vials; shortest equipment setup time due to the absence of any active mechanical fixture.



Conclusions

To summarize, this new technology can be the right answer to the following issues:

- Nothing can be considered truly innovative if it requires human intervention within a sterile manufacturing.

- Complexity is always the enemy of a reliable system.

- Less moving parts means less generation of particles, reduced probability of jamming and lower maintenance/operating costs.