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ROBOTS IN ASEPTIC FILL-FINISH — A SWISS ARMY KNIFE SOLUTION?

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ABSTRACT

Robotic systems in aseptic fill-finish have evolved from simple transport solutions to highly integrated, GMP- and Annex 1-compliant platforms supporting complex handling and control tasks.
Regulatory expectations, particularly regarding cleanability and first-air protection, are driving optimized robot design.
A clear trend is the reduction or elimination of glove interventions through advanced automation, up to fully gloveless isolator and workcell solutions.
Combined with automated material logistics and supply chains, robotics are a key enabler for improved product quality, reduced contamination risk, and future-ready facility designs.

Fig. 1: Fully automated fill-finish setup – "Lights out Production"
Source: Pharmabotix AG, CH-Seengen

EVOLUTION OF ROBOTIC SYSTEMS

Robotic applications are not a new invention, neither within the pharmaceutical industry nor within critical Grade A environments. First solutions were already implemented in the early 1990s, particularly in Western European countries. What most of these early solutions had in common was a, from today's aseptic perspective, rather limited level of compliance and functionality.

In those early years, the focus of robotic applications was often limited to transport-related activities. Robots primarily replaced traditional transport systems (e.g. walking beam conveyors) to move syringes, vials or other primary containers within the machinery.
Over time, vendors expanded robotic functionalities beyond pure transport. Basic tasks such as in-process-controls (IPC), handling of tubs, Tyvek® covers, and nests for ready-to-use (RTU) packaging materials, as well as other repetitive motions, were gradually implemented.

GMP, GRADE A AND ANNEX 1 READINESS

In parallel, robotic systems evolved significantly with respect to Good Manufacturing Practice (GMP) and aseptic compliance.
Applications in Grade A (ISO 5) environments require the highest standards for cleanability and disinfection. Modern robotic systems must be compatible with pharmaceutical cleaning agents as well as common decontamination media such as hydrogen peroxide (H_2O_2). Surface quality and chemical resistance therefore represent key design criteria.
With the increased requirements introduced by the Annex 1 update in 2022,

KEY FACTORS AND ENABLER FOR ROBOTICS IN ASEPTIC ENVIRONMENTS

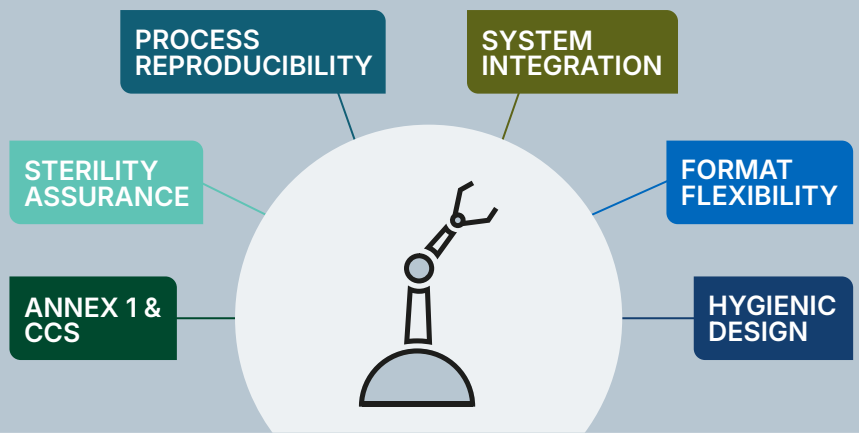

Fig. 2: Key factors and enabler for robotics in aseptic environments

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particular focus has been placed on the concept of first air within barrier systems. HEPA-filtered air should not be interrupted by equipment before contacting exposed product and product-contact surfaces. This creates specific challenges, especially for 4- and 6-axis robotic systems. Robot movements and handling sequences must be optimized to avoid airflow disturbance above open containers. Consequently, the use of Computational Fluid Dynamics (CFD) simulations as well as airflow visualization and testing should already be applied during the development phase of new solutions.

GLOVE-REDUCED AND GLOVELESS APPLICATIONS

Most glove interventions on modern filling lines are linked to environmental monitoring activities or troubleshooting. Technical solutions such as automated settle-plate change systems and other routine intervention concepts are increasingly being implemented.

Fig. 3: Gloveless filling with focus on first air compliance
Source: Syntegon Technology GmbH, D-Crailsheim

Every operator intervention that can be reduced, or ideally eliminated, represents a clear gain in pharmaceutical and aseptic quality. However, aseptic setup of direct and indirect product-contact parts (e.g. filling system or stopper sorting related elements) remains one of the most challenging operations in closed barrier systems.

New fill-finish machine concepts therefore increasingly aim for designs with a limited, or in the best case no, need for glove interventions.

Leading developments in this field are gloveless isolator concepts, often referred to as workcells. In this approach, the entire aseptic fill-finish process is fully decoupled from human intervention. All process steps from container supply and filling to IPC, container closure, and monitoring activities are performed by robotic systems within the cell. In addition to compact integration of robotic units, the implementation of flexible, application-specific tools and grippers is essential.

AUTOMATION OF SUPPORTING PROCESSES

Supporting processes surrounding the filling line represent another important element in overall automation concepts. Reducing personnel presence, movements, and manual handling in adjacent Grade B, C, or D cleanroom areas through automated logistics for components (glassware, stoppers, caps, etc.), consumables, as well as filled and closed containers, is seen as a key opportunity to improve efficiency and further strengthen Annex 1 compliance.

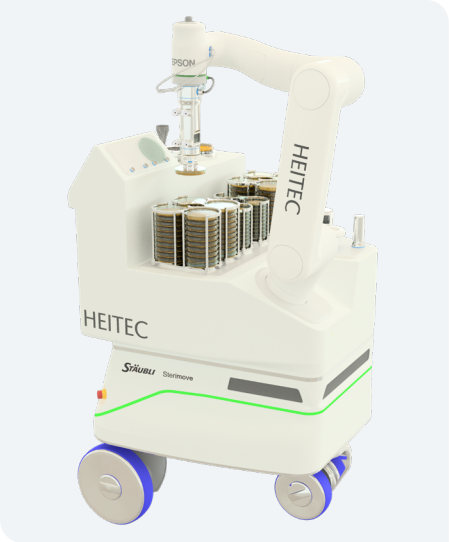

Fig. 4: Mobile GMP-compliant cleanroom robot
Source: HEITEC AG, D-Erlangen

IMPLICATIONS FOR FACILITY DESIGN

Automation of the entire supply chain around the fill-finish process, from incoming goods at the warehouse through to shipment of inspected and finally packed products using Automated Guided Vehicles (AGV) and automated warehouse solutions is expected to be one of the main future drivers of facility design.

WHAT'S IN IT FOR YOU

Comprehensive process knowledge and understanding of fill-finish operations and their supporting areas are essential for modern and efficient pharmaceutical manufacturing. The implementation of robotic solutions and highly automated concepts in aseptic processing facilities represents a powerful lever for improved product quality and more robust, sustainable processes.

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