WHITE PAPER

Redefining aseptic transfer

# Annex 1's influence on aseptic transfer solutions

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## Redefining aseptic transfer


### Abstract

This whitepaper explores the impact of the Annex 1 revision on aseptic transfer solutions within the pharmaceutical industry, focusing on the transition from aseptic filling lines using traditional glove ports and internally openable transfer ports to gloveless filling lines requiring externally openable transfer ports. This new process emphasizes reduced contamination risk, improved process efficiency, enhanced operator ergonomics, and alignment with regulatory requirements. The paper discusses the challenges faced in pharmaceutical production and the industry's shift towards externally operated rapid transfer ports to enhance sterility and simplify workflows.


### Introduction

Aseptic transfer is a critical process in pharmaceutical manufacturing, ensuring that products remain free from contamination. Since the 1970s, Getinge has been providing a robust transfer system (Rapid Transfer Port – RTP), widely recognized in the pharmaceutical industry for its reliability and innovation, under the name DPTE®.

Traditional manufacturing processes often involve glove ports, which, while effective, introduce several challenges related to contamination risk, operator ergonomics, and process efficiency. The recent revision of the guidelines for Good Manufacturing Practices Annex 1, effective from 2023, underscores the need for innovation in aseptic manufacturing.

A central theme of the updated Annex 1 is the reduction of contamination risk through improved facility design, validated processes, and the integration of advanced technologies. Here, Getinge proposes a paradigm shift: externally operated rapid transfer ports to be actioned without the use of gloves that align with Annex 1 principles, offering technologies that minimize human intervention and optimizes sterility assurance.

# Regulatory context: Annex 1 overview

## Principle

Annex 1 of the GMP emphasizes the importance of designing, qualifying, and validating facilities, equipment, and processes to protect products from contamination. The new revision of the Annex 1 strongly encourages the use of advanced technologies barriers such as Restricted Access Barrier Systems (RABS), isolators, robotic systems, and rapid/alternative methods to increase product protection.

## Premises

Annex 1 encourages the industry to reduce manual interventions, especially in critical zones such as filling areas and stopper bowls. The traditional reliance on glove ports contradicts these principles due to the inherent risk of breaches and ergonomic limitations.

### Challenges in Pharmaceutical Production

The pharmaceutical production process presents several challenges related to aseptic transfer. Getinge addresses these challenges with its externally openable ports, available in both automated (DPTE®-EXO) and manual (DPTE®-FLEX) versions.

### Reduced Contamination Risks

Externally openable ports eliminate the need for glove ports, minimizing direct human contact and exposure to critical areas. This significantly reduces the risk of contamination, ensuring a more robust and consistent aseptic transfer process. By limiting human interaction, these ports contribute to preserving an aseptic environment - an essential factor in ensuring quality of sterile pharmaceutical products

### Enhanced Sterility Assurance

Getinge's solution provides a robust and consistent aseptic transfer process, reducing the risk of sterility breaches. The new DPTE® Alpha, designed to eliminate the need for glove ports, supports enhanced sterility assurance and facilitates alignment with regulatory expectations. Its thorough validation process confirms that externally openable ports retain their integrity and performance over time, offering reliable protection against contamination.

### Improved Process Efficiency

By reducing the number of manual steps involved in the transfer process, externally openable ports streamline workflows and decrease the overall time required for component transfer. This enhances process efficiency and productivity, allowing for faster and more reliable production cycles. The simplified transfer process also reduces the likelihood of errors, contributing to higher quality outcomes.

### Enhanced Operator Ergonomics

Eliminating tasks associated with glove ports improves operator ergonomics, reducing physical strain and the likelihood of errors. This leads to a safer and more comfortable working environment, without the need to reach into isolators or RABS environments. Operators can perform their tasks more efficiently and with greater precision, which is essential for maintaining high standards of sterility.

**DPTE®-EXO**
The automated and externally operated rapid transfer port

Specifications:
https://www.getinge.com/int/products/dpte-exo-alpha-port/

**DPTE®-FLEX**
The manual and externally operated rapid transfer port

Specifications:
https://www.getinge.com/int/products/dpte-flex-alpha-port/

## Design & validation excellence

Leak-tightness is foundational to aseptic assurance. Getinge's externally openable ports also feature, like the entire range of DPTE® system, double-door technology with extensive barriers to prevent particulate and microbial ingress. The DPTE® undergo thorough validation processes to ensure leak tightness and reliability. This includes rigorous testing to confirm that the ports maintain leaktightness during transfer and prevent contamination.

Validation documentation is aligned with Annex 1 expectations, ensuring inspection readiness and regulatory alignment.

## Integration with automated and single-use systems

The shift toward compact, robotized aseptic lines and Single-Use Systems (SUS) necessitates transfer solutions that minimize manual intervention. Getinge's solution seamlessly integrates with robotic and automated handling systems and features an optimized design for rapid, repeatable connections. This compatibility future-proofs facilities and simplifies compliance with evolving GMP expectations.

## From filling lines with multiple gloves to compact gloveless lines

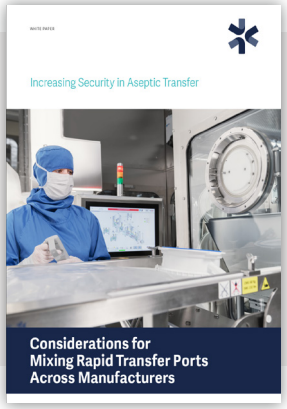
The pharmaceutical industry is undergoing a significant shift. As automation and advanced isolator technologies become standard, glove ports are increasingly seen as outdated. The move toward externally operated RTPs reflects this evolution, offering:

- A more hygienic, operator-free approach to aseptic transfer
- Lower risk of process interruptions and deviations
- A design philosophy rooted in Quality Risk Management (QRM)

This transition supports the Annex 1 goal of reducing human interaction in operations done inside RABS and isolators and simplifying contamination control.

## Conclusion

The revised Annex 1 sets a new benchmark for aseptic manufacturing, emphasizing the critical role of technology in minimizing contamination risk. Getinge's externally operated rapid transfer ports, actioned without the use of gloves, provide a cutting-edge solution that aligns with these regulatory requirements, while also delivering operational and ergonomic benefits. By redefining aseptic transfer, Getinge is enabling pharmaceutical manufacturers to meet the highest standards of sterility assurance, efficiency, and compliance.




## White Paper: Considerations for Mixing Rapid Transfer Ports across Manufacturers

The DPTE® transfer system, pioneered by Getinge, was designed to maintain leak tightness and microbial integrity through the combination of its Alpha and Beta ports. However, the growing availability of standalone transfer ports from different suppliers, along with claims of cross-compatibility has led some users to mix components.

**Learn more**: risks of combining Alpha and Beta ports from different manufacturers.

**References**
1. EMA. "Annex 1 - Manufacture of Sterile Medicinal Products." https://www.gmp-compliance.org/files/guidemgr/20220825_gmp-an1_en_0.pdf



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