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Reducing Facility Costs Through Optimized Design With Biosafe® Rapid Transfer Ports

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Abstract

The Biosafe® Rapid Transfer Port enables direct, secure aseptic liquid transfer between cleanroom zones, reducing footprint requirements in high-classification cleanroom areas. This optimizes pharmaceutical facility layouts and supports significant capital and operational cost savings while streamlining logistics, minimizing manual handling, and lowering contamination and quality risks.

This application note demonstrates the benefits of integrating Biosafe® Rapid Transfer Ports in a downstream process in which liquid is transferred from the buffer preparation area to an adjacent downstream area. By modeling two layout scenarios, we demonstrate that Biosafe® Rapid Transfer Ports can decrease Class C cleanroom area by approximately 20%, allow reclassification of 50 m² from Class C to Class D, provide a net CAPEX reduction of over €40,000, and reduce annual operating costs by more than €600,000. These findings highlight that the Biosafe® Rapid Transfer Port improves efficiency, safety, and cost-effectiveness for both engineering firms and pharmaceutical companies designing new production layouts.

Introduction

Designing pharmaceutical production facilities requires a careful balance between regulatory compliance, operational efficiency, and cost management. One critical challenge is the transfer of liquids between cleanroom zones, particularly in the buffer preparation area of the downstream process.

The transfer strategy must support the preparation, storage, and delivery of buffers under stringent aseptic conditions, with direct implications for product quality and facility throughput.

Traditional facility layouts often dedicate significant footprint to high-classification cleanroom areas and require complex logistics to move materials between zones. These approaches can introduce operational inefficiencies, increase contamination risks, and complicate both daily operations and future facility modifications. The need for multiple airlocks, extensive manual handling, and rigorous cleaning protocols further adds to the operational burden.

The Biosafe® Rapid Transfer Port addresses these challenges by facilitating closed, validated liquid transfer between cleanroom zones, offering an alternative approach to facility design (Figure 1). This technology supports more flexible zoning, reduces reliance on extensive Class C areas, and simplifies the movement of critical fluids.

This application note focuses on the buffer preparation area within the downstream process, illustrating how adoption of the Biosafe® Rapid Transfer Port can streamline workflows, enhance process safety, and support more agile and efficient pharmaceutical production environments. The same exercise could be performed for other process steps, such as upstream media and buffer preparation, with the same results.

Figure 1: Zone-to-zone liquid transfer using the Biosafe® Rapid Transfer Port



Materials and Methods

To evaluate the impact of Biosafe® Rapid Transfer Ports on facility design and operations, we developed and modeled two layout scenarios for our client's buffer preparation and downstream processing (DSP) rooms.

Scenario 1: Conventional transfer

Buffers are prepared and filled into Palletank® containers in the buffer preparation room. Palletank® containers are then manually moved along the corridor, passing through multiple airlocks, until they reach the DSP room for use. This approach requires significant manual handling, complex logistics, and larger high-classification cleanroom areas to maintain aseptic conditions throughout the transfer route, especially with the unidirectional layout flow concept.

Scenario 2: Biosafe® Rapid Transfer Ports

Buffers are prepared and stored in the buffer preparation room. The Palletank® containers are then connected to equipment located in DSP rooms via wall-mounted Biosafe® Rapid Transfer Ports. This supports buffer distribution without moving containers through corridors or airlocks, reducing manual handling and allowing for a more compact, flexible cleanroom layout.

Both scenarios were analyzed for their effect on cleanroom classification, operational workflow, and associated costs, with a particular focus on the buffer preparation area within the downstream process.

Assumptions

- For calculating cleanroom construction costs, we assumed €3,100/m² for a Class C cleanroom and €2,070/m² for a Class D cleanroom.
- For calculating annual cleanroom running costs, we assumed €3,840/m² for a Class C cleanroom and €2,400/m² for a Class D cleanroom. These include energy consumption, maintenance, consumables, labor, certification, and additional miscellaneous costs.

These costs may vary significantly by region due to differences in construction costs, labor rates, and utilities.

Results and Discussion

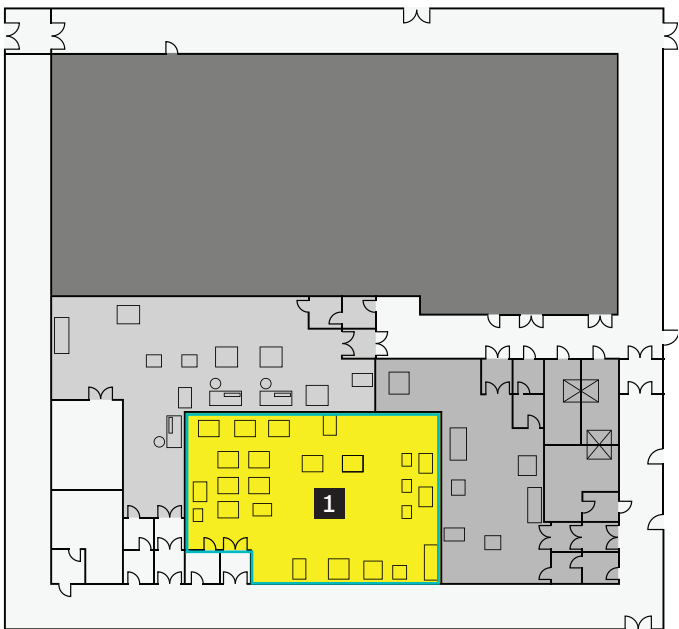
The two layout scenarios (Figure 2) were evaluated for their effect on capital expenditure (CAPEX) and operating expenditure (OPEX). The assessment covered cleanroom construction, equipment investment, cleanroom running costs, and consumable costs.

Figure 2: Facility layout for the two tested transfer strategies

Scenario 1: Conventional transfer



Scenario 2: Biosafe® Rapid Transfer Ports



■ Seed train and USP operations ■ DSP 1 ■ DSP 2 ■ Buffer preparation room

- 1** Palletank® storage containers for capture and first polishing chromatography step
- 2** Palletank® storage containers for second polishing chromatography to be relocated to the DSP1 room during use
- 3** Palletank® storage containers for ultrafiltration | diafiltration

- 1** All Palletank® storage containers required for DSP

Impact on cleanroom construction costs (CAPEX)

The first assessment evaluated the impact of the transfer strategy on cleanroom surface area and associated construction costs. By enabling direct wall-through buffer transfer into the DSP area, while keeping the Palletank® storage containers in the buffer preparation room, the Biosafe® Rapid Transfer Port reduces the required Class C cleanroom footprint and supports the reclassification of 50 m² from Class C to Class D (Table 1). This results in lower total cleanroom construction costs compared with the conventional approach, while maintaining the required segregation and aseptic conditions.

Table 1: Comparison of cleanroom surface areas and construction CAPEX for conventional and Biosafe® Rapid Transfer Port approaches

Scenario 1: Conventional transfer

Room	Surface area (m²)	Construction cost (€)
Buffer preparation (Class D)	93	192,510
DSP1 (Class C)	173	536,300
DSP2 (Class C)	93	288,300
Total construction cost		1,017,110

Scenario 2: Biosafe® Rapid Transfer Ports

Room	Surface area (m²)	Construction cost (€)
Buffer preparation (Class D)	143	296,010
DSP1 (Class C)	135	418,500
DSP2 (Class C)	80	248,000
Total construction cost		962,510
Area converted from Class C to Class D [m²]	50	
CAPEX reduction [€]		54,600

Impact on equipment investment (CAPEX)

Beyond facility construction, the choice of transfer strategy also affects equipment investment. The conventional approach relies on a higher number of mobile Palletank® containers to transport buffers through corridors and airlocks. In contrast, the Biosafe® Rapid Transfer Port configuration enables buffers to be transferred directly from Palletank® containers located in the buffer preparation area to the point of use in the DSP area.

Table 2 shows that the layout scenario using Biosafe® Rapid Transfer Ports reduces the need for redundant Palletank® containers used solely for logistics, but requires the addition of two Biosafe® Rapid Transfer Port units and associated hardware, resulting in a small increase in equipment CAPEX (specifically for DSP buffer preparation). However, the Biosafe® Rapid Transfer Port scenario remains favorable when considering the overall facility design.

This impact is also clear in the facility layouts. In the conventional transfer strategy, multiple portable Palletank® containers are required for capture chromatography, two polishing chromatography steps, and final ultrafiltration | diafiltration step in the second DSP suite. In contrast, with the Biosafe® Rapid Transfer Port, all Palletank® storage containers required for DSP are located in the buffer preparation room and connected to systems in the DSP rooms via a wall-through connection. Large, fixed Palletank® containers can also replace multiple smaller containers, reducing footprint and OPEX (Figure 2).

Table 2: Comparison of equipment CAPEX for conventional and Biosafe® Rapid Transfer Port approaches

Scenario 1: Conventional transfer

Equipment	Number of units
Palletank® 500 L for in-process fluid handling	21
Total investment cost [€]	124,320

Scenario 2: Biosafe® Rapid Transfer Ports

Equipment	Number of units
Palletank® 1,000 L for in-process fluid handling	6
Palletank® 1,500 L for in-process fluid handling	3
Biosafe® 200 inside right opening	2
Dummy connector for Biosafe® 200	2
Vertical support for Biosafe® 200	2
Total investment cost [€]	138,960
CAPEX reduction [€]	- 14,640

Impact on cleanroom running costs (OPEX)

Cleanroom operational costs represent a major contributor to long-term facility expenses. These costs scale directly with cleanroom classification and surface area, including HVAC operation, environmental monitoring, and cleaning. The reduced Class C footprint enabled by wall-through transfer using the Biosafe® Rapid Transfer Port lowers annual operating costs for DSP cleanrooms by over €75,000 compared with the conventional transfer strategy (Table 3). Since cleanroom running costs are a major component of total cleanroom OPEX, this annual saving contributes to lower cleanroom operating expenditure over the lifetime of the facility.

Table 3: Annual cleanroom OPEX for conventional and Biosafe® Rapid Transfer Port approaches

Scenario 1: Conventional transfer

Room	Surface area (m²)	Annual running cost [€/year]
Buffer preparation (Class D)	93	223,200
DSP1 (Class C)	173	664,320
DSP2 (Class C)	93	357,120
Total annual running cost [€]		1,244,640

Scenario 2: Biosafe® Rapid Transfer Ports

Room	Surface area (m²)	Annual running cost [€/year]
Buffer preparation (Class D)	143	343,200
DSP1 (Class C)	135	518,400
DSP2 (Class C)	80	307,200
Total annual running cost [€]		1,168,800
OPEX reduction [€]		75,840

Impact on consumable costs (OPEX)

In addition to facility-related costs, the transfer strategy impacts routine consumables used for buffer handling and aseptic connections. The conventional approach requires multiple transfer sets and additional consumables linked to the movement of Palletank® containers. In contrast, the Biosafe® Rapid Transfer Port simplifies the fluid path and reduces the number of consumables required per batch. This leads to lower consumable costs per batch and substantial annual savings (€550,600) when extrapolated to 100 batches (Table 4).

Importantly, in the conventional scenario, the client chose to automate all aseptic connections between mixing and storage bags using the Biowelder® TC. Another strategy, such as manual aseptic connections and disconnections, would have further increased the delta between the two scenarios. This analysis further strengthens the operational cost benefit of closed, connected buffer transfer.

Table 4: Comparison of consumable OPEX per batch and per year for conventional and Biosafe® Rapid Transfer Port approaches

Scenario 1: Conventional transfer

Equipment	Number of units	Total cost [€]
Flexsafe® 3D Bag for Palletank® (500 L)	21	
Extension lines (TPE)	5	
Total cost of consumables [€]		14,096

Scenario 2: Biosafe® Rapid Transfer Ports

Equipment	Number of units	Total cost [€]
Flexsafe® 3D Bag for Palletank® (1,000 L)	6	
Flexsafe® 3D Bag for Palletank® (1,500 L)	3	
Biosafe® RAFT system with 6 TPE lines	2	
Total cost of consumables [€]		8,590
OPEX reduction per batch [€]		5,506
OPEX reduction per year [€]		550,600

Conclusion

This comparative analysis demonstrates that integrating Biosafe® Rapid Transfer Port technology for zone-to-zone liquid transfer in pharmaceutical production facilities offers substantial advantages over conventional transfer methods. By enabling direct aseptic transfers through the wall, the Biosafe® Rapid Transfer Port can reduce the footprint requirements in high-classification areas, minimize handling and interventions, and streamline facility logistics.

It is important to note that this study focused exclusively on the buffer preparation area for DSP. However, the same strategy could be applied to other critical areas, such as the media preparation room for upstream processing, thereby extending the benefits of cost savings, operational efficiency, and risk reduction across the entire facility.

While the financial impact — demonstrated by a net CAPEX reduction of more than €40,000 and annual OPEX savings exceeding €600,000 — is significant, cost is not the only factor to consider. The Biosafe® Rapid Transfer Port also reduces the complexity and frequency of cleaning procedures for Palletank® containers, simplifies standard operating procedures for operators, and minimizes quality risks associated with manual handling. The same technology can also be leveraged to segregate pre- and post-virus inactivation cleanrooms, further supporting robust contamination control strategies and regulatory compliance.

Overall, adopting Biosafe® Rapid Transfer Port technology supports the creation of more efficient and future-ready pharmaceutical production environments. Beyond cost reduction, facilities planning new builds or upgrades should evaluate the Biosafe® Rapid Transfer Port for its potential to simplify operations, support process safety, and strengthen long-term contamination control.

The presented scenarios reflect one such optimization case study. However, different designs and solutions using Biosafe® Rapid Transfer Port technology can also be evaluated on a case-by-case basis through a Conceptual Design (CD) or Feasibility Study (FS) executed by the Sartorius Process Consulting team.

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