

## Success Story

# Flexibility First: How Bausch+Ströbel Streamlined Aseptic Manufacturing With Sartorius

With the introduction of the new EU GMP Annex 1 regulations, Bausch+Ströbel sought to evolve its platforms to remain user-friendly, flexible, and future-ready. The VarioSys® platform offers a safe, modular, and adaptable production solution. Bausch+Ströbel turned to Sartorius to incorporate the Biosafe® Rapid Transfer Port (RTP) into its system, ensuring enhanced sterility, ease of use, and compliance.

### Challenge

Annex 1 created significant regulatory shifts across the fill & finish landscape:

- Isolators as the standard, replacing open aseptic processing.
- More automation and robotics to minimize human interventions.
- Fast changeovers and modular systems to adapt to varied batch sizes.
- Seamless contamination control strategies and RTPs to maintain sterility.

### Provided solution

- Standardizing the Biosafe® 110 mm RTP, ensuring reliable and sterile material transfer via stopper bags qualified by main component manufacturers.
- Co-developing an RTP with a top-mounted lever, making outside opening possible on either side and improving bag positioning

~20%  
footprint reduction

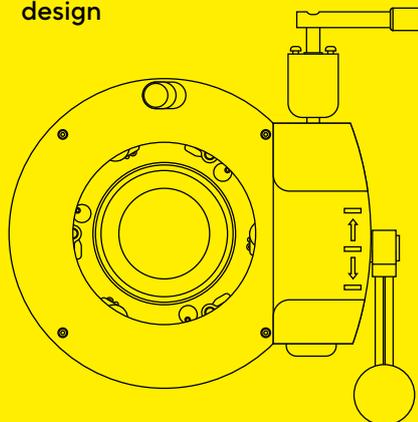
Minimized  
handling  
reduces contamination risk

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For details on the registrations please refer to <https://www.sartorius.com/en/patents-and-trademarks>

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Scalable and  
Annex 1-  
compliant  
design



## Case profile

Company type:  
Original equipment manufacturer

Related molecule:  
Proteins, vaccines, cell and gene therapies

Related process steps:  
Drug formulation, fill and finish



Before

- **Two inside gloves isolator intervention**  
Opening of RTP and deployment of flexible sleeve



After

- **Gloveless intervention**  
External opening and pushing rigid sleeve from the external side of the isolator
- **No steam sterilized accessory needed**

“Our collaboration with Sartorius has been especially valuable in advancing aseptic transfer systems. A key outcome was the standardization, and the co-development of an adapted RTP that made the system significantly more user-friendly and efficient. This innovation was successfully integrated into VarioSys®, providing customers with scalable, modular and standardized solutions.”

**Juergen M. Metzger**, Director of Turnkey Projects & New Technologies

 **Learn more about our fill & finish solutions**  
[sartorius.com/en/patents-and-trademarks](https://www.sartorius.com/en/patents-and-trademarks)