

SINGLE USE SUPPORT.

PIONEERING BIOPHARMA



CASE STUDY: **Reducing Product Loss**

Process-Independence

1 | The Situation

With the implementation of RoSS® shells, a multinational CDMO has been able to standardize its fluid management process thanks to the protective shell's bag-independence, and regardless of size and type of single-use bag used.

RoSS – abbreviation for "**robust storage and shipping**":

- helps to streamline the liquid transfer process and
- optimizes each full cold chain management process by enabling full flexibility.¹

The CDMO has now planned an extension of their manufacturing site and is searching for single-use technologies to implement a state-of-the-art manufacturing process.

2 | The Problem

The lack of prior infrastructure as well as process constraints required process flows that were conceptually thought through from scratch. It opened doors to optimize fluid handling functionalities that fostered operational and cost benefits in the long term. With having different single-use technologies in place, though, the CDMO had already planned to implement existing spare platform systems for their new facilities.

With the resulting balancing act between saving costs and achieving a process-efficient manufacturing setup, the company needed to find a way to limit the total cost of ownership, consisting of capital expenditures (CAPEX) upfront and operational expenditures (OPEX), while at the same time improving their biopharmaceutical fluid management's overall performance and minimizing product loss.



Process-independent single-use technologies, like RoSS.pFTU, increase process flexibility.

3 | The Solution

Siloed platform systems were identified as the biggest cost drivers.

Until now, manufacturers were mostly dependent on specific suppliers. Lack of compatibilities of single-use bags and lack of interconnectedness among different platform systems from multiple suppliers has resulted in limited process flexibility, inhibited process flows, and slowed speed-to-market.

With RoSS technologies around biologics liquid transfer the customer is free to choose from any of the platform solutions that can be embedded in an end-to-end process covering aseptic fluid management and cold chain logistics in an automated manner. In fact, Single Use Support's end-to-end process does not exclude any types or sizes of single-use container – making the RoSS® shell an enabler to unify all single-use bioprocess containers and to standardize the process steps in biomanufacturing. Moreover, the robust protection reduces product loss towards 0 % for single-use bags, saving the manufacturing company OPEX continuously.² Furthermore, the process-independent approach of RoSS technologies also decreases the need for single-use technologies that are solely designed to match with selected products.

ADVANTAGES OVER SILOED PLATFORM SYSTEMS



Reduced product loss



Single-use bag-independent



Bigger range of scalability
from 10mL to 400L



Improved efficiency through
automation and RFID tracking

The implementation of RoSS technologies

- Reduces the number of platform systems required for filling, freezing and cold storage, leading to more storage space
- Offers a wider range of applicability
 - Use of different primary packaging (any single-use bag, vial, bottle)³
 - Use for cell and gene therapy manufacturing, bulk drug substances, and more
- Enables advanced process flexibility thanks to scalable solutions with transferable filling and freezing recipes
- Minimizes operational errors and product loss thanks to automated workflows⁴
- Thus facilitates the implementation of a cGMP compliant reproducible and standardized manufacturing process

4 | The Result

Less vendor-specific systems and more universally compatible technologies, like RoSS, **simplify the process flow thanks to a reduced need for different platform systems.** This drives further cost-efficiency due to reduced need of staff for manual handling, staff training, cleaning and validation.

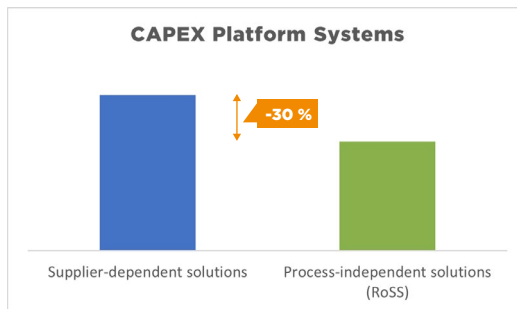
Required number of single-use technologies depends on batch sizes but can be reduced even further through performances at increased speed.

-80 % Aseptic filling of up to 300L with RoSS.FILL takes 1 hour, in contrast to other platform systems with customary 5 hours

-75 % Freezing to -80°C with RoSS.pFTU takes approx. 6-8 hours, in contrast to other platform systems with customary 30 hours



The CDMO has reported **CAPEX savings of more than 30 %** through the use of process-independent RoSS technologies for its facility expansion – **adding to OPEX savings of more than 50 % per year², primarily by reduced product loss.**



1. [Advantages of single-use bag-independent shell solutions \(susupport.com\)](https://www.susupport.com/en/advantages-of-single-use-bag-independent-shell-solutions)
2. [Reducing product loss in Biopharma to save costs \(susupport.com\)](https://www.susupport.com/en/reducing-product-loss-in-biopharma-to-save-costs)
3. [Single Use Support, 2022. Case Study: Hybrid by primary packaging](https://www.susupport.com/en/single-use-support-2022-case-study-hybrid-by-primary-packaging)
4. [How to reduce "Human Error" in Biopharma? \(susupport.com\)](https://www.susupport.com/en/how-to-reduce-human-error-in-biopharma)