SINGLE USE SUPPORT.

PIONEERING BIOPHARMA

CASE STUDY:

Reducing Product Loss

Cost Efficiency

1 | The Situation

The customer, **a global biotechnology company** with a total turnover of > USD 5 billion, manufactures different drug substances (BDS) of **highly valuables mABs** in batch sizes ranging from **10L to 700L** for clinical phases up to commercialized products. The BDS is frozen at < -85 C (-121°F), and shipped within Europe or on transatlantic routes over periods of max. 200 hours, and then stored, all the while being kept cool with dry ice. At the fill & finish site, the BDS is thawed to be used in the production of the drug product.

2 | The Problem

The biotech company planned to rely on **single-use bioprocess containers** as preferred **primary packaging** for BDS bulk filling, freezing, storing and shipping. This was due to **various advantages of single-use bags** like filling in a closed system, higher volumes, scalability and high storage density.

On the flipside, the **biggest challenge** of single-use bags was the **high loss rate of 0.5 % to 5 %** due to their sensitivity at sub-zero temperatures. The product loss rate depends on the bag used, the product's clam shell, the process and the shipper/shipping route. Therefore, the **goal was to reduce the current product loss below 0.5 %**.

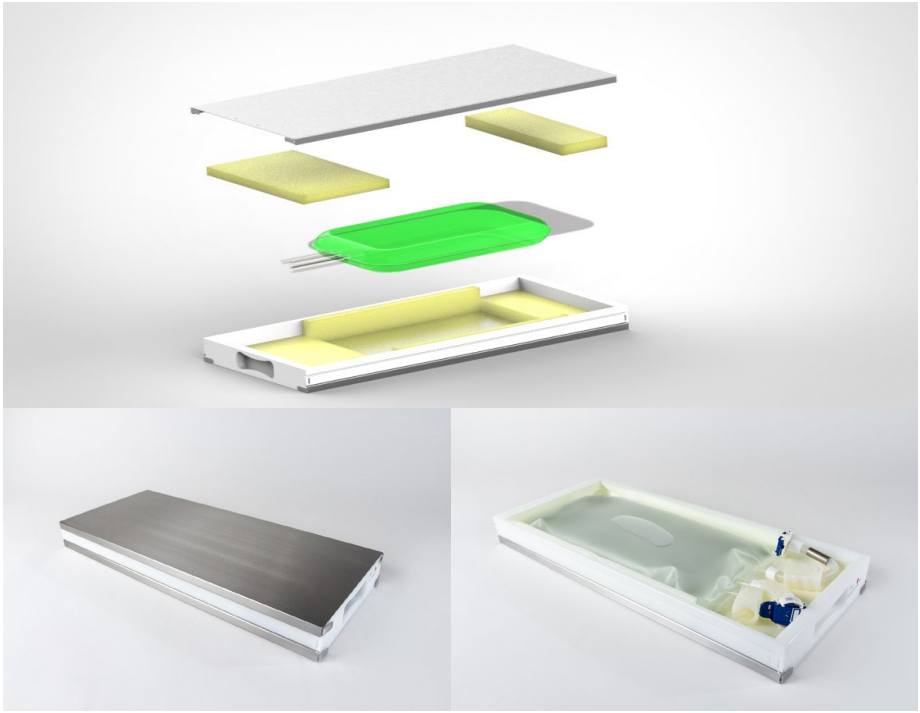
3 | The Solution

The biotechnology company compared available solutions to reduce the breakage rate of frozen and shipped single-use bags.

Representatives have reached out to **Single Use Support for initial trials to set up a cold chain process** and implement robust technologies around the brittle single-use bags and to consequentially reduce product loss.

The **RoSS® (Robust Storage and Shipping) shell** has been selected as a robust secondary packaging solution for the single-use bioprocess containers. The bag is **covered by soft 3D foam**, which provides a protective embedding of the single-use bag and absorbs about 8 % of the bag's/liquid's expanding energy due to the density drop during freezing. The **heavy-duty plastic and stainless-steel lids** that make up the robust frame of the RoSS shell withstand even the lowest temperatures.

See more about RoSS® Shell.



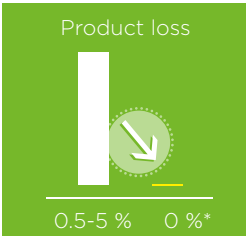
RoSS® Shell: Robust Stoarge and Shipping

4 | The Result

Mapping and analyses of the cold chain process on-site have shown that bag breakages were caused by a combination of having in place many manual handling steps, the sensitivity of single-use bags at sub-zero temperatures and a missing robust secondary packaging. The customer validated the new process with RoSS shells over several weeks with more than **500 bags** filled with frozen buffer media.

The implementation of RoSS with the effect of a much more robust secondary packaging has **diminished the risk of leakages or breakages to 0 %**.

The single-use bag and its tubings adapt to perfectly fit into the 3D foam in the RoSS shell, which in turn maximizes the protective effect. The introduction of an end-to-end process for freezing and shipment based on RoSS has led to a decrease of product loss from **up to 5 % down towards 0 %**.



*sample of 500 bags

Given a batch volume of **500 x 10L bags per year** with a filling volume of 8L at a value of USD 80,000 per bag, this mimics the situation at the biotech producing mAbs. An average product loss rate of 2.5 % had resulted in a **value loss of USD 1,000,000 per year** previously.

Investing in **500 RoSS shells** that reduce product loss from 2.5 % to 0 % leads to **savings of approx. USD 700,000**. Higher initial purchase costs for RoSS shells pay off very soon. **ROI is achieved after 150 single-use bags or only 4 months**, since they are compensated through the diminished risk of product loss towards 0 %.