

**SINGLE
USE
SUPPORT.** 



GUIDE

From fill to freeze

A connected workflow for efficient batch handling of bulk drug substance in 2D single-use bags

THE STEP BETWEEN THE STEPS

Handling drug substances throughout the bioprocess workflow

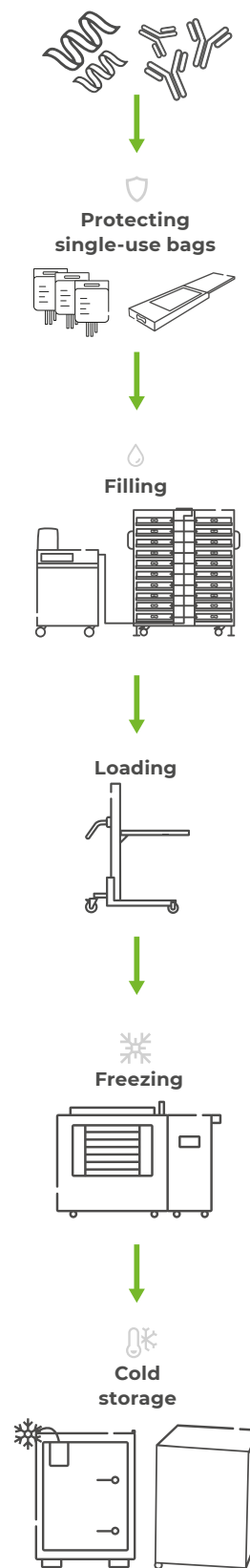
Bulk drug substances are mostly aliquoted into 2D single use bags to be then frozen. Filling platforms deliver the required safety, accuracy and throughput followed by freeze-thaw platforms cooling drug substances in the desired capacity and freezing profile.

Yet filling and freezing are often specified as independent unit operations, each with its own requirements, equipment, and performance targets. Consequently, the transfer between these systems is rarely defined.

- How does the filled bag move from the filling platform to the freezer?
- How long does that transfer take?
- When does product protection begin?
- And how is the entire process documented?

Questions like these sometimes fall outside the specification of either system. Nevertheless, they can have a significant impact on process efficiency, product handling, and batch traceability. For high value drug substances, the period between filling and freezing should not be considered a logistical detail. It is part of the manufacturing process and deserves the same level of attention as the operations on either side.

It's a mix of many aspects that are relevant to efficiency which are also dependent on product specifications or facility requirements. A connected and compatible fill-to-freeze workflow considerably helps improve process operations. Rather than optimizing filling and freezing separately, both operations can be designed as one coordinated fluid and cold chain process with aligned equipment, handling concepts, and documentation structures.



DECISION POINTS AT THE HANDOVER

The transition from filling to freezing introduces a series of operational decisions that can influence product protection, process consistency, and manufacturing efficiency.

The following questions highlight the key decisions manufacturers face at this handover point with conventional workflows versus integrated approaches.

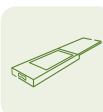
Key question	Separate systems	Connected workflow
How are bags handled after filling?	Requires transfer to another carrier	Remains in the same shell
When does product protection begin?	Begins at the freezing step	Begins before filling starts
How are hold times managed?	Handled as an operational gap	Defined as a process step
How does filling influence freezing performance?	Fill variability can affect batch consistency	Consistent filling supports homogeneous freezing
How is the batch documented?	Filling and freezing recorded separately	One continuous batch record
Which bags can be used?	Restricted by freezer format	Independent of bag supplier



The RoSS® shell protecting 2D single-use bags during filling and freezing.

CONNECTED WORKFLOW FOR BATCH FILLING AND FREEZING

In what ways do Single Use Support's fluid and cold chain management solutions contribute to efficient batch handling? RoSS.FILL and RoSS.pFTU were developed to support the same objective: consistent handling of bulk drug substance from aliquoting through freezing. Accurate filling creates the basis for batch consistency, while controlled-rate freezing preserves it. By sharing the same handling philosophy and compatibility with the RoSS® shell, both systems become part of one connected workflow rather than isolated unit operations.



Protecting single-use bags | RoSS® Shell

BAG INDEPENDENT

REDUCED PRODUCT LOSS

2D single-use bags are protected by a robust shell for fluid and cold chain processes. Applicable for all bag types, sizes and manufacturer.

HANDS OVER: A robust construction of bag and shell for safe handling and transport.



Fill | RoSS.FILL Bag

1 L TO 1,000 L+

HIGHEST ACCURACY

Automated, aspecically closed aliquoting of the bulk batch into 2D bags, at a consistent fill weight from the first bag to the last.

HANDS OVER: A full batch of bags prepared for downstream freezing with consistent fill volumes.



Load | RoSS.LODR

BAGS UP TO 20 L

ERGONOMIC HANDLING

The semi-automated assisted loading device helps operators to lift heavy single-use bags load into filling or freezing equipment.

HANDS OVER: A full freeze-thaw platform loaded without manual lifting.



Freeze | RoSS.pFTU Large-Scale

DOWN TO -80° C

CONTROLLED-RATE

Controlled-rate freezing of consistently filled single-use bags according to defined freezing protocols, supporting homogeneous freezing across the complete batch.

HANDS OVER: A frozen batch documented as one run, ready for storage and shipping.



Cold storage | RoSS.ULTF

SAME-SIZED PLATFORM

OPTIMIZED BATCH TRANSFER

Consistent storage of drug substances at ultra-low temperatures until it is shipped and thawed.

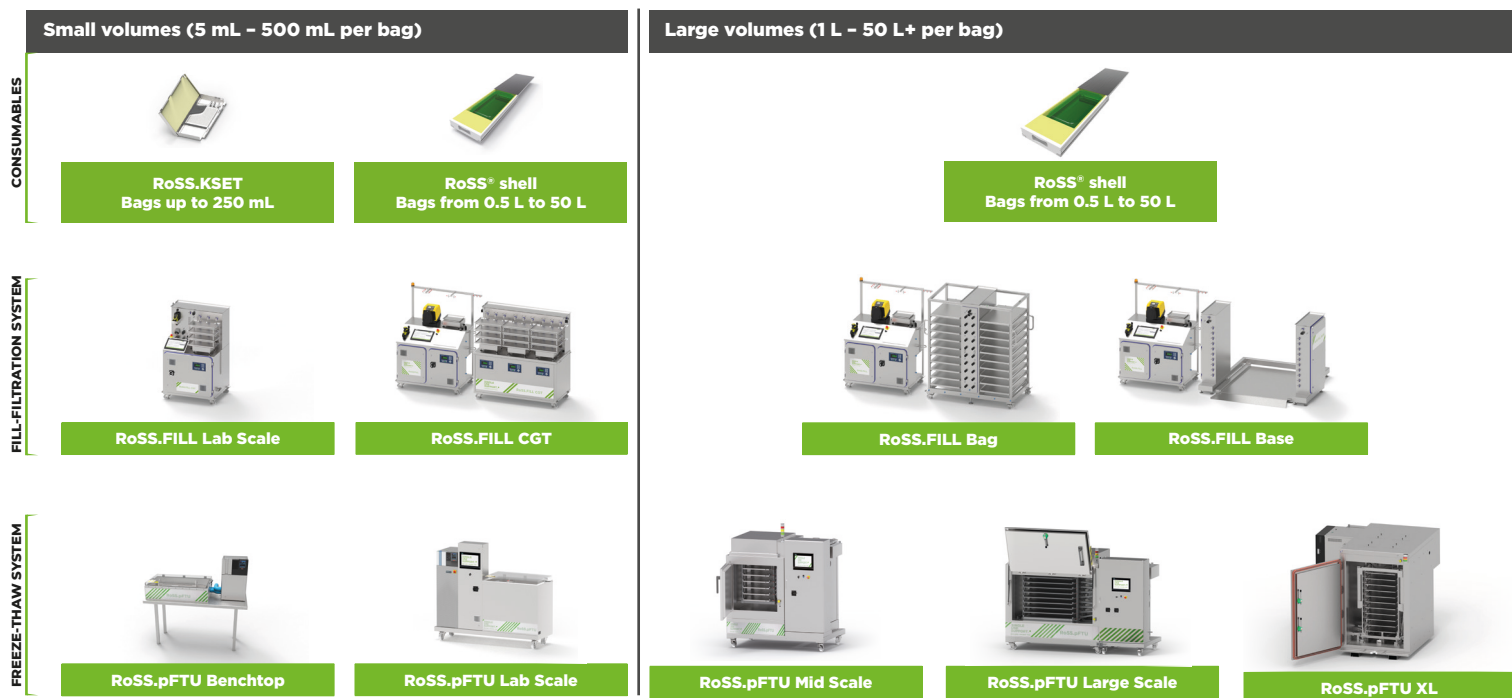
HANDS OVER: Mobile transport racks on wheels help reduce handling steps and risk of errors.

THE SAME WORKFLOW FOR DIFFERENT VOLUMES

Scaling a process should not require redesigning how material moves through it. Batch volumes change, bag sizes change, freezing capacity change. The underlying workflow does not: Protection, filling, loading, freezing, and thawing continue to follow the same handling logic across different scales.

The modularity of Single Use Support's platforms and the independence of selected single-use bags allow manufacturers to maintain process flexibility and free choice of single-use bioprocess containers.

Filling defines the batch. Freezing preserves it. RoSS.FILL and RoSS.pFTU connect these two critical operations into one standardized fill-to-freeze workflow. Together, they enable efficient batch handling across scales without introducing new handling concepts, transfer procedures, or validation strategies.



EFFICIENT

-50 % less
manual handling

PROCESS FLEXIBILITY

Modular equipment

INDEPENDENT

Bag agnostic
equipment

SCALABLE

Different volumes,
same result

Tell us where your handover sits.
Your batch size, your bag format,
your current process.

We will take it from there.

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