

**SINGLE
USE
SUPPORT.**

PIONEERING BIOPHARMA



Automated Aseptic Filling

Fill better with unprecedented flexibility

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Automated filling: The way to go

Several surveys have shown that more than half of all CMOs and Biopharma manufacturers still use manual filling to dispense drug substance into primary packaging, such as single-use bags and bottles.¹ However, manual handling comes with a higher potential risk of “human error” than automated filling. With 8 out of 10 cases of process deviations in pharmaceutical manufacturing environments, human error is the biggest cause of operational errors.²

Which of these terms best describes the process at your site for drug substance filling?

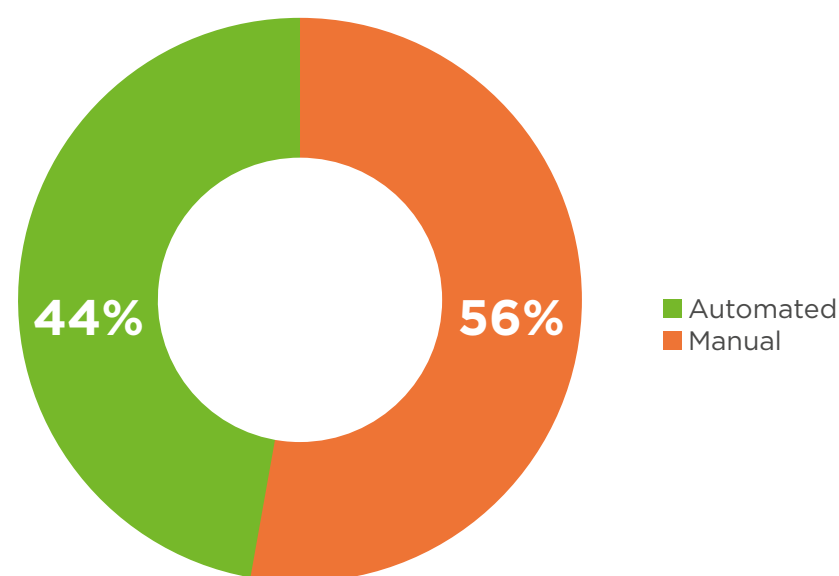


Figure 1: Automated vs. manual process at drug substance filling¹

Automated filling systems are recommended by many market experts to reach the next level in drug substance management. Many users are starting automation initiatives, which is proof of an overall trend towards automated filling.

In general, they help to reduce both contamination risks and the risk of human errors. Among all available systems for automated filling of drug substance, RoSS.FILL, a bulk filtration, filling and draining platform for primary packages such as single use bags, bottles and vials, outshines its competitors with regards to the following product characteristics: accuracy, scalability, flexibility, speed, its process upgrade options and its process integration.

Precise & controlled filling with RoSS.FILL

Single Use Support’s fill & filtration platform RoSS.FILL outperforms all automated filling systems on the market:

Table 1: Comparison of different automated filling systems

	Automated Filling Platform 1	Automated Filling Platform 2	RoSS.FILL	Comments
Accuracy	~	✗	✓	RoSS.FILL can achieve a filling accuracy of less than 1mL
Scalability & Flexibility	✗	✗	✓	One Control Unit to attach different racks for simple scale-up and scale-out filling - 1 bag up to 72 bags+ - 2D bags from 10mL to 50L - Any type of 2D and 3D single-use bags and bottles
Speed	✓	~	✓	Parallel and sequential filling for highest throughput
Automation & Process Control	~	~	✓	Fully automated process control for dispensing and sealing of all primary packagings with user-friendly HMI and integration into preferred MES
Operator Effort	~	~	✓	RoSS.FILL with cGMP-compliant process solutions for dispensing and sealing of primary packagings

ACCURACY

The lower the filling volume, the more important the accuracy.

Overall, accuracy is of great importance to reduce manufacturing deviations when filling drug substances into single-use systems.

RoSS.FILL from Single Use Support is an automated aseptic filling system that aliquots active pharmaceutical ingredients into single-use bioprocess containers with the highest accuracy. Different types of modular filling platforms are available depending on customer requirements in terms of single-use bag size and batch quantity.

RoSS.FILL Lab Scale and RoSS.FILL CGT are designed for filling multiple smaller volumes between 1mL and 1000mL into single-use bioprocess containers. Depending on filling technology type, gravimetric or flow, highly precise aliquoting can now be performed:

- **Gravimetric filling** with integrated load cell scales ensure a weighing accuracy with deviations of down to **± 2g**.
- **Filling with a flow sensor** enables a filling accuracy down to **± 1mL**.

Unprecedented accuracy in filling low-volume single-use systems provides operators with greater control.



SCALABILITY

RoSS.FILL opens doors to unprecedented scalability in terms of both number of bags and size of bags. For example, it fills 100 single-use bags at 50mL each or 20 single-use bags at 20L each per rack, thus being suitable for small volumes of cell and gene therapy, mABs or other early-phase studies as well as for commercialized bulk drug substance. It is even possible to attach one or more additional filling racks to the control unit, which enables aliquotation and filtration of 400L or more of drug substance in one batch run.

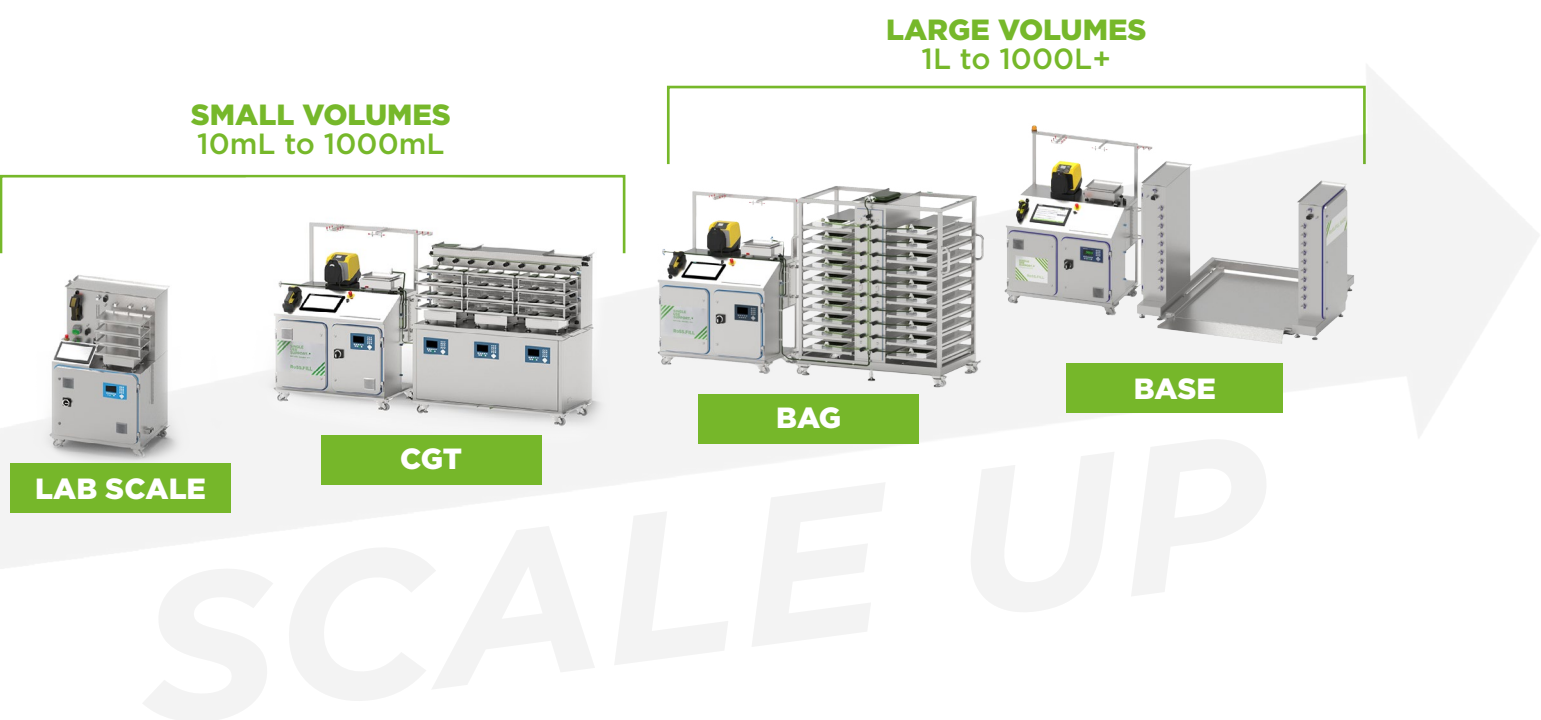


Image 1: Unlimited scalability for aseptic filling from laboratory to commercial production.

RoSS.FILL Lab Scale | 1mL to 1000mL

Fully automated aseptic filling of up to 12 small single-use bags for clinical studies and cell & gene therapies.

RoSS.FILL CGT | 1mL to 1000mL

Fully automated aseptic filling of up to 72 small single-use bags for clinical studies and cell & gene therapies.

RoSS.FILL Bag | 1L to 20L

Fully automated bulk drug substance handling with 20 individual weighing scales.

RoSS.FILL Base | up to 1000L

Fully automated system for aseptic filling for large volume bulk drug substances.

FLEXIBILITY

Aseptic filling processes differ from manufacturer to manufacturer. Modular systems, like RoSS.FILL, are able to adapt to all custom requirements with one platform.

Modular: RoSS.FILL's control unit and its GMP-compliant software facilitates the attachment of different filling racks. It is thus easily and quickly configurable to meet the needs of different processes. Its modular system allows for hybrid filling of single-use bags and bottles with the option to attach one or multiple filling racks to increase process efficiency.

Vendor-agnostic: Eliminate dependency on vendors of primary packagings. Regardless of the size and type of single-use bag or bottle that needs to be filled, Single Use Support follows its vendor-independent path and provides solutions for all different scenarios.



Image 2: Modularity enables hybrid filling with (A) RoSS.FILL Bottle and (B) RoSS.FILL Bag



PROCESS UPGRADE OPTIONS

Filtration

Single-use filters can be integrated in the process flow of liquid transfer during the process of sterile dispensing into single-use systems. This option resolves complexities in bulk filtration. With its modular fluid management solutions, Single Use Support literally filters complex demands that need to be considered into practical and effective solutions.

Automated stepper & sealer valve

Advanced sealer and stepper pinch valves can be integrated optionally in any of the modular RoSS.FILL platform racks. With a variable fluid control to accelerate the throughput for fast filling, and simple aseptic decoupling of single-use bags, these valves offer two functions that significantly enhance the fluid management process. Both functionalities are fully automated and integrated in the process step of aseptic filling and filtration to considerably advance process efficiency.

SPEED

RoSS.FILL facilitates unrivalled throughput and speed. With RoSS.FILL Bag, more than 100L of bulk drug substance can be dispensed into 10L single-use bags within 60 minutes. The industry benefits enormously from skyrocketed efficiency in fluid management.

The RoSS.FILL CGT bag filling system is specifically designed for use in cell & gene therapies with batch sizes at low volumes. The platform provides filling for up to 36 bags with one rack - offering the option to attach additional racks. Speed is important, especially for CGT, when liquids are required to be frozen in single-use bioprocess containers within periods of time as short as one hour. Speedy performance supports manufacturers in securing timely business continuity with maintained product stability. Moreover, an automated and speedy filling process saves resources and reduces the risk of operational errors due to manual filling.



Image 3: Automated stepper and sealer valve enables integrated aseptic decoupling of single-use assemblies



PART OF END-TO-END PROCESS

It is increasingly important to break free from silo thinking and to streamline the manufacturing environment. The risk of product loss will be diminished once the entire ecosystem from drug substance to drug product site has been covered by a single provider and the primary packaging protected throughout the entire journey.

Already, this is reflected in the flexible end-to-end process solutions provided by Single Use Support. They allow for seamless filling, freezing, shipping, thawing and draining. This approach will be crucial in the quest to guarantee a controlled manner of transportation and will eliminate any chances of incompatibilities or damages.

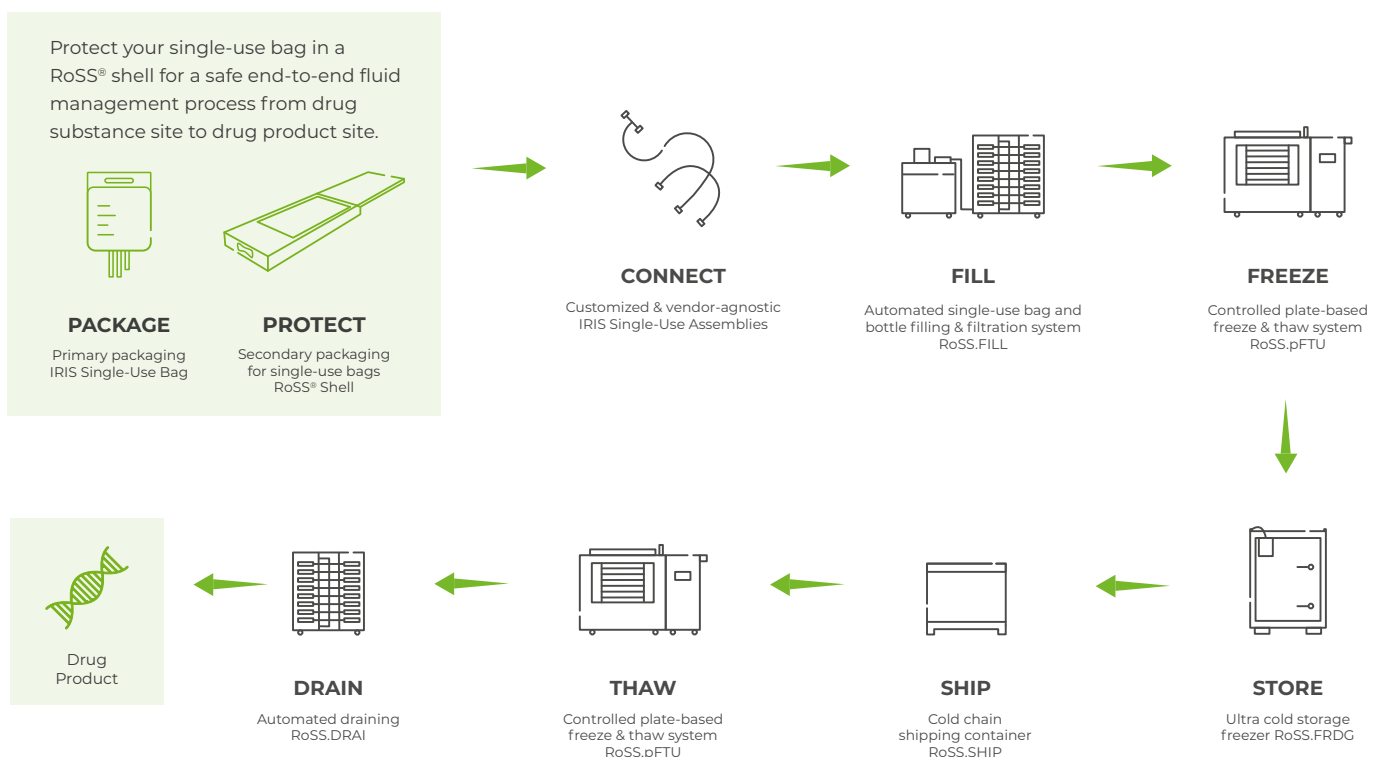


Figure 2: End-to-End process for single-use bags in biopharmaceutical manufacturing

References

1. Aspen Alert Survey: Which of these terms describe best the process at your site for drug substance filling? April 2022, available at: <https://www.aspenalert.com/asq-787-2022-0401-which-of-these-terms-best-describes-the-process-at-your-site-for-drug-substance-filling>.
2. Lowe, M.: Avoiding Human Error in Pharmaceutical Manufacturing, 2022, available at: <https://www.worldpharmatoday.com/articles/avoiding-human-error-in-pharmaceutical-manufacturing/>