

How Do Your Freezing Choices Affect the Cost and Time To Freeze Your Drug Substance?

Outsourcing fill finish to CMOs globally

With the expansion of biopharmaceutical manufacturers' global distribution of multiple bioprocesses to CMOs, networks are becoming increasingly complex.

Growth in cold chain logistics

\$21B BY 2024

To support biopharmaceutical manufacturers' increase in biologic drug production combined with the growing network of CMOs, spending on cold chain logistics, for drug substance and drug product, is forecast to grow to reach \$21.3 billion by 2024.

Ref: 2020 Biopharma Cold Chain Sourcebook, <https://www.pharmaceuticalcommerce.com/viewsourcebook>

Pharmaceutical cold chain spending heats up

Global biopharmaceutical cold chain spending, billions



Allegro™ single-use biocontainer bags vs bottles

	Allegro biocontainer bags RoSS® plate freezer	Bottles Blast freezer
Freezing rate	Fast Up to 5 times faster than blast freezer Homogeneity of drug substance is maintained	Slow Up to 5 times slower than plate freezer Geometry of bottle creates longer freezing path Cryoconcentration
Operational effort	Low Automated biocontainer bag filling	Medium Bottle filling manual process
Closed system	Yes	Not always Caps must be removed to fill aseptically
Scalability	Yes 50 mL to 20 L Scalable plate freezing system	No
Control/predictability	High High degree of reproducibility and uniformity	Low Depends on temperature and velocity of air in freezer
Storage density	High Small footprint	Low Freezers have large footprints
Risk of product loss	Low Towards 0% with robust platform RoSS shell	Medium Product loss due to contamination from sterility barrier breaches

Desired improvements for freezer storage containers

Biologic production is expensive and logistics of transporting valuable bulk drug substance to locations around the world typically involve freezing the drug substance either in bottles or single-use biocontainers/bags.



Ref: Aspen Media, Inc. survey <https://aspenchange.com/>

Higher storage density



Storage capacity for bulk drug substance

Cold room / freezer storage volume reduced by a factor of 4, from 80 L/m³ to 330 L/m³ when replacing bottles with stackable Allegro biocontainer bags protected by RoSS shells.

Ref: Case study, Storage density, Single Use Support, 2018

Costs of cold room storage

Assuming that 1000 liters of bulk drug substance requires cold room/freezer storage, the annual cost savings when replacing bottles with single-use Allegro biocontainer bags protected by RoSS shells are approx. \$48k.

Ref: Case study, Storage density, Single Use Support, 2018



Saving \$48k

Product loss

Loss of high value drug substance due to breakages of frozen single-use biocontainer bags encased in clam shells is between 1-5%. For 500 biocontainer bags, each filled with drug substance worth \$2m, a loss of 1.5% would equate to a value loss of \$15m per year.

Allegro Biocontainer bags protected by **rigid RoSS shells** reduce this risk towards 0% saving up to \$15m.

Ref: Danaher Corporation, Unpublished Confidential Report, June 2020



* sample of 500 biocontainer bags

10k L

Average annual volume shipped
500 x 20 L biocontainer bags

\$100k

Typical end-market value of 1 L product

1.5%

Typical loss rate using conventional freezing technologies

150 L

Average annual product loss (10,000 L x 1.5%)

\$15m

Average market value loss (150 L x £100k)

Want to know more?

Find out how Pall's Freeze & Go Solutions can reduce the costs of freezing, storage and transport of your drug substance. Watch our video and book a personalized virtual seminar.

Watch Video & Request a Virtual Seminar

Pall® Freeze & Go Solutions

Protected by RoSS® technology

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