

LYOBEAD PRODUCTION SYSTEMS

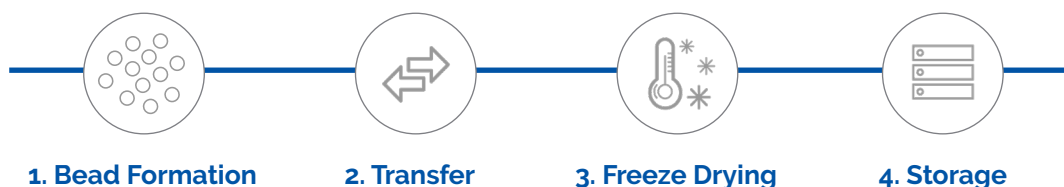
Turn-Key Solutions for Lyophilized Beads

Millrock Technology offers turn-key solutions for LyoBead production that include a bead dispenser (BeadLab™), sealable tray, and freeze dryer. The combination provides all the necessary parts to quickly implement using LyoBeads.

The BeadLab automated micro-dispensing system is used to create the beads, which are collected in the freeze drying tray. Once collected, the lid is sealed, enabling non-contact transfer to the freeze dryer. The product is held in a frozen state inside the freeze dryer until the entire batch is loaded and ready for freeze drying. At the end of the freeze drying process, the trays are sealed under vacuum, isolating the product from the environment and protecting the operators from exposure. The sealed tray can be used for long term storage or for transfer to further processing.



Steps for LyoBead Production



SPECIFICATIONS				
FREEZE DRYER	STELLAR 4 shelf - 10x18, 5 sq ft	REVO 4 shelf - 12x24, 8 sq ft	MAGNUM 8 shelf - 12x24, 16 sq ft	MAGNUM XL 10 shelf - 12x24, 20 sq ft
BEAD PER BATCH (APPROX)	80,000	112,000	224,000	280,000
TRAY SIZE	10" x 10" OD	12" x 12" OD	12" x 12" OD	12" x 12" OD
BEADS PER TRAY (7.5 microL)	10,000	14,000	14,000	14,000
TRAYS PER BATCH	8	8	16	20
# BEADLABS**	1	1	2	3
BEADS PER HOUR**	6,000+	6,000+	12,000+	18,000+

The freeze drying process can typically be completed overnight, enabling one batch to be produced per day. Expected drying time: 12 hours.
** For faster loading times, additional BeadLabs can be used. Each BeadLab can produce 8,000+ beads per hour. Number of beads per hour may vary based on bead size and pump size.

LYOBEAD PRODUCTION SYSTEMS

LyoBeads are spheres of customizable lyophilized material that contain a specific volume of material, typically in the 5 microL to 20 microL range. LyoBeads are created through instant freezing of the liquid formulation in liquid nitrogen and then freeze drying. The final product is a consistent volume stable dry bead ready for long term storage that is easily reconstituted.



Types of materials that may benefit from LyoBeads

- Diagnostic reagents
- PCR assays
- Bacterial vaccines
- Buffers and chromophores
- Enzymes, enzyme substrates, and co-factors
- Antibodies and antibody conjugates
- Calibrators and controls
- Probiotics



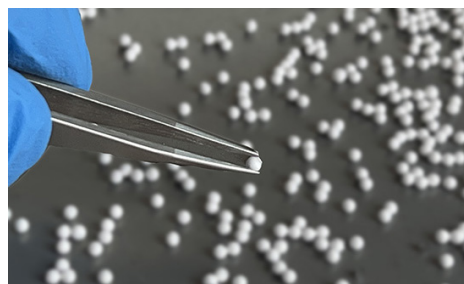
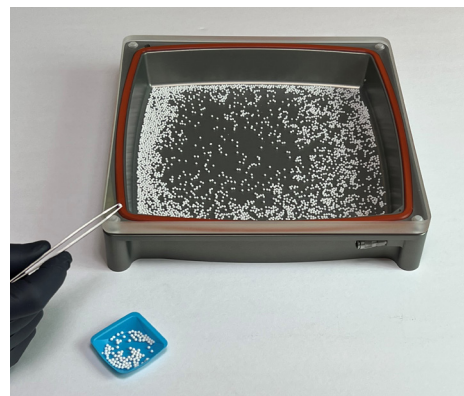
Advantages of LyoBeads

- Reduced setup time for assays
- Reduced pipetting errors
- Reduced freeze drying time
- Long term stability at room temperature
- Fast reconstitution



Advantages of the Vacuum Sealable Tray

- Eliminates operator exposure
- LN2 compatible for bead creation
- Sealable for oxygen free transfer between BeadLab and freeze dryer
- Sterilizable
- Vacuum sealable post-freeze drying for long term storage



BEADLAB



The liquid drops fall into an LN2 filled tray where they are collected.

At the end of the bead production process, a borosilicate lid seals the tray for transport to the freeze dryer.

TRAY



An aluminum tray with anodized finish combined with a borosilicate lid enables bead production and collection, transfer, freeze drying process, and post-freeze drying storage.

The sealable trays offer a method for isolating the operator from exposure to the product in the tray.

At the end of the freeze drying cycle, the trays are vacuum sealed to protect both the product and operator.

The trays are cleanable and sterilizable.

FREEZE DRYER



The freeze dryer is designed to accommodate LyoBead specific application requirements including pre-frozen shelves for storage of the frozen beads prior to freeze drying.