

LYOPHILIZATION SCALE-UP

7 INPUTS BEFORE GMP PRODUCTION

Process transfer starts with evidence - not copied shelf-temperature, pressure and time setpoints.

API

Peptide

Sterile vials



THE REAL QUESTION

**Will the product stay inside its critical limits
when heat transfer, vapor flow and batch
geometry change?**

Know what the formulation can tolerate

1 Critical temperature

Review collapse, eutectic or other product-specific limits before defining the primary-drying window.

2 Formulation and solids

API concentration, excipients, solvent system and freezing behavior influence cake structure and resistance.

3 Finished-product target

Residual moisture, reconstitution, potency, purity and stability must be defined by the product program.

A good-looking cake is useful evidence - but it is not a substitute for analytical testing.

Geometry changes the process

TOTAL ICE LOAD

is not the same as shelf area

Count the water to remove - not only the number of shelves or vials.

4

Vial and stopper

Use the actual drawings, including partially inserted stopper height, tray and edge-clearance needs.

5

Fill volume

Fill depth changes the frozen product geometry, primary-drying resistance and batch ice load.

6

Batch size and loading pattern

Center, edge and corner vials do not see identical conditions. Partial loads and full loads should be reviewed separately.

Scale the heat and mass transfer - not just the recipe



A Shelf heat transfer

Map usable shelf conditions and understand edge effects.

B Pressure evidence

Review capacitance, Pirani and product-temperature evidence.

C Condenser margin

Match total ice load, sublimation rate and refrigeration capacity.

D Vapor path and vacuum

Avoid assuming the same chamber pressure means the same product condition.

Equipment equivalence needs engineering evidence, not visual similarity.

YOUR URS STARTS HERE

Send these inputs for an engineering review.



- ✓ **Product and formulation limits**
- ✓ **Vial and stopper drawings**
- ✓ **Fill volume and target batch size**
- ✓ **Total water or solvent load**
- ✓ **Endpoint and analytical requirements**
- ✓ **Aseptic boundary and loading method**
- ✓ **Qualification and data-integrity scope**

Creator-to-Command configuration review

sjialab.com | Final scope depends on the approved project URS.