



# Extra Large R&D Freeze Dryer - QualiRFD™ 15S



## STANDARDS

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21 CFR Part 11

ASTM E2500

ISO 13408-3

ISO 14644-1

ISO 14644-2

## Extra Large R&D Freeze Dryer - QualiRFD™ 15S

Food Freeze Dryer projects often start in R&D, where you lock down a repeatable lyophilization cycle before scale-up. QualiRFD™ 15S is an R&D Freeze Dryer platform stoppering configuration, built for vial-based drying and small-scale production work.

The model is presented for bioproduct research, in-vitro diagnostic reagents, and similar lab-to-pilot workflows. It also supports drying of bulk materials such as liquids, pastes, and solids when your process allows. Stoppering after drying helps reduce moisture reabsorption and supports long storage.

QualiRFD™ 15S uses an in-situ, dual-chamber layout with a drying chamber and a cold trap to support automated freeze-drying runs. The controller is described as PLC-based with PID temperature regulation for stable shelf control.

Each shelf layer includes independent sample temperature probes to help you track product temperature during development. A nitrogen backfill function is listed for inert-gas handling at the end of a cycle. The control system is described with a large touchscreen and the ability to store many programs with multi-segment temperature steps.

## APPLICATIONS

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## Extra Large R&D Freeze Dryer - QualiRFD™ 15S Application

- Vial-based R&D and small-scale production: Formulation teams can portion product into vials, run a programmed cycle, then stopper to support storage and transport. This workflow helps reduce secondary contamination risk during post-drying handling. It also supports controlled comparison studies across batches when you are optimizing cycle parameters.
- Bioproducts and IVD reagent development: The product page positions SY-100FY as suitable for R&D work on bioproducts and in-vitro diagnostic reagents. Stable temperature control and program storage help repeat cycle settings during screening and verification runs. Vial capacity listings make it easier to plan batch loading for bench-to-pilot studies.
- Bulk materials in multiple physical forms: The QualiRFD™ 15S is described as suitable for bulk (liquid, paste, solid) conventional substances, beyond vial-only use. That flexibility helps when you need to compare container formats or evaluate drying behavior across different sample geometries. Stoppering remains available when vials are used for the final pack format.



## Standards

- ISO 13408-3 (Aseptic processing — Lyophilization): guidance specific to lyophilization within aseptic processing.
- ASTM E2500 (Specification, design, and verification of pharma/biopharma manufacturing systems): risk- and science-based verification approach for systems and equipment.
- ISO 14644-1 / ISO 14644-2 (Cleanrooms): classification and monitoring to support controlled environments around filling and loading areas.
- 21 CFR Part 11 (electronic records/e-signatures): relevant when you manage electronic data, audit trails, or signatures within regulated workflows.

## FEATURES

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### **Extra Large R&D Freeze Dryer - QualiRFD™ 15S Key Feature**

- Stoppering workflow supports sealing vials after drying to help limit moisture pickup during handling and storage.
- Dual-chamber architecture separates the cold trap and drying space for stable vapor capture and cycle control.
- Independent product temperature probes on each layer support development work and cycle tuning.
- Shelf control is described with  $\pm 1$  °C accuracy and PLC + PID temperature regulation for repeatable ramps and holds.
- Nitrogen backfill capability supports inert handling at the end of a cycle when your product requires it.
- Touchscreen system stores many recipes and supports multi-segment programs, including the ability to adjust or skip segments during runs.
- Safety and uptime functions include alarms, emergency stop, overpressure protection, and maintenance reminder features.

## THEORY & METHOD

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## Theory and Method

Freeze drying starts by freezing the product so water becomes ice inside the matrix. Vacuum is applied so ice transitions directly to vapor through sublimation during primary drying. Water vapor is captured in the cold trap, which helps keep chamber conditions stable.

Secondary drying then reduces bound moisture using controlled shelf temperature steps. This platform also describes a choice between stepwise and linear ramp control using a sublimation-curve switch.

## TECHNICAL SPECIFICATIONS

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### Extra Large R&D Freeze Dryer - QualiRFD™ 15S Technical Specification

Specification	QualiRFD™ 15S
Freeze-drying area	1.15 m <sup>2</sup>
Cold trap temperature	< -75 °C (no-load)
Vacuum level	≤ 1 Pa (no-load)
Shelf temperature range	-55 to +70 °C (no-load)
Maximum ice capacity	≥ 15 kg / 24 h
Shelf layers	4 + 1
Material tray	480 × 600 mm
Shelf spacing	100 mm
Loadable materials	11

<b>Specification</b>	<b>QualiRFD™ 15S</b>
Loadable vials	Φ12 mm: 8624 pcs; Φ16 mm: 4788 pcs; Φ22 mm: 2460 pcs
Defrost mode	Electric defrost
Safety devices	Audible alarm, emergency stop switch, overpressure protection
Power	7.5 kW
Voltage	Three-phase 5-wire, 380 V
Weight	1000 kg
Dimensions	1823 × 1144 × 2014 mm



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