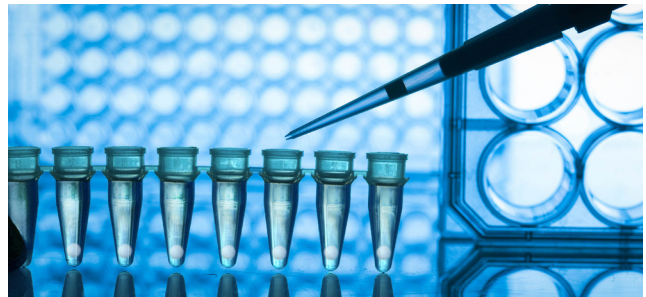


Production & Pilot Freeze Dryers

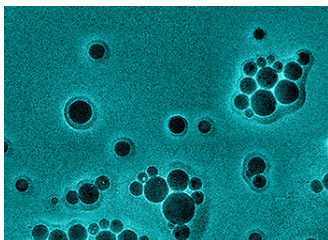
Engineered for Your Success



Quanta™
rev 1/19/2023

MILLROCK
TECHNOLOGY 

Introduction to the Quanta™ Freeze Dryer and Millrock Technology



Custom Designed for Your Application Needs

At Millrock, each production freeze dryer is custom designed and manufactured to meet your specific application needs. With 40+ years of experience, whether you need a laboratory quality (cGMP) or a production freeze dryer, Millrock Technology has a solution to meet your requirements. As the science and equipment of freeze drying continues to evolve, Millrock's freeze dryers are continuously updated with the latest features and technology. Our production lyophilizers are designed to provide you with optimum performance for business success.

Applications:

- Pharmaceutical
- Diagnostics
- Biotech
- API
- Tissue
- Nanoparticles
- Enzyme
- Microbiome
- Nutraceuticals
- Vaccines
- Animal Health
- & More

We make freeze drying easy.

Selecting a production freeze drying manufacturing partner can be a difficult task. At Millrock, we understand that choosing the right freeze dryer is often pivotal to the production of great products and to your company's long-term success. Our team uses a step-by-step collaborative approach for specification setting and design to ensure we provide the highest performance solution for your needs.

Experience the Millrock Difference

Customer Service
Application Knowledge
Quality

Quanta™

MILLROCK
TECHNOLOGY

Our Approach to Project Design & Management



Discovery

Our collaborative approach to system selection and design provides the best freeze dryer for your production needs. We will provide you with the latest information on the current state of applications in your industry, new technology design features and their implementation, and help set your initial budget expectations. A thorough discovery session will dig deep into your freeze drying application needs and provide the details that are necessary to move to proposal and contract.



Design

It is in this step that our deep knowledge of freeze drying and our attention to detail makes the difference. Specifications are created for the mechanical, electrical, instrument, control hardware and control software system components of your freeze dryer. We submit the specifications and layout drawings for your acceptance and approval. This iterative process will help to ensure that when system design and manufacturing begins there is a complete communication and understanding of the design scope of your freeze dryer.



Production

You can trust Millrock Technology to provide you with a high-quality, high-performing freeze dryer for your application. We are ISO 9001 certified, the international standard signifying our commitment to quality and customer satisfaction. This certification demonstrates our ability to consistently provide products and services that meet customer and regulatory requirements. We ensure all product components are of the highest quality and sized to provide the best possible performance during the lyophilization process.



Quality Control

Before your product ships to your location, we will execute our Factory Acceptance Test (FAT) protocol, confirming the specification and operational performance of your product. This includes component serial numbers and drawing verification.

Once your unit is fully installed and all utilities are connected at your location, the Site Acceptance Test (SAT) can be conducted, including execution of the Installation Qualification (IQ)/Operational Qualification (OQ) workbook. This process is utilized to guarantee that all of the utilities are correctly installed and to confirm that the system will perform to the performance specifications.



Ongoing Expert Customer Service

Service is our priority. Our service team's goal is to keep your unit up and running 24/7.

Freeze Drying is the only thing we do. Our people have deep knowledge of the production and operation of freeze drying equipment. When you call Millrock you speak to someone who has experience building and operating the equipment. Our freeze drying support staff can quickly answer your questions, saving you time.

We pride ourselves in our responsiveness and product knowledge.

Quanta™ Production Freeze Dryer

Versatile Lyophilizers

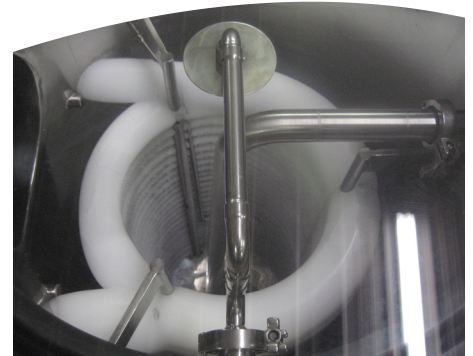
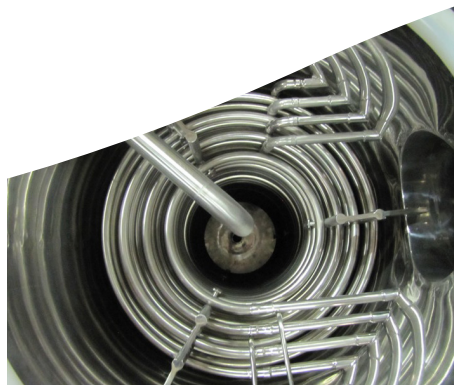
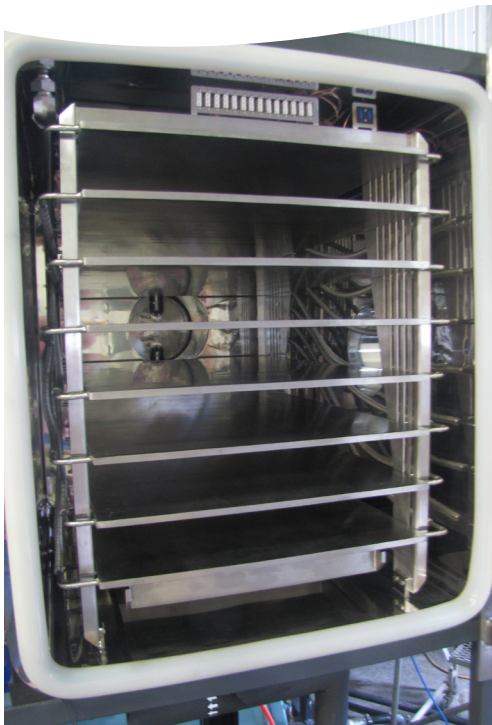
The Quanta cleanroom production freeze dryer is a production-scale lyophilizer ready to be customized to fit your existing facility and production requirements. This versatile freeze dryer is available with a shelf area of 8-300 sq. ft. (.74-28 sq. m.), accommodating a wide range of application needs. The Quanta features the same control system as our laboratory-scale freeze dryers allowing you to easily scale-up for production.

To accommodate the wide range of requirements between each industry, Millrock Technology offers Freeze Dryers in the following specifications:

- 304L stainless steel for non-pharmaceutical applications
- 316L stainless steel for pharmaceutical applications

Custom Designed to Fit Your Application Needs

- Vials
- Syringes
- Bulk liquids
- Lyophilized beads
- 96-well plates
- Custom devices
- Anaerobic applications
- Solvent handling



Quanta™ Production Freeze Dryer

SPECIFICATIONS

QUANTA PRODUCTION STANDARD SPECIFICATIONS

CONTROL SYSTEM	Opto 22 or Allen-Bradley®
SHELF TEMPERATURE RANGE	-60C to +65C (+80C option)
SHELF HEAT TRANSFER	Hollow, Fluid Filled
SHELF MATERIAL & FINISH	316L, 20 Ra or better. Optional Electropolish
SHELF AREA	8 to 300 sq ft
SHELF ASSEMBLY	Bulk or Hydraulic Stoppering
CONDENSER TEMPERATURE	-75C
CHAMBER CONFIGURATION	Cylindrical or Rectangular
CHAMBER RATING	Full Vacuum
CONDENSER STYLE	Exposed Coil, Internal/External
COMPRESSORS	Two Stage, Carlyle, Bitzer, Mycom (screw)
DEFROST	Hot Gas or Hot Water
VACUUM PUMP	Leybold Rotary Vane or Dry Pumps
VACUUM CONTROL	Pirani with Solenoid & Needle Valve
GAS BACKFILL	Included
PRODUCT SENSORS	One per shelf standard
FRAME	Welded and painted

Note: Performance specifications are estimates and may change based upon design. Specifications subject to change without notice. All specifications based on 20C ambient on 60Hz.

LYOPHILIZER VIAL CAPACITY by Shelf Area (sq ft)

VIAL (ml)	8	12	30	50	60	96	144	300
2 ml (15mm)	3496	5080	13190	21424	26780	43888	66500	131000
5 ml (22mm)	1612	2380	6100	10050	12560	20120	30900	60450
10 ml (24mm)	1288	1835	4940	8170	10220	17032	25500	4830
20 ml (29mm)	872	1290	3320	5610	7020	11344	17400	32700

Number of vials is an approximation. Actuals can be provided as required.

Options:

- 304 or 316L stainless steel
- Clean-in-Place piping and control
- Pass-through design
- Single height door loading with pizza door
- Auto Load/Unload options
- Internal condenser or external condenser
- Isolation valve
- Bulk or hydraulic stoppering
- Bellows seal on hydraulic stoppering
- Acrylic or stainless steel door
- MKS proportional vacuum control
- Water Ring Pump
- 21 CFR Part 11 Compliant software
- Validation documentation
- Factory acceptance testing
- Site acceptance testing
- IQOQ Workbook

CONFIGURATION EXAMPLES

CONFIGURATION	8	12	30	50	60	96	144	300
SHELF AREA SQ FT SQ M	8 .74	12 1.1	30 2.78	48 4.44	60 5.57	96 9.29	144 13.30	300 29.73
# OF SHELVES	4	6	10	5	6	8	12	15
SHELF SIZE IN x IN MM X MM	12 x 24 300 x 600	12 x 24 300 x 600	18 X 24 450 X 600	30 X 48 600 X 915	30 X 48 600 X 915	36 X 48 915 X 1219	36 X 48 915 X 1219	48 X 60 1219 X 1500
CONDENSER CAPACITY (LITERS)	25	30	75	100	150	200	300	600
CONDENSER TEMPERATURE	-75C							
SHELF TEMPERATURE	-60C to +60C							
COOLING	WATER COOLED COMPRESSORS							

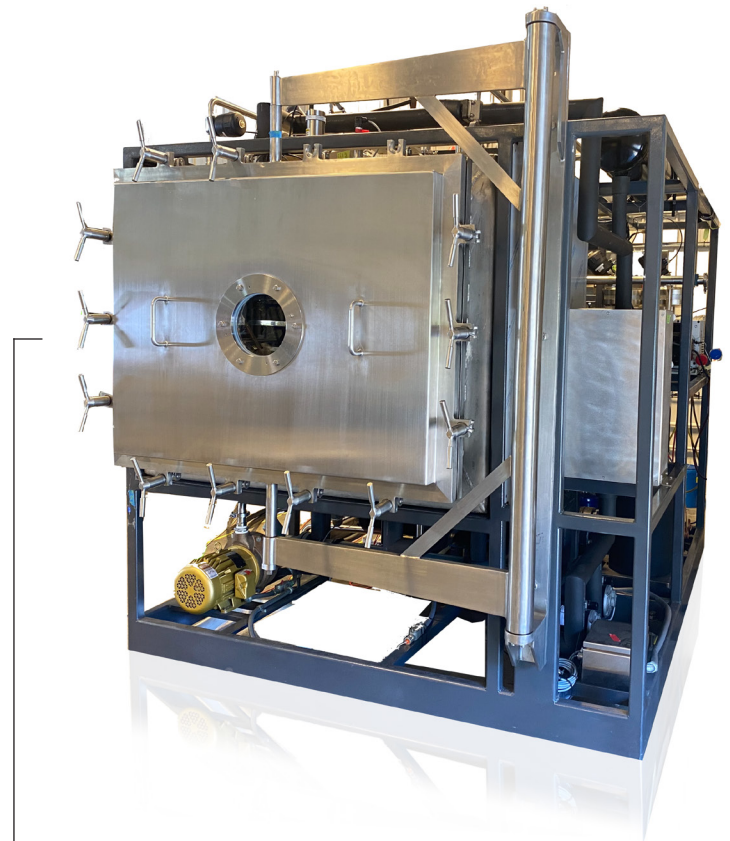
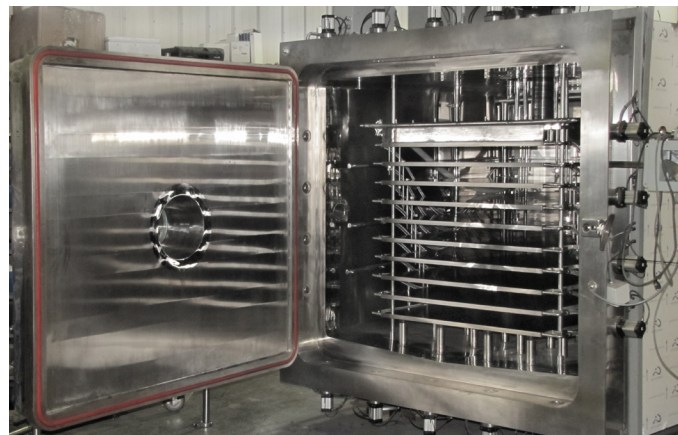
For reference only. Actual configurations may vary based on design for application needs.

QuantaS™ Steam Sterilizable Production Freeze Dryer

Pharmaceutical Freeze Drying in a Sterile Environment

Choosing the right lyophilizer is pivotal to the production of a great product and to long term company success. At Millrock Technology, our collaborative approach to system selection, customization and design provides the best freeze dryer for the most demanding applications. Our support lasts throughout the production freeze dryer life cycle to help ensure that your project starts successfully and remains successful.

The QuantaS features the same design basis and control system as our laboratory-scale freeze dryers, allowing you to easily scale-up for production. We also offer two design options: cylindrical or rectangular chambers so you can select the best fit, price and performance requirements for your application.



Our Steam Sterilizable Production Freeze Dryers include:

- All wetted components 316L stainless steel
- Sterilization (SIP) temperature: Controllable 121-125 degrees C
- Evacuation and drying: Water ring pump
- Insulation: High temperature CFC-Free foam with a stainless steel shroud around both chambers
- Filter: 0.2 micron with integrity testing ports
- Slope to drain
- Customized for your application needs

QuantaS™ Steam Sterilizable Production Freeze Dryer

SPECIFICATIONS

QUANTA-S STANDARD SPECIFICATIONS	
CONTROL SYSTEM	Opto 22, Allen-Bradley®
SHELF TEMPERATURE RANGE	-60C to +65C (+80C option)
SHELF HEAT TRANSFER	Hollow, Fluid Filled
SHELF MATERIAL & FINISH	316L stainless steel, 20 Ra or better. Optional Electropolish
SHELF AREA	250 sq ft
SHELF ASSEMBLY	Bulk or Hydraulic Stoppering
PRODUCT PROBES	1 "T" type thermocouple/shelf
CONDENSER TEMPERATURE	-75C dry and empty
CHAMBER CONFIGURATION	Cylindrical or Rectangular
CHAMBER RATING	ASME 25psi at 125C
CONDENSER STYLE	Exposed Coil, Internal/External
COMPRESSORS	Two Stage, Carlyle, Bitzer, Mycom (screw)
DEFROST	Steam
VACUUM PUMP	Two Stage Oil Sealed Rotary Vane, Dry (optional)
VACUUM CONTROL	Capacitance Manometer, Proportional Vacuum Control (optional)
WATER RING PUMP	Included standard
FRAME	Welded and painted

Note: Performance specifications are estimates and may change based upon design. Specifications subject to change without notice. All specifications based on 20C ambient on 60Hz.

LYOPHILIZER VIAL CAPACITY by Shelf Area (sq ft)

VIAL (ml)	8	12	30	50	60	96	144	250
2 ml (15mm)	3496	5080	13190	21424	26780	43888	66500	109166
5 ml (22mm)	1612	2380	6100	10050	12560	20120	30900	50375
10 ml (24mm)	1288	1835	4940	8170	10220	17032	25500	40250
20 ml (29mm)	872	1290	3320	5610	7020	11344	17400	27250

Number of vials is an approximation. Actuals can be provided as required.

Options:

- Cooling Jacket on Chamber and Door
- Clean-in-Place piping and control
- Pass-through design
- Single height door loading with pizza door
- Auto Load/Unload options
- Internal condenser or external condenser
- Isolation valve
- Bulk or hydraulic stoppering
- Bellows seal on hydraulic stoppering
- Acrylic or stainless steel door
- MKS proportional vacuum control
- Water Ring Pump
- 21 CFR Part 11 Compliant software
- Validation documentation
- Factory acceptance testing
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CONFIGURATION EXAMPLES

CONFIGURATION	8	12	30	50	60	96	144	250
SHELF AREA SQ FT SQ M	8 .74	12 1.1	30 2.78	48 4.44	60 5.57	96 9.29	144 13.30	250 23.22
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SHELF SIZE IN x IN MM X MM	12 x 24 300 x 600	12 x 24 300 x 600	18 X 24 450 X 600	30 X 48 600 X 915	30 X 48 600 X 915	36 X 48 915 X 1219	36 X 48 915 X 1219	48 X 60 1219 X 1500
CONDENSER CAPACITY (LITERS)	25	30	75	100	150	200	300	600
CONDENSER TEMPERATURE	-75C							
SHELF TEMPERATURE	-60C to +60C							
COOLING	WATER COOLED COMPRESSORS							

For reference only. Actual configurations may vary based on design for application needs.

Opti-Dry® Control System

Our state-of-the-art control technology, **Opti-Dry**, provides real-time, continuous process measurement and unparalleled control of both the freeze drying and primary drying cycles. Each of our freeze dryers use the same control systems for research and development through production, allowing rapid scaling from lab-scale to production.

Our PC/PLC based software communicates via Ethernet for high speed data collection and control, allowing the system to be monitored and controlled from a remote PC connection if available. All systems **are remotely accessible**, with customer approval, for troubleshooting process issues.

Our optional **21 CFR Part 11 compliance module** allows all data to be stored in a secured database to prevent manipulation. Program access is controlled through a multi-level password system to limit access to critical areas. New and modified data entry requires electronic signature that is level controlled to prevent unauthorized changes. Changes are logged in a change log database to provide a full audit trail that meets FDA requirements and batch reporting is data encrypted.

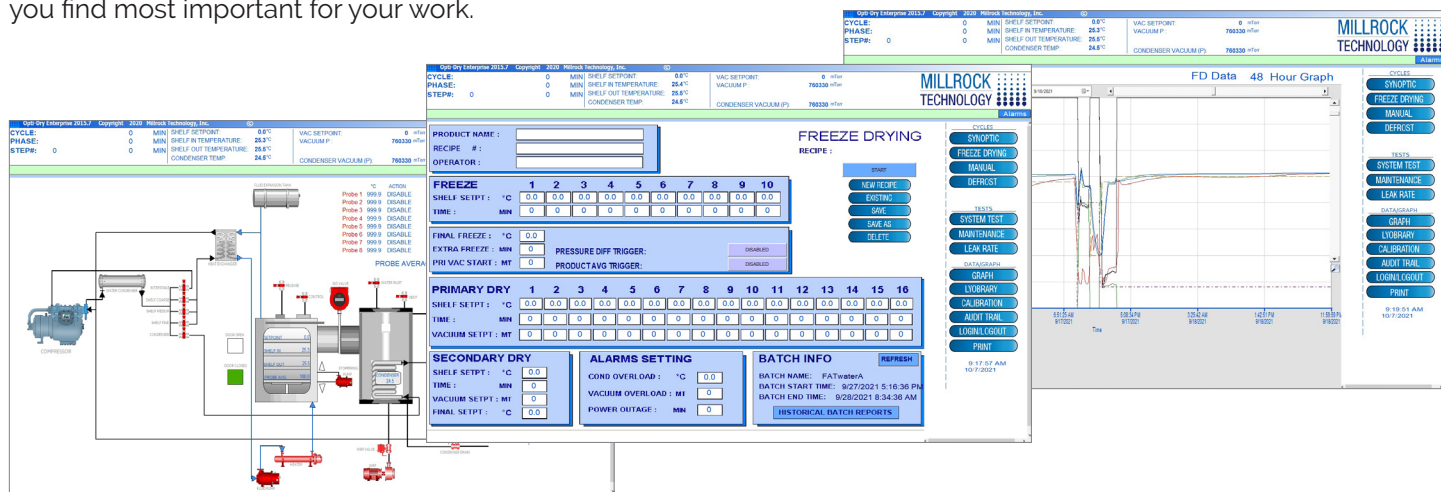
Millrock Reporter provides the data you need at your fingertips. No more exporting data to CSV files and manipulating with Excel. Millrock Reporter provides full batch reporting after the cycle is complete in the format that you design, including recipe, graphs, data, and alarms in a single report. You can rearrange the data being monitored right in our software for the view you find most important for your work.

Opti-Dry Standard Features:

- Manual and Automatic Modes
- 21CFR Part11 Compliant Software Option
- PC/PLC Platform with Ethernet Communication
- Windows Based Control Software
- 10 Freezing and 16 Primary Drying Steps
- System Status on Every Screen
- Synoptic Overview Screen
- Maintenance/Troubleshooting Screen
- Automatic System Test with History Data Storage
- Automatic Defrost
- Automatic Leak Rate Test
- Graphing – 4 and 24 Hour
- Numeric Data Collection by Run – Excel Importable
- 'Out of Range' Product Thermocouple Correction
- Remote Monitoring and Control Capability
- 4 to 16 Thermocouples
- Product Temperature Feedback optimizes the recipe, both freezing and primary drying
- Primary Drying End Point Determination Methods
 - Product Temp
 - Capacitance Manometer Differential
 - Dew Point
 - Pressure Rise
- Synoptic Screen
- Recipe Programming Screen

21 CFR Part 11 Software Option:

- Data Encryption
- E-Signature's with Change Log
- Batch reporting
- Provides multiple levels of security



When you purchase a Millrock product you get more than a freeze dryer. You get a long-term partner delivering industry-changing innovations, high-performing products, and on-call expert support.

Long-Term Partner

Partnering to develop the right solution for your business

Choosing the right freeze dryer is often pivotal to the production of a great product and to long term company success. At Millrock Technology, our collaborative approach to system selection, customization and design provides the best freeze dryer for your production needs. Our expert customer support is available throughout the life cycle of your production freeze dryer to help ensure that your project starts successfully and remains successful.

Industry-Changing Innovations

Continuous improvement of freeze drying performance and process

We are constantly working on new innovations and technologies for the freeze drying industry. These innovations are designed to enhance our customers' experience, allowing customers to produce their products with a higher yield and decreased cycle time, reducing processing risks. As a result of our combined experience and purposeful approach to engineering, we offer robust, efficient and high-performing freeze dryers.

High-Performing Products

Designed to be more robust and reliable than the competition

Millrock Technology's engineering staff ensures our products are industry leading, more robust, and reliable. We partner with customers to truly understand their challenges and design products around these specific needs. Millrock Technology products are designed with the customers' real-world challenges in mind, and every component is designed with a purpose. From the coils to compressors, all product components are high-quality and right for the job. Our equipment specifications are the best in the industry.

On-Call Expert Support

Trust Millrock to keep you up and running 24/7

Customer service is not a department at Millrock. It is the very foundation of our philosophy, mission and culture. Every department and every person in our company is committed to our customers as their number one priority. We are dedicated to offering high-performance products along with the most responsive support services in the industry for the entire life cycle of our products. Most importantly, we know that our customers are best served when we listen to your needs and work in partnership to create the proper solution for your business.

Experience the **Millrock Difference**

When you purchase a Millrock product, you get more than a freeze dryer. You get a long-term partner delivering industry-changing innovations, high-performing products, and on-call expert support.

Contact us to learn more about how Millrock Technology can partner with your business to provide the highest-performance, advanced freeze drying services.

Sales: 845.339.5700 • sales@millrocktech.com | Service: 845.331.1279 • service@millrocktech.com



Millrock Technology, Inc. • 39 Kieffer Lane • Kingston, NY 12401

Visit our website at <https://www.millrocktech.com>