Quanta

Production Freeze Dryers

MILLROCK TECHNOLOGY®

Our commitment is to your freeze drying success.

Selecting the Right Freeze Dryer and Designer /Manufacturer Can Be Hard.

Selecting a production lyophilizer vendor can be a difficult task for the person new to freeze drying and to the seasoned professional. We recognize that choosing the right freeze dryer is often pivotal to the production of great product and to long term company

SUCCESS

A Collaborative Approach to System Selection, Customization and Design Helps Create the Best Solution.

At Millrock Technology, Inc. we have successfully designed and installed Quanta production units for our clients and they keep coming back for more. This is because we take a step-by-step collaborative approach to ensure that you get the best freeze dryer for your needs.

Needing a production freeze dryer is a good problem to have...

…it means you are on your way to commercializing a successful product. Take the time to fully understand your financial boundaries, timeline for a successful installation and technical requirements.

Don't try to design the freeze dryer but rather make sure you know what you need to accomplish with regard to product processing.

Keep in mind that laboratory freeze dryers and production freeze dryers do not necessarily have the same features and performance and cycle adjustments may need to be made.

Depending on the size of the unit it can take some time from the specification to actual installation and commissioning of a production freeze dryer.

Some initial discussions with Millrock Technology should provide you with great information on the current state of manufacturing, new design features and their implementation, and help set your initial budget expectations. In addition, a thorough discovery session will very likely uncover items or issues you had not thought of previously. This will help ensure that when you build and publish your User Requirements Statement that you have included all of the salient information needed to obtain good and detailed responses to your request for proposals.

Each Production Dryer is Different Because Each Situation is Different.

A sample of some questions to ask:

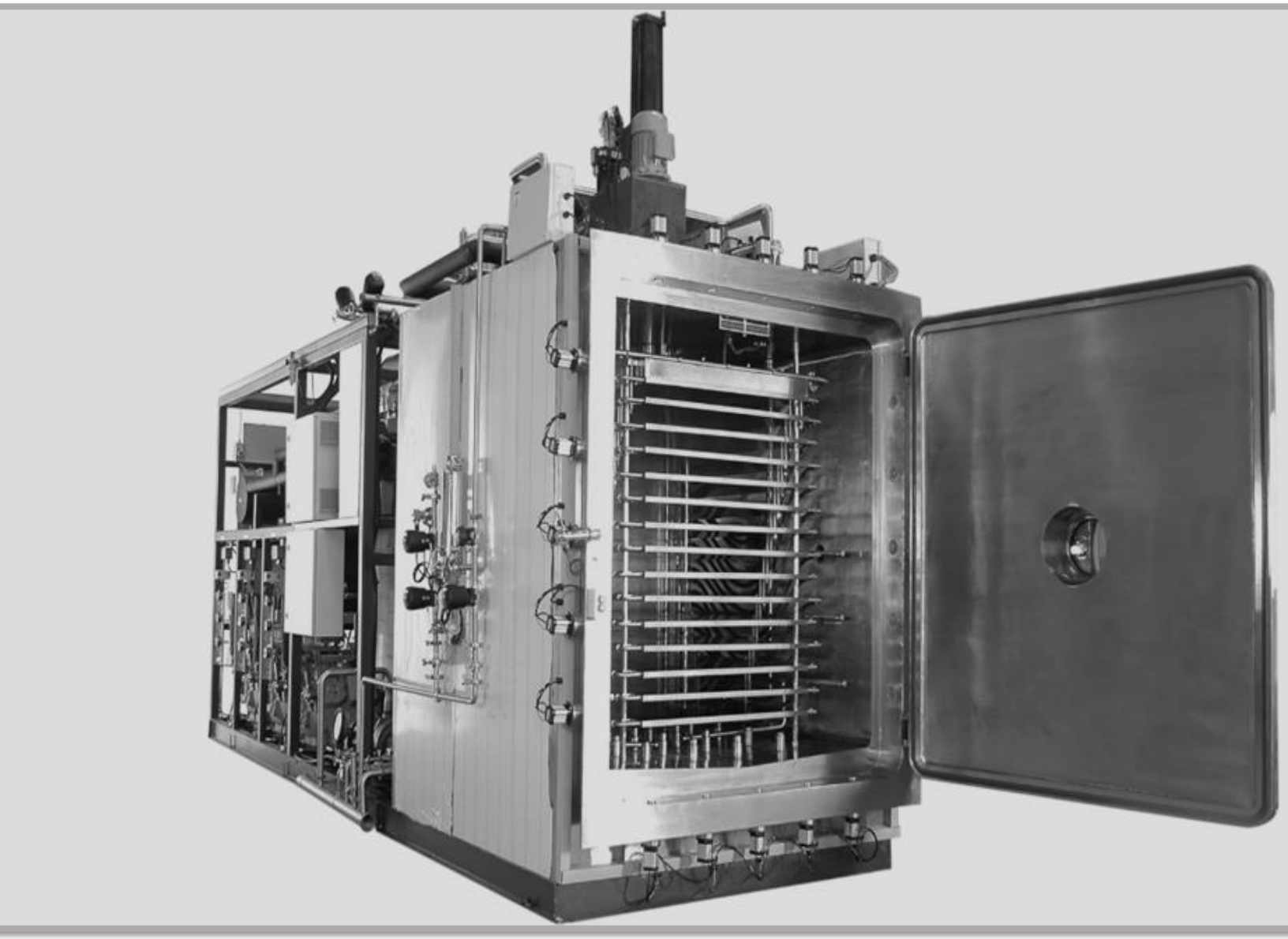
- Bulk or stoppering?
- Shelf area needed? (we suggest that bulk product is not more than ½ inch thick if possible.)
- Distance needed between shelves?
- Steam or non steam?
- 316L stainless steel or 304 stainless steel?
- Clean in Place or no clean in place?
- Isolation valve?
- Heaviest water load from the product?
- Any solvents other than water?
- Level of sophistication of controls?
  - Subject to 21 CFR?
  - Metrology required? Number of product probes, vacuum sensor types and locations?
  - Validation ports & locations?
- Redundant refrigeration or vacuum components for back-up?
- Check utilities?
  - Water for water cooled compressors?
  - Electrical available?
  - Compressed air?
- Space constraints?
  - Clean side space constraints?
    - Door swing?
    - Bezel size?
    - Controls on clean side?
  - “Dirty” side restraints?
    - Any weight restraints?
    - Space constraints?
    - Controls on dirty side?
  - Constraints on getting equipment into facility and into place?

The formal URS will lead to additional discovery as proposals are submitted. This process of URS and Proposal discussions will continue until you make your decision.

Step 2

URS, Proposal & Contract

The proposal, in response to your URS, is part of your contract with Millrock. Included will be deliverables by the supplier as well as deliverables from the client. A time-line, points of communication, and sign-off procedure should be put in place and agreed on in order to create the most seamless working relationship possible.



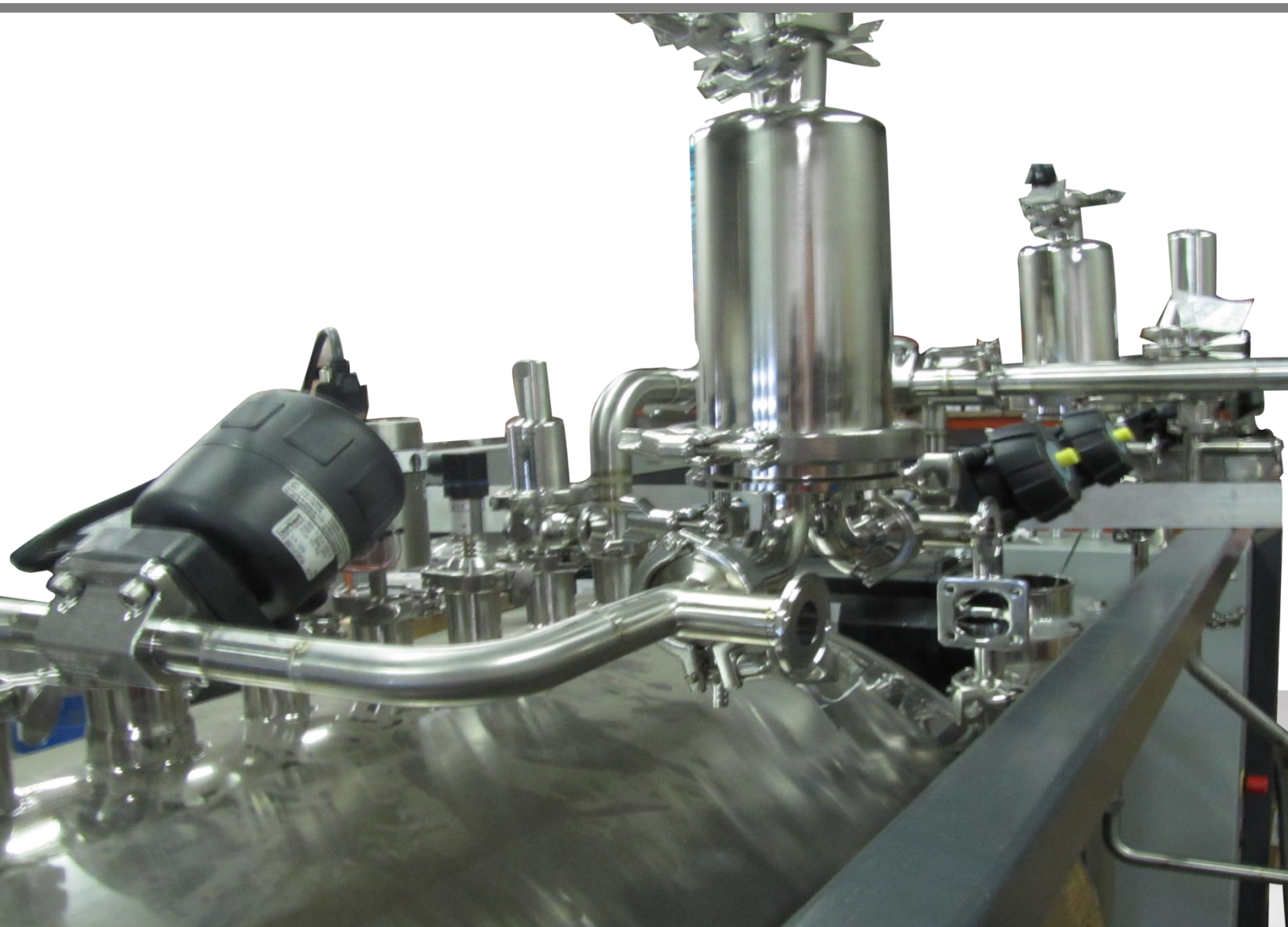
Step 3

Functional Specification

Our attention to detail makes the difference.

After the contract is completed we develop the functional specification for your freeze dryer based on your URS and our accepted proposal.

Functional Specifications are created for both the mechanical and control components of the freeze dryer. Before proceeding you will be asked to review these Functional Specifications. This iterative process will help to ensure that when system design and manufacturing begins there is a complete communication and understanding on the scope of the design of the freeze dryer



All communications converge during Design Specification and layout drawings are created and agreed on.

Step 4

Design Specifications

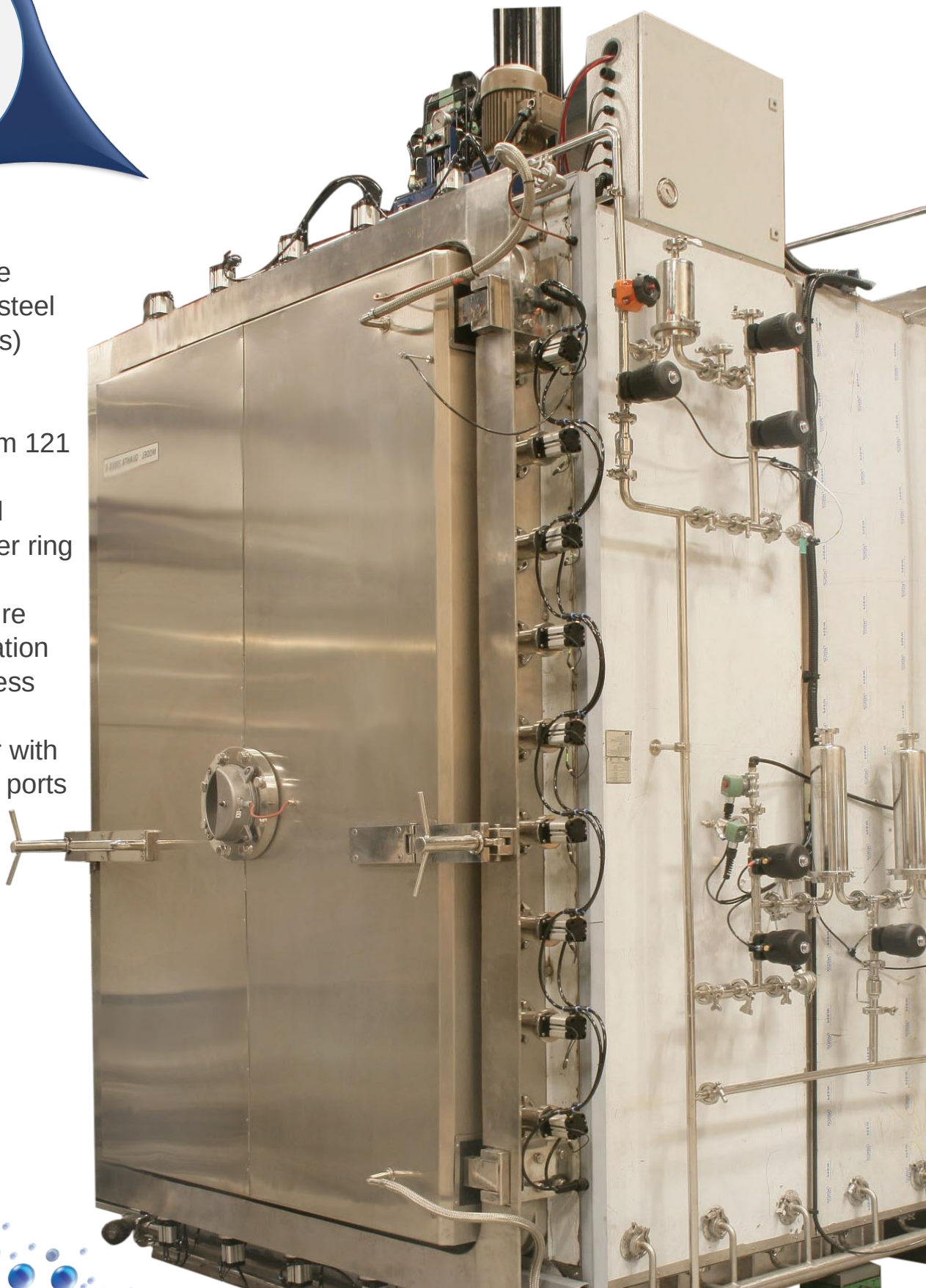
The final step during the design process is to create the design specification for the mechanical, electrical, instrument, control hardware and control software systems. Once again we submit the design specification and layout drawings for customer acceptance and approval.

QuantaS™
Steam Sterilizable Freeze Dryers

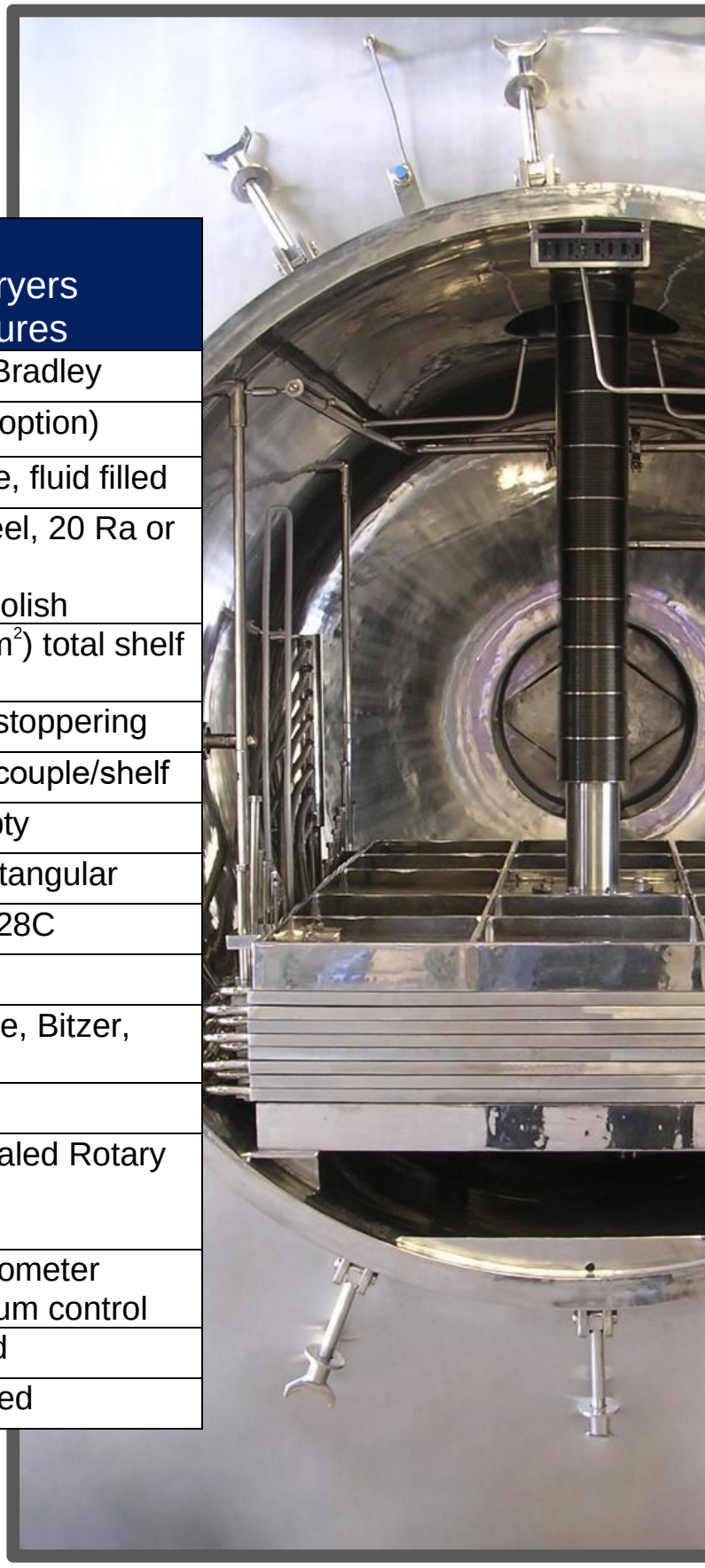
Step 5

Equipment Manufactured & Initially Tested

- All wetted components are 316L stainless steel
- Validation port(s)
- Sterilization temperature controllable from 121 to 125C
- Evacuation and drying with water ring pump
- High temperature CFC free insulation clad with stainless steel
- 0.2 micron filter with integrity testing ports



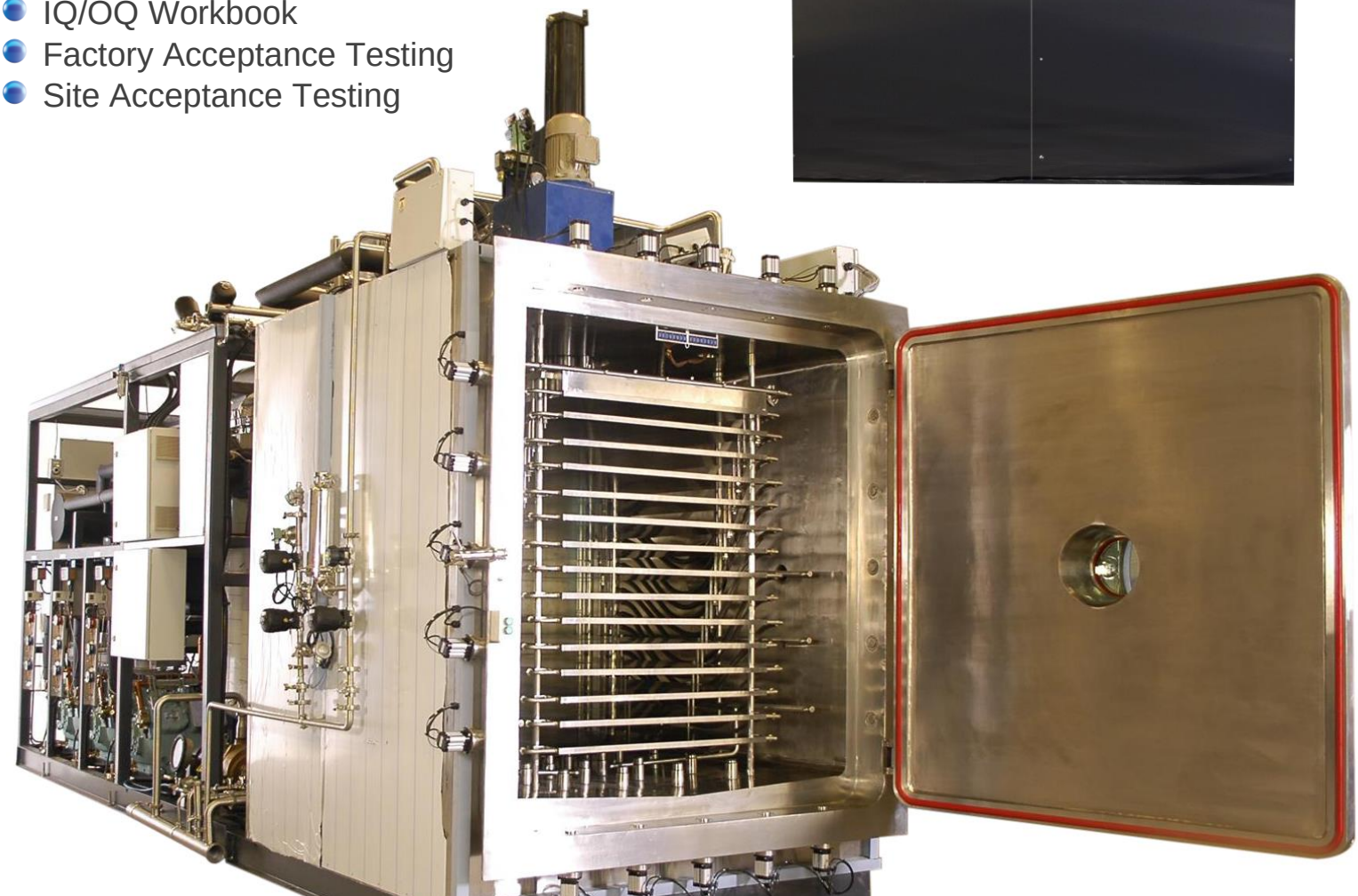
QuantaS™ Steam Sterilizable Production Freeze Dryers Typical Operating Specifications & Features	
Control System	Opto 22 or Allen-Bradley
Shelf Temperature Range	-60 to +65C (+80 option)
Shelf Heat Transfer	Hollow, serpentine, fluid filled
Shelf Material and Finish	316L stainless steel, 20 Ra or better Optional electro-polish
Shelf area	Up to 400 ft^2 (37 m^2) total shelf area
Shelf Stack	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 25 psi at 128C
Condenser Style	Coil
Compressors	Two Stage, Carlyle, Bitzer, Mycom (screw)
Defrost	Steam
Vacuum Pump	Two Stage Oil Sealed Rotary Vane or Dry
Vacuum Control	Capacitance manometer proportional vacuum control
Water Ring Pump	Included Standard
Frame	Welded and painted



QuantaS™
Steam Sterilizable Freeze Dryers

Sample of Options-

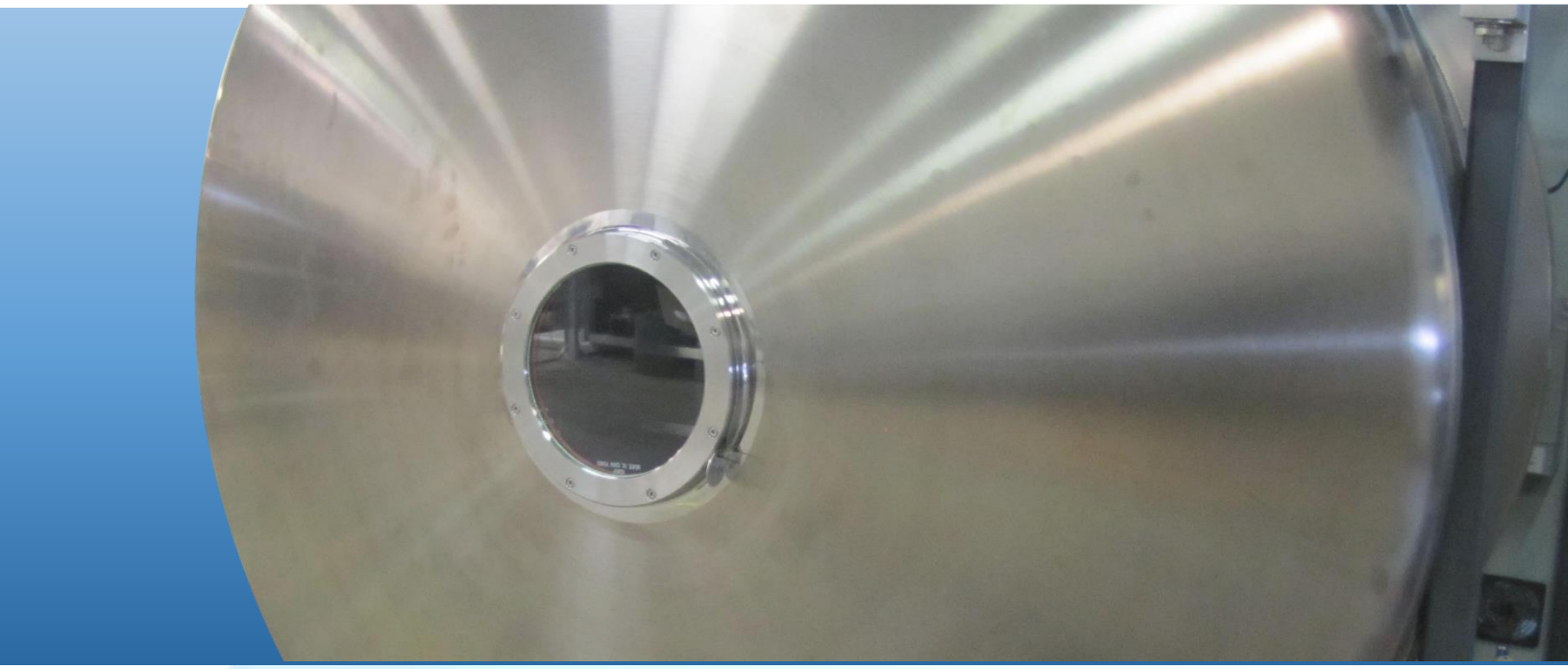
- Hydraulic Stoppering with Bellows Seal
- Bottom up or top down stoppering
- Isolation Valve
- Isolator interface
- Screw Refrigeration Compressors
- MKS Proportional Vacuum Control
- Clean-In-Place Piping and Control
- Electro-polished Shelves and Chamber
- Auto-Locking Doors
- Single Height Loading with Pizza Door
- Pass Through Design
- Cooling Jacket on Chamber and Door
- 21 CFR Part 11 Compliant Software
- Validation Documentation
- IQ/OQ Workbook
- Factory Acceptance Testing
- Site Acceptance Testing



Quanta

Freeze Dryers without Steam Sterilization

The range of applications for large production freeze dryers goes beyond pharmaceutical freeze drying in a steam sterilized freeze dryer.



Active Pharmaceutical Ingredients

Bulk Chemicals

Tissue

Diagnostic

Banking

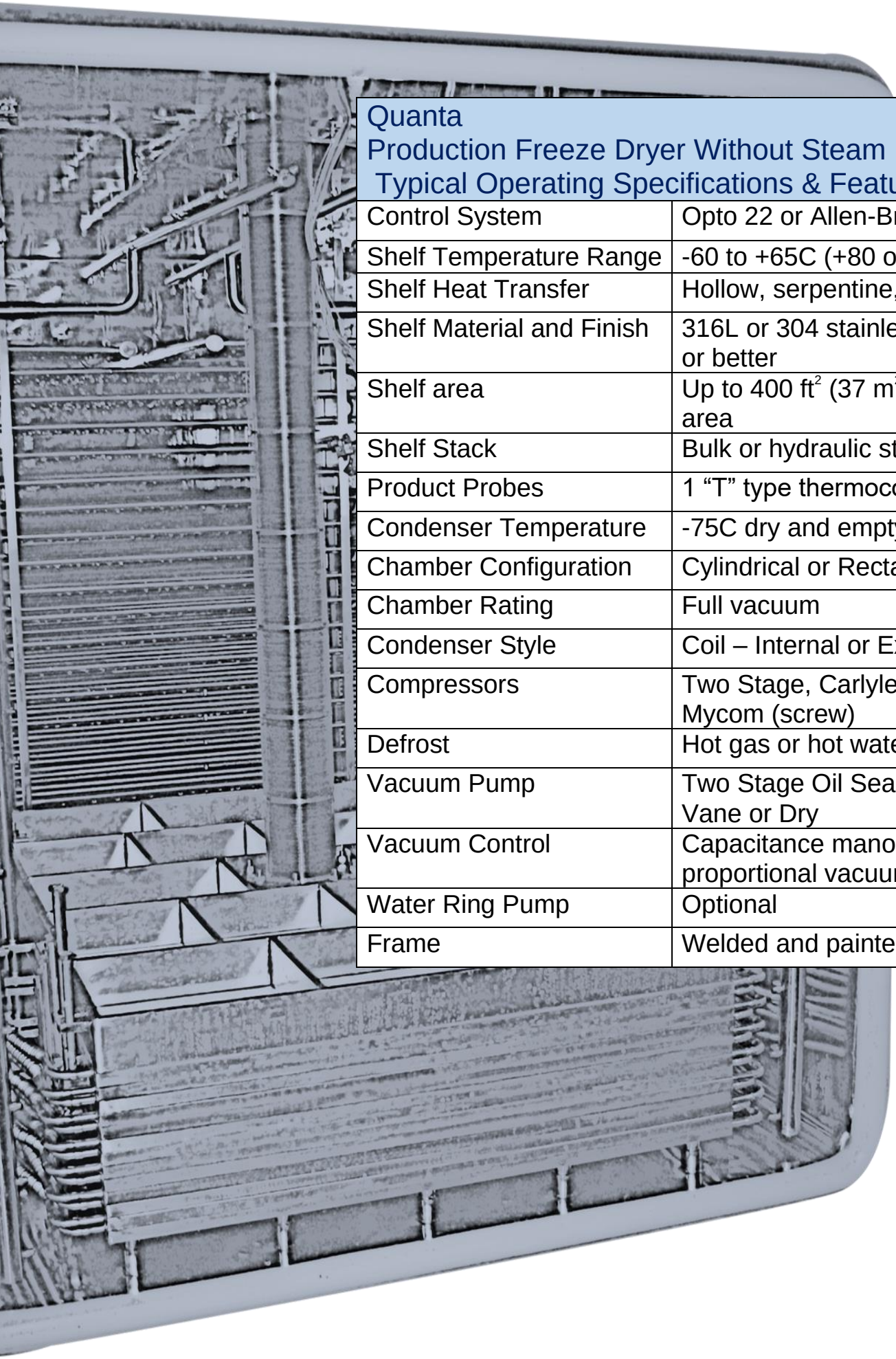
Kits

Nutraceuticals

Veterinary

Vaccines

Other Biologicals



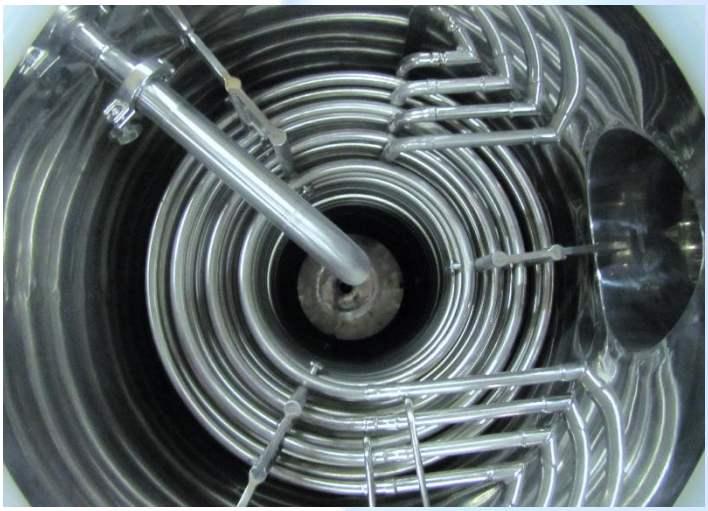
Quanta
Production Freeze Dryer Without Steam
Typical Operating Specifications & Features

Control System	Opto 22 or Allen-Bradley
Shelf Temperature Range	-60 to +65C (+80 option)
Shelf Heat Transfer	Hollow, serpentine, fluid filled
Shelf Material and Finish	316L or 304 stainless steel, 20 Ra or better
Shelf area	Up to 400 ft^2 (37 m^2) total shelf area
Shelf Stack	Bulk or hydraulic stoppering
Product Probes	1 “T” type thermocouple/shelf
Condenser Temperature	-75C dry and empty
Chamber Configuration	Cylindrical or Rectangular
Chamber Rating	Full vacuum
Condenser Style	Coil – Internal or External
Compressors	Two Stage, Carlyle, Bitzer, Mycom (screw)
Defrost	Hot gas or hot water
Vacuum Pump	Two Stage Oil Sealed Rotary Vane or Dry
Vacuum Control	Capacitance manometer with proportional vacuum control
Water Ring Pump	Optional
Frame	Welded and painted

Quanta
Freeze Dryers without Steam Sterilization

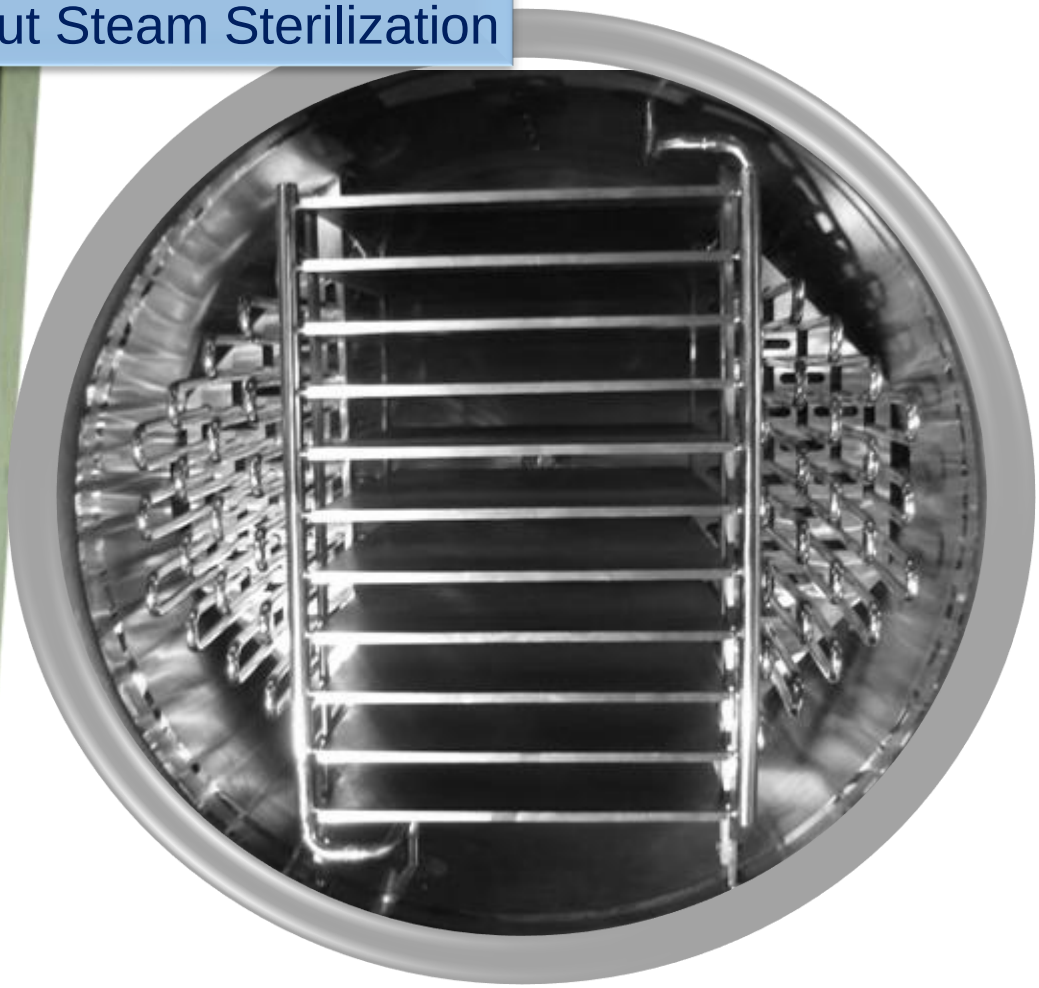
Sample of Options-

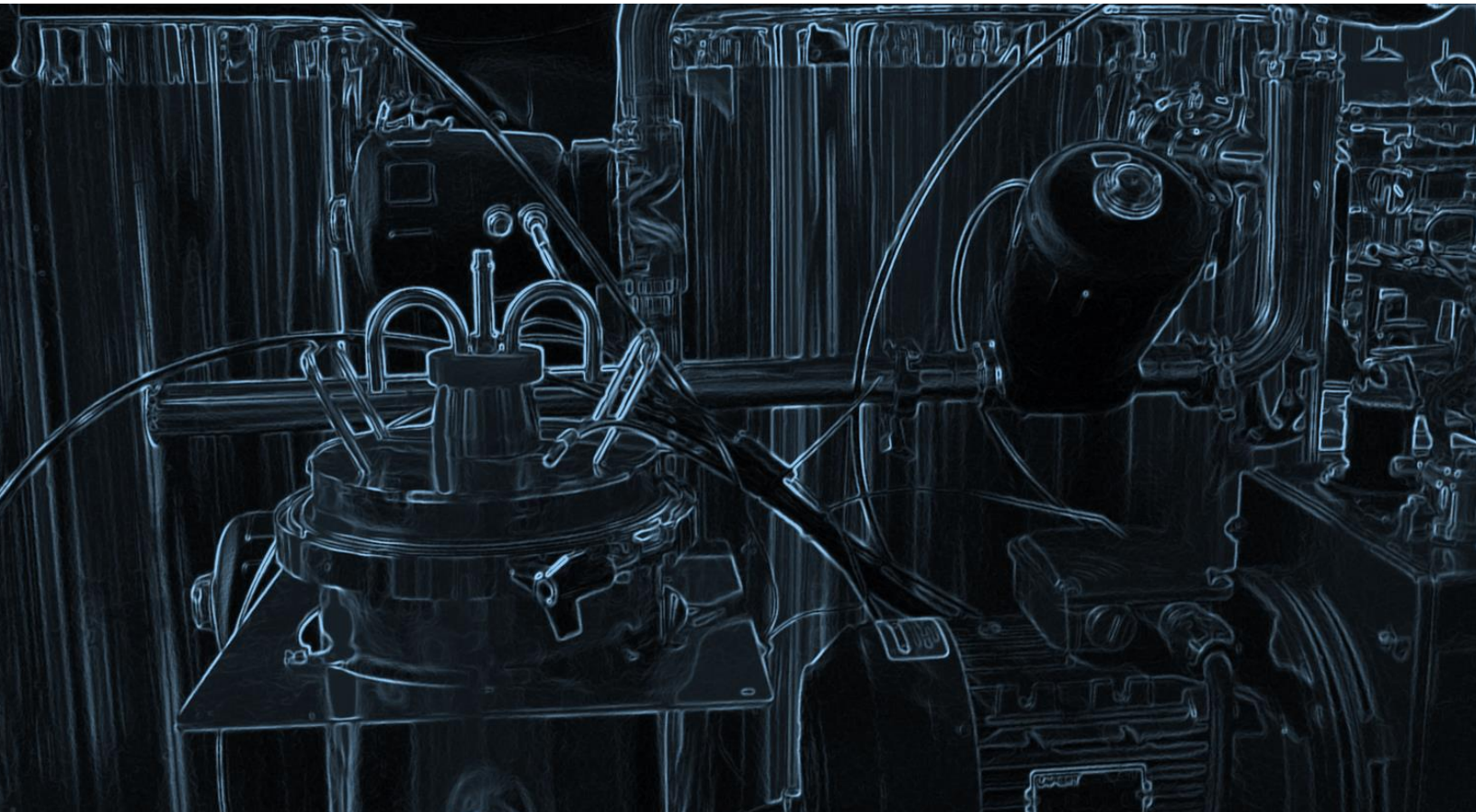
- 304 or 316L stainless steel
- Internal condenser or external condenser
- Isolation valve
- Bulk or hydraulic stoppering
- Bellows seal on hydraulic stoppering
- Acrylic or stainless steel door
- MKS proportional vacuum control
- Clean-in-Place piping and control
- Single height door loading with pizza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



Quanta

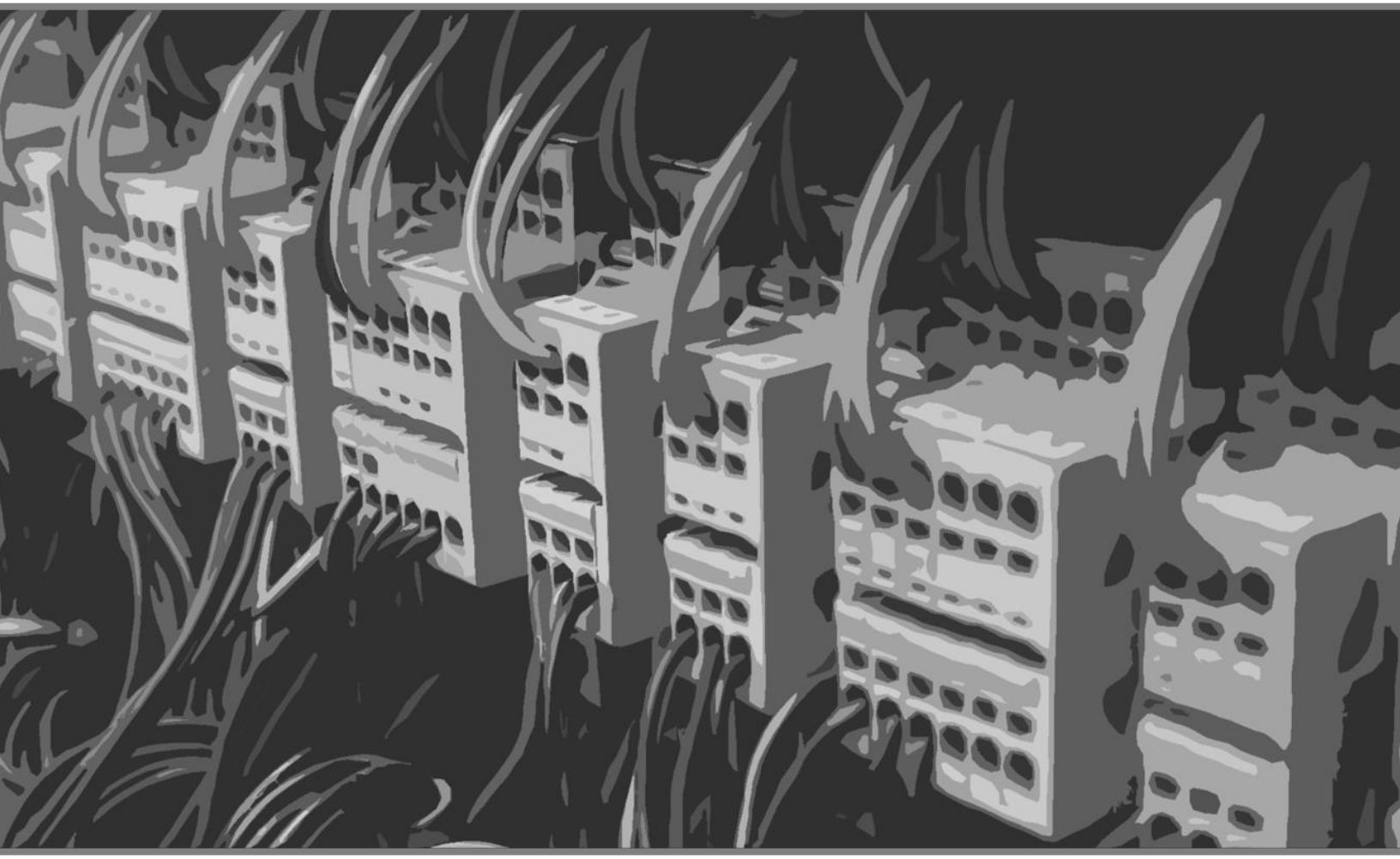
Freeze Dryers without Steam Sterilization



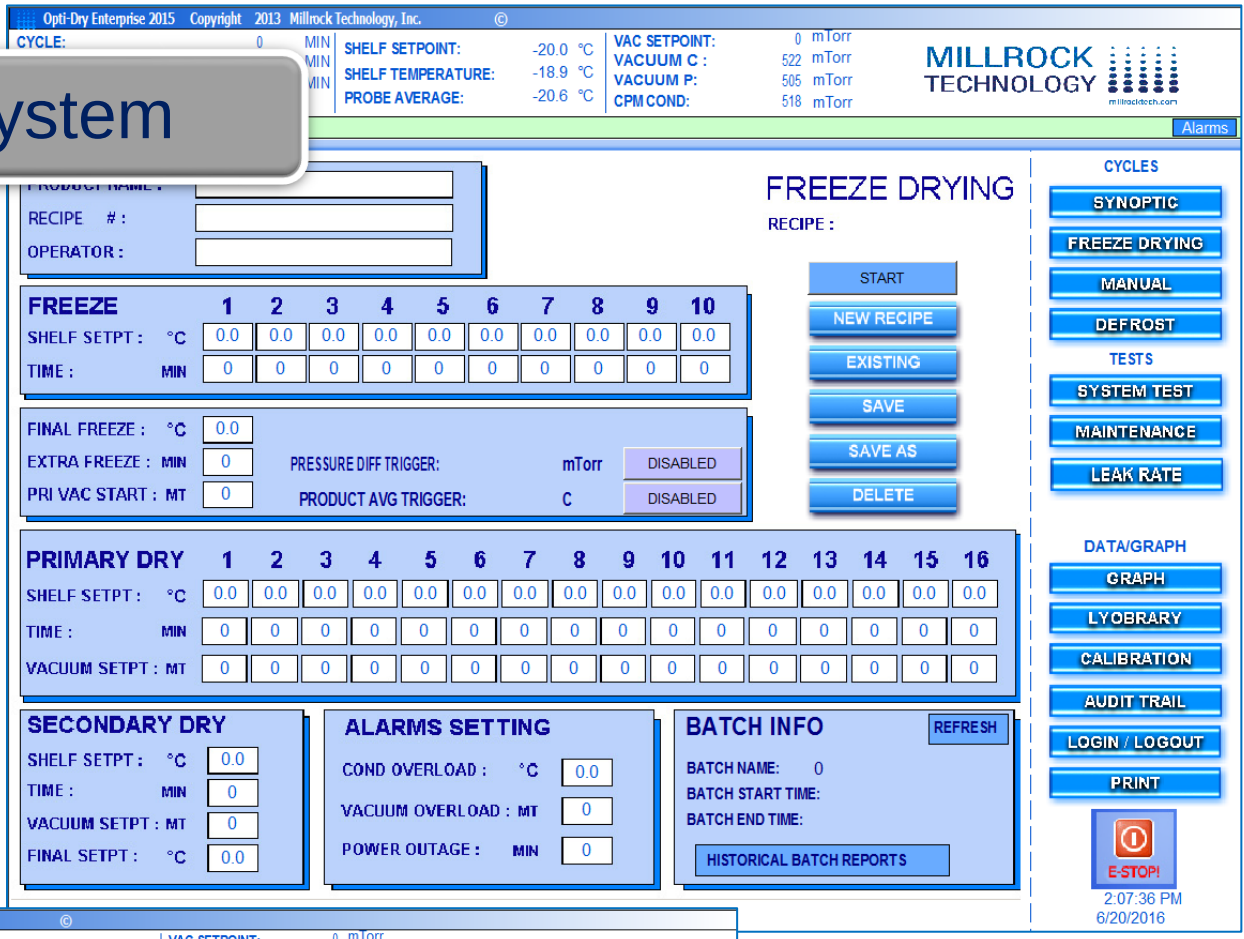


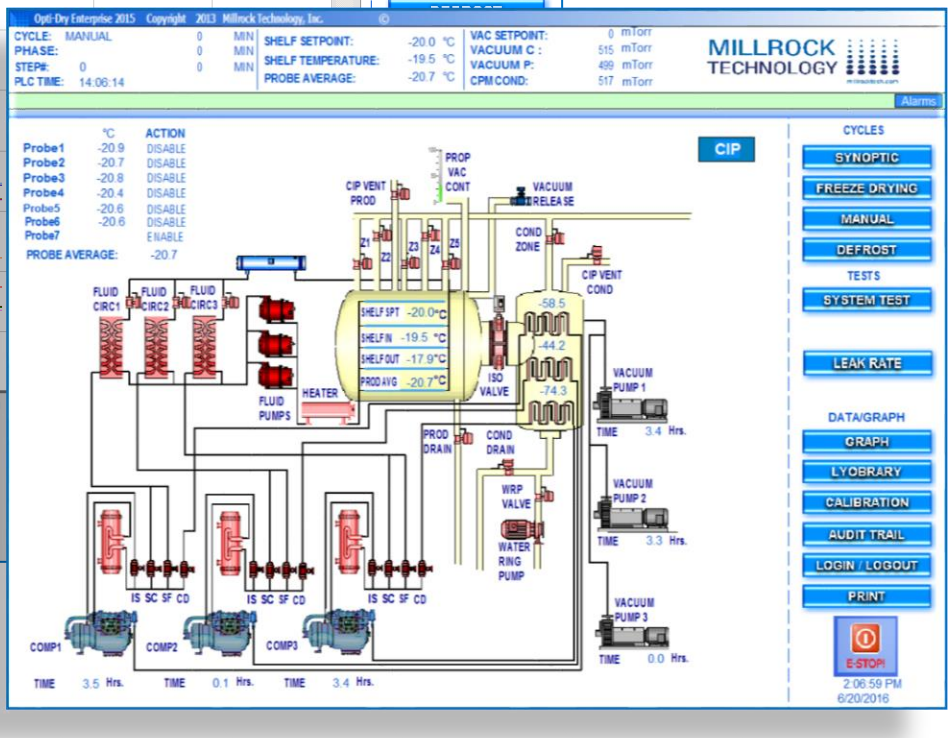
Control System

- PC/PLC platform with Ethernet communication
- Windows based control platform
- 10 freezing and 16 primary drying steps
- Unlimited recipe storage
- System status on every screen
- Synoptic overview
- Maintenance/troubleshooting screen
- Manual operation
- Automatic system test with history data storage
- Automatic defrost
- Automatic leak rate test
- Graphical display of runs
- Numeric data collection by run – excel importable
- Out of range product thermocouple correction’
- Remote monitoring and control capability
- Batch report
- 21 CFR Part 11 compliance module



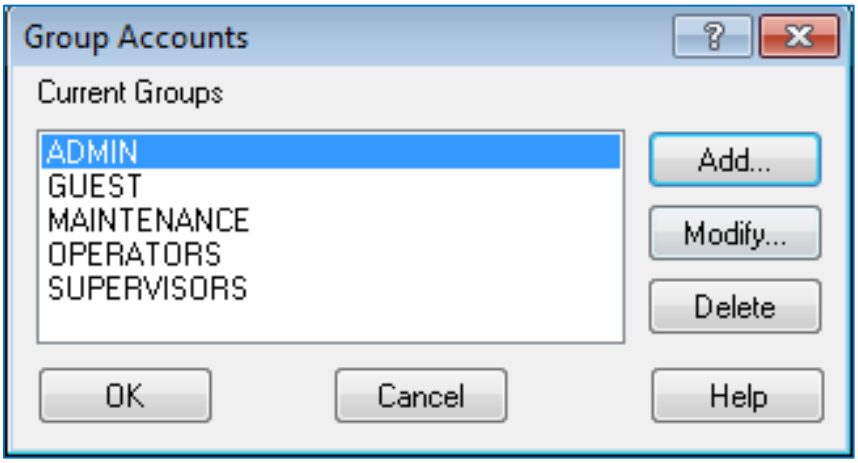
Control System

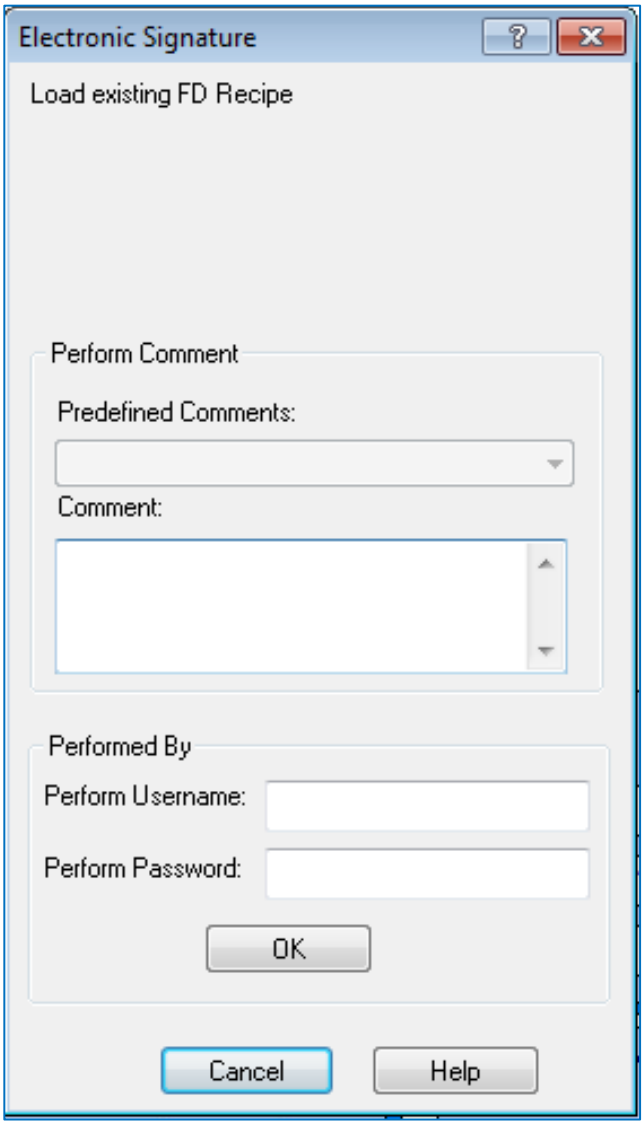


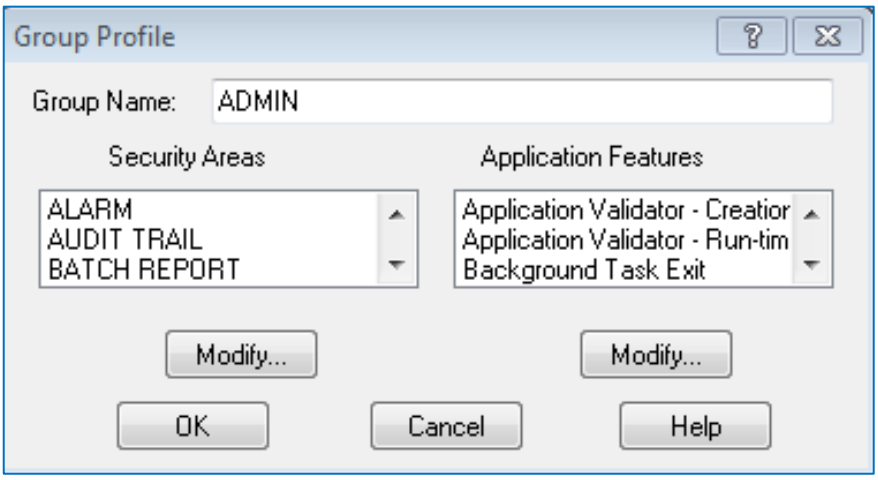


Control System – 21CFR Part 11 Option

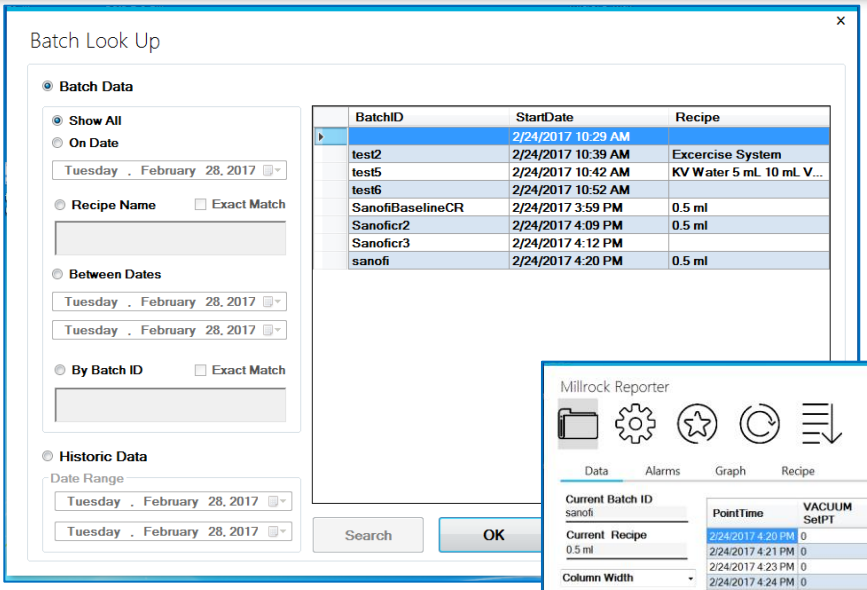
Millrock Technology, Inc offers 21 CRF Part 11 control system that provides the necessary platform to meet the needs of cGMP freeze drying manufacturing. All data is stored in a secure SQL database to prevent manipulation. Program access is controlled through a multi-level password system to limint access to critical areas. New and modified data entry requires electronic signature that is level controlled to prevent unauthorized changes. All changes are logged in a change log database to provide a full audit trail that meets FDA requirements.

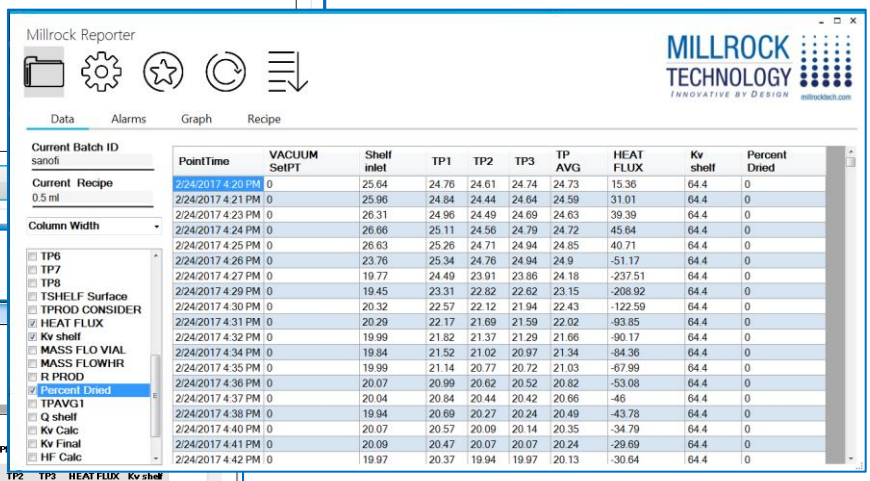


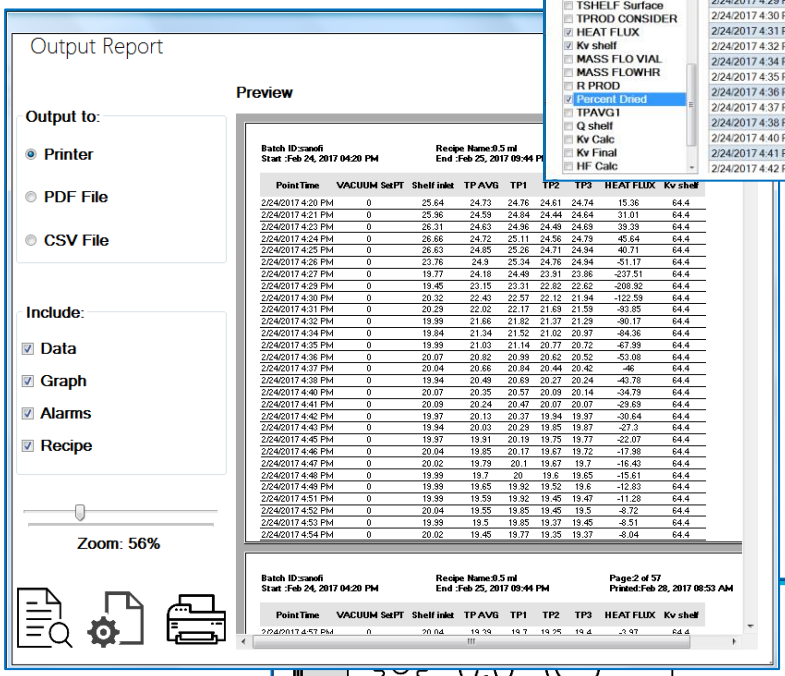


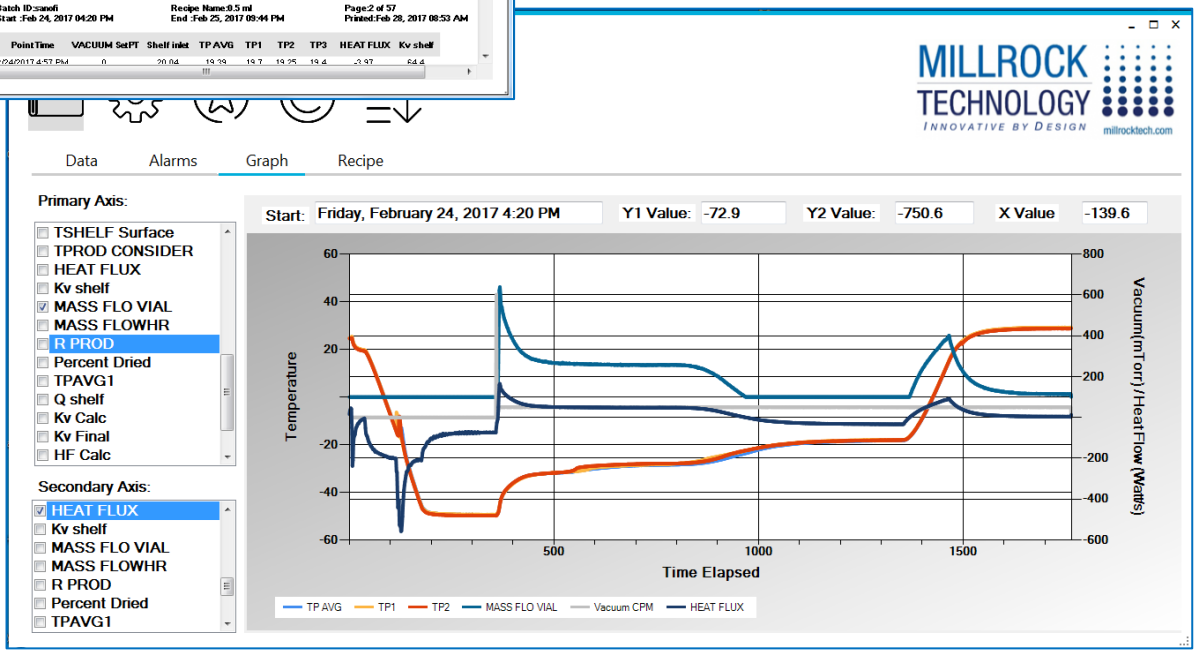


Control System – Batch Reporting





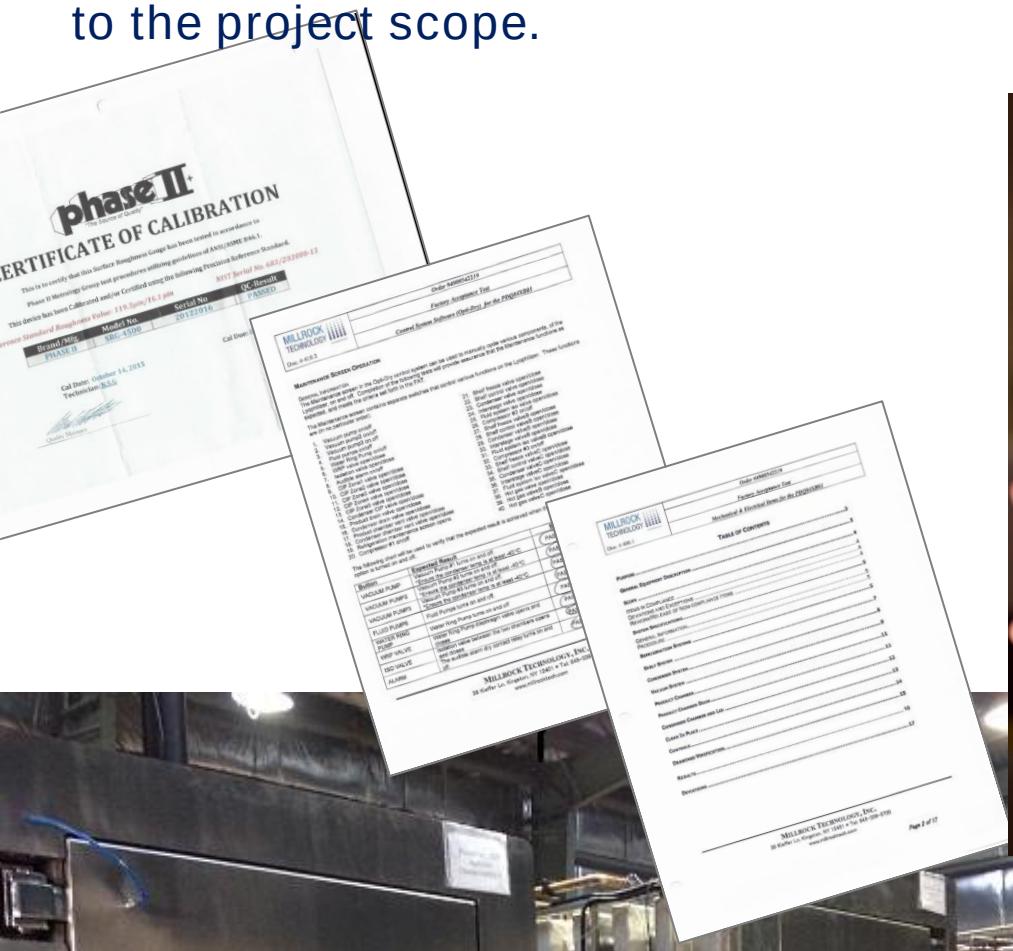




Factory Acceptance Testing (FAT) provides the first hand-off from Millrock to you. While at the factory you will test your system and verify its conformance to the project scope.

Step 6

Factory Acceptance Testing



Step 7

Packaged & Shipped with Care

At the conclusion of the FAT we work with you to explore the best and most economical ways to transport your equipment to you – safely and securely.

It is your responsibility to make sure that all utilities and building requirements are taken care of at your facility and that you have the appropriate staff to move the system into place and make utility hook-ups.

Once your unit is fully installed and all utilities are connected the Site Acceptance Test (SAT) can be ***conducted…and we will be there to*** support you through this process.

Step 8

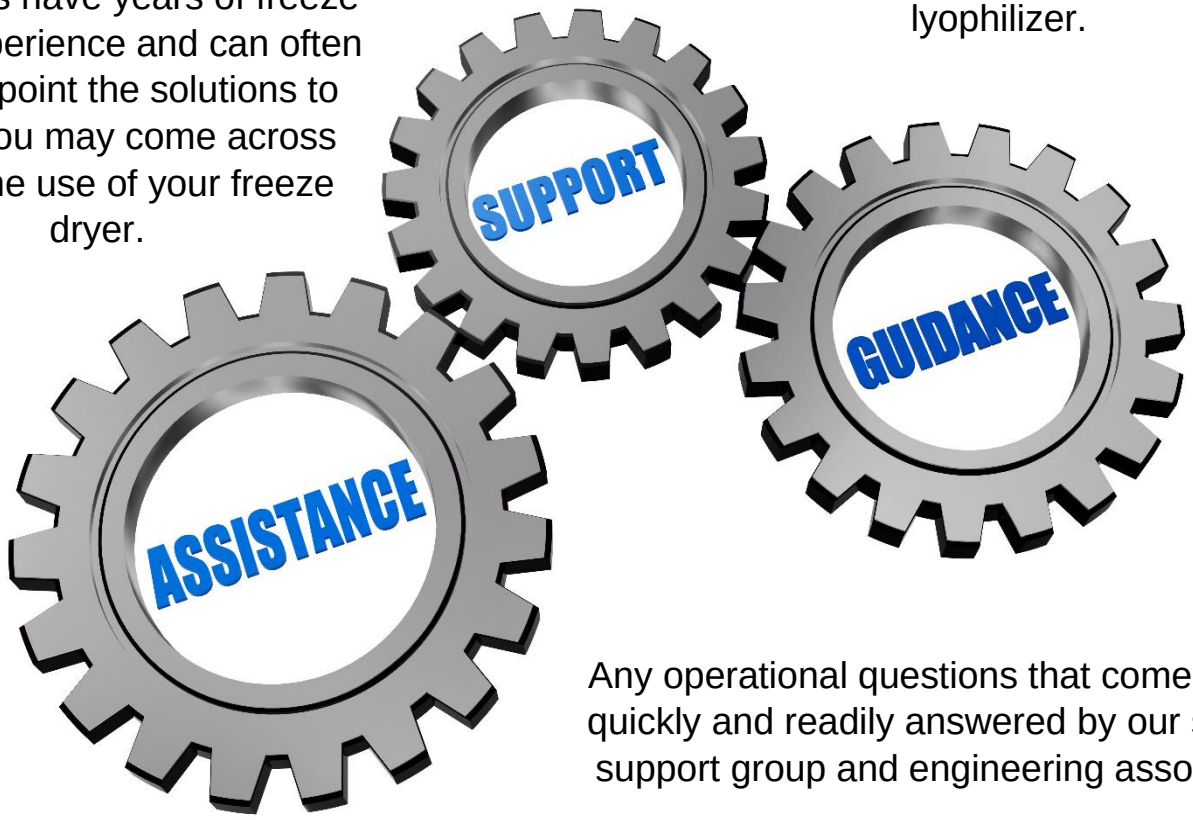
Site Acceptance Test

The Site Acceptance Test is a repeat of the Factory Acceptance Test. This process is utilized to guarantee that all of the utilities are correctly installed and to confirm that the system works exactly as it did during the Factory Acceptance Test -- that had been previously confirmed and accepted by you. This is another step to ensure that your equipment is running properly and that *"all systems are go".*

…and our relationship continues through the successful use of your freeze dryer.

Although we cannot be responsible for your freeze drying process we are happy to provide guidance and help in whatever way we can. Millrock associates have years of freeze drying experience and can often help pin point the solutions to issues you may come across during the use of your freeze dryer.

We also offer maintenance contracts. During your shut down we would be happy to assist you through the maintenance of the system and to help train your staff in the maintenance of your lyophilizer.



Any operational questions that come up are quickly and readily answered by our service support group and engineering associates.

Each Quanta is custom made to your specifications for your particular application and needs. The charts below are meant to provide a general guideline or sample of system configurations.

Quanta Configuration Examples	12	30	50	60	96	144	320
Shelf Area Sq ft Sq M	12 1.1	30 2.78	48 4.44	60 5.57	96 9.29	144 13.30	320 29.73
Number of Shelves	6	10	5	6	8	12	16
Shelf Size in x in mm x mm	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)	30	75	100	150	200	300	600
Condenser Temperature	-75C						
Shelf Temperature	-60C						
Cooling	Water cooled compressors						

Vial Capacity	12	30	50	60	96	144	320
2 ml (15mm)	5080	13190	21424	26780	43888	66500	148200
5 ml (22 mm)	2380	6100	10050	12560	20120	30900	68500
10 ml (24mm)	1835	4940	8170	10220	17032	25500	57500
20 ml (29mm)	1290	3320	5610	7020	11344	17400	39300

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

Additional Products and Services Offered By Millrock Technology

We offer a full line of freeze dryers, from manifold type BenchTop freeze dryers and laboratory R&D and cycle development to the Production Quanta Steam Sterilized Lyophilizers.

Millrock Technology proudly offers LyoRevival™. This program can be used to trade in your old freeze dryer or to revive one for continued use. Contact us about the details of this program.

If the Quanta is not quite right for your needs we offer the Epic™ and the Magnum®. Both freeze dryers are capable of processing large amounts of product at an affordable price—particularly if steam sterilization is not required.

LyoSight™

Lyo insight information

TIP

The LyoSight™ section of our website provides the freeze drying community with

- Papers and Presentations
- Tech Notes
- Webinars
- Events
- Courses
- Tools

We take pride in matching the correct freeze dryer to your needs. Call us today so we can help you make the right choice in equipment.

MILLROCK TECHNOLOGY®

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

+1.845.339.5700 www.millrocktech.com info@millrocktech.com sales@millrocktech.com

MILLROCK TECHNOLOGY®