

FREEZE DRYING SOLUTIONS

AND LOADING/UNLOADING SYSTEMS



Freeze Drying Solutions

THE BEST IN FREEZE DRYING TECHNOLOGY	2
SOLUTIONS, PRODUCTS AND SERVICES	4
LYOMAX	6
LYOFAST	12
MINIFAST	20
LOADING SYSTEMS	24
IMA LIFE INNOVATION	30
IMA LIFE SERVICES	32

THE BEST IN FREEZE DRYING TECHNOLOGY



THE BEST IN FREEZE DRYING
TECHNOLOGY, HAND-IN-HAND
WITH THE WORLD'S LEADING NAME
IN ONE STOP ASEPTIC PROCESSING
AND FILLING SOLUTIONS FOR THE
PHARMACEUTICAL AND BIOTECH
INDUSTRY.

HISTORICAL NOTES

IMA LIFE has been supplying pharmaceutical process equipment for more than 50 years, but its origins arise from when the Edwards Vacuum company was founded in the UK at the beginning of the 20th century. Having initially focused solely on vacuum equipment, Edwards broadened its product portfolio with the major step of entering the pharmaceutical freeze drying sector in the early 1950's.

This freeze drying business evolved from the UK into a production facility in Italy, and having been acquired by BOC Group in 1968, it further expanded in the 1980's with a production site in Germany. As the pharmaceutical market grew in the US so did Edwards freeze drying business by establishing IMA LIFE current facility in Tonawanda, NY in 1989. Moving to 1995, the Dongen facility in The Netherlands was acquired, bringing with it considerable expertise in vial handling which has spurred Edwards' existing leadership position in automated loading and unloading systems.

Today the Edwards freeze drying business stands as integral part of the IMA LIFE division, making it widely recognised as the world leader in freeze drying solutions.

For more than half a century, IMA LIFE has provided the benchmark for freeze drying solutions to the pharmaceutical and biotech industry. We have a truly global presence with our main facilities well positioned to serve customers in all corners of the world. With over 1000 freeze dryers installed in over 50 different countries, we are ready to leverage this experience to better serve your needs.

SOLUTIONS PRODUCTS AND SERVICES

We strive to make our name synonymous with best-in-class solutions across the complete spectrum of our scope of supply: from research, development and design, into freeze drying and automated loading, onto project management, full turn-key systems integration, and on-going services. We want to be your partner of choice through the complete life cycle of your freeze drying systems.

WE ARE THE GLOBAL FREEZE DRYING SOLUTIONS PARTNER OF CHOICE.
BUILDING ON DECADES OF VALUED RELATIONSHIPS, WE WORK WITH OUR CUSTOMERS IN THE CONTINUOUS PURSUIT OF OPERATING EXCELLENCE TO PROVIDE BEST-IN-CLASS SOLUTIONS THROUGHOUT THE PRODUCT LIFE CYCLE.



LYOMAX

The most comprehensive range of custom-built freeze dryers for those who require more than a standard solution.



LYOFAST

The most versatile standard lyophiliser is available as a stand-alone unit, or as part of a complete integrated pharmaceutical packaging system.



LYOFAST MINI

The ideal solution for pilot work or clinical trials production. Its compact footprint allows also for product development and process cycle optimisation.



MINIFAST

The connecting factor between a typical bench-top freeze dryer used in laboratories and the industrial range of freeze dryers.



LOADING SYSTEMS

The automatic loading and unloading systems are designed to continuously transfer vials from the liquid filling equipment to the freeze dryer and from the freeze dryer to the alu-capper, maintaining the level of protection around the products.

LYOMAX

The legendary reliability and performance of IMA LIFE is epitomised by the Lyomax freeze drying range. Lyomax offers the most comprehensive range of custom-built freeze dryers for those who require more than a standard solution. Lyomax can provide the solution from 1m² to 100m² applying state of the art engineering in vacuum, refrigeration, stoppering and heat transfer technology.

CREATED FOR CONFIGURE-TO-ORDER APPLICATIONS USING MODULAR DESIGN TECHNOLOGY, LYOMAX CAN BE DESIGNED, MANUFACTURED AND QUALIFIED TO MEET ANY REQUIREMENT. WITH LYOMAX, VIRTUALLY ANY CONFIGURATION IS POSSIBLE, WHETHER SINGLE FLOOR, MULTI-LEVEL OR PASS-THROUGH.



BUILDING ON SUCCESS

Lyomax has been the solution of choice for the leading pharmaceutical and biotech companies for over 50 years.

There are now in excess of 1000 Lyomax installations, many integrated with both automated loading systems and isolators, supporting our customers across the globe in over 50 countries. Lyomax is a global solution meeting the differing local requirements of all our customers. This history of partnership with our global customers and listening to their needs has allowed Lyomax to remain the leader in freeze dryer development.

INTELLIGENT ENGINEERING

IMA LIFE's employees bring over 3000 man years of pharmaceutical design and manufacturing experience to providing 'best-in-class' solutions for all your freeze drying needs. In order to gain control of development time and cost in custom engineering, we use the Modular Design Technology (MDT), which allows for the well-balanced use of pre-engineered modules wherever possible. The Lyomax range is equipped with the latest SCADA system, managing a robust series of PLCs to cover global requirements. The machines are all qualified in accordance with GAMP4 and comply with the latest FDA and EMEA requirements.



REDUCED CAPITAL AND OPERATING COSTS

The benefits of a modular approach and IMA LIFE unique position as a global manufacturer with a streamlined supply chain, allows us to pass on capital cost savings to you, the customer. This is supplemented by our continuing initiatives to reduce customer operating costs by introducing superior solutions to the market such as our Fusion™ solution for product shelves.

COMPREHENSIVE DOCUMENTATION, SWIFT VALIDATION

Our internal Quality Management system has, for many years, been accredited with ISO9001-2000. This system provides integrated, comprehensive documentation relating to the manufacture of all products, ensuring the user is provided with full details of the equipment. In order to assist in swift and painless equipment validation, we can also provide a standardized IQ and OQ documentation package.

APPLICATION DEMANDS

- COMPACT, MONOBLOC DESIGN USING LYOMAX CONFIGURATION
- TWO-STOREY CONFIGURATIONS
- PASS-THROUGH CONFIGURATIONS
- MULTI-SKID CONFIGURATIONS
- BULK, VIAL, AMPOULE AND SYRINGE APPLICATIONS
- INTEGRATED SYSTEMS WITH AUTOMATED, SEMI-AUTOMATED AND MANUAL LOADING AND UNLOADING EQUIPMENT
- CONSTRUCTED FROM PROVEN SUB ASSEMBLIES TO COMBINE FLEXIBILITY OF DESIGN AND LAYOUT WITH EFFICIENT MANUFACTURE, EASE OF SHIPMENT AND INSTALLATION. THE DESIGN OF THE SYSTEM PROVIDES GOOD ACCESSIBILITY FOR CLEANING AND MAINTENANCE AND FACILITATES WORKING TO cGMP STANDARDS.

PROCESS ENVIRONMENT

- Fusion solution for product shelves enhances process performance and reduces operating cost and business risk
- Our patented Fusion Plus technology eliminates the risk of vial stoppers “sticking” to shelves and disrupting the automated unloading process
- We are leading the way in development of a reliable, industrial solution for wireless product temperature monitoring
- Lyomax designs allow for ease of integration with isolators and cRABs.

PRODUCT SAFETY BY DESIGN

- IMA LIFE PLACE HIGH EMPHASIS ON PRODUCT SAFETY. FOR THIS REASON KEY COMPONENTS OF THE SYSTEM ARE DUPLICATED
- THE SHELF TEMPERATURE CONTROL SYSTEM, WHICH HAS A DOUBLE PUMPING SYSTEM, ONE PUMP BEING SUFFICIENT FOR OPERATION
- THE CONDENSER HAS OVER-CAPACITY FOR ICE, ALLOWING PERFORMANCE OF MULTIPLE CYCLES BETWEEN CONDENSER DEFROSTS OR COMPLETION OF CYCLES IN EVENT OF FAILURE OF A REFRIGERATION COMPRESSOR WHEN THERE ARE MULTIPLE CONDENSER COMPRESSORS
- THE CONTROL SYSTEM HAS A WIDE RANGE OF FEATURES TO PROTECT IN CASE OF MALFUNCTION OR OPERATOR ERROR
- THE REFRIGERATION SYSTEMS ARE INDEPENDENT AND WILL SERVE BOTH SHELVES AND CONDENSER. ROUTINE OR EXTRAORDINARY COMPRESSOR MAINTENANCE MAY BE PERFORMED DURING A CYCLE USING THE OTHER COMPRESSORS TO MAINTAIN THE CYCLE IF REDUNDANT COMPRESSORS ARE INCLUDED
- THE CHAMBER AND CONDENSER ARE DESIGNED IN ACCORDANCE WITH THE APPROPRIATE VESSEL CONSTRUCTION CODE AND GOOD VACUUM CONSTRUCTION PRACTICES
- NUMEROUS SAFETY INTERLOCKS TO SAFEGUARD PRODUCT/OPERATOR
- LYOMAX IS A PROVEN SOLUTION FOR SOLVENT, POTENT COMPOUND AND ATEX APPLICATIONS.



IMA LIFE LEGENDARY RELIABILITY AND PERFORMANCE ARE EPITOMISED BY THE LYOMAX FREEZE DRYING RANGE... THE BENCHMARK ENGINEERED SOLUTION.



FULLY AUTOMATED CONTROL

THE CONTROL AND RECORDING OF THE LYOPHILISATION PROCESS IS A CRITICAL FACTOR IN ENSURING A HIGH LEVEL OF QUALITY ASSURANCE:

- eLYOMASTER MODULAR CONTROL SYSTEM BASED ON INDUSTRY STANDARD iFix SCADA
- MULTIPLE PLC PLATFORMS SUPPORTED (SIEMENS, ALLEN-BRADLEY, MODICON, MITSUBISHI)
- DCS CONTROL ARCHITECTURE (EG DELTA V™) SUPPORTED
- HISTORICAL TRENDING
- CONFIGURABLE BATCH REPORTS
- 21 CFR PART 11 COMPLIANCE
- DUAL ELEMENT TEMPERATURE PROBES
- PAPERLESS CHART RECORDERS
- EQUIPMENT MAY BE MANUALLY CONTROLLED VIA THE CONTROL SYSTEM (FOR SAFETY REASONS THE SIP CYCLE IS EXCLUDED)
- FLEXIBLE CONFIGURATION TO ENABLE COMPLEX PROCESS CYCLES
- COMPREHENSIVE GUI SIMPLIFIES PROGRAMMING
- FULL PROGRAMMING DOCUMENTATION, SOURCE CODE AND LADDER LOGIC, PROVIDED FOR EASE OF VALIDATION.

CLEAN AND STERILE

Lyomax lyophilisers comply with international cGMP guidelines regarding cleanliness and sterility for aseptic processing. Equipment features:

- AISI 316L for machines with SIP for product contact parts with a surface roughness of 0.25 - 0.4 µRA
- Designed for sterilisation with saturated steam at 127°C
- Free draining surfaces
- Easy access for cleaning
- Corners with generous radii to ease cleaning
- Compatibility with common sterilizing/sanitizing chemicals
- Innovative design for ease of cleaning of back of slot door
- SIP measurement/control based on the equipment 'cold spot'
- CIP skids and recirculation systems available
- Rotating and/or fixed CIP spray nozzles
- Hydrophobic filter with filter integrity testing (WIThin™)
- Water ring pump to remove residual water post-sterilisation
- Flexible bellows to enclose the hydraulic piston in chamber
- Pressure plate and counter pressure plate provided in lattice design for ease of cleaning.

LYOMAX PRODUCT SOLUTIONS & TECHNICAL FEATURES

INTELLIGENT DESIGN

LYOMAX LYOPHILISERS ARE DESIGNED AND TESTED TO MEET ALL YOUR PERFORMANCE REQUIREMENTS:

- SHELVES DESIGNED AND MANUFACTURED USING OUR PATENTED FUSIONTM TECHNOLOGY
- SHELF PLANARITY OF 0.5MM/M
- CHLORIDE-FREE INSULATION
- CHAMBERS CLAD IN ALUMINIUM OR STAINLESS STEEL
- CHAMBER JACKET COOLING UTILISING WATER OR SILICON OIL
- FULLY AUTOMATED DOOR LOCKING SYSTEM
- ORBITALLY WELDED STERILE PIPEWORK
- DOCUMENTED BOROSCOPIC INSPECTION OF ALL ORBITAL WELDS
- FULL PENETRATION TIG WELDS AVOID DIFFICULT TO CLEAN CREVICES AND POTENTIAL LEAKAGE PATHS
- PIPEWORK CONNECTIONS ARE KEPT SHORT TO EASE CLEANING
- CONSTANT LEVEL LOADING
- VARIABLE STOPPERING PRESSURE CONTROL
- FUSION PLUS SOLUTION TO AVOID VIAL STOPPERS "STICKING"
- REMOVEABLE CONDENSER HEADS AVAILABLE
- SLOT DOOR AND SHELF INTERFACE DESIGNED FOR COMPACT AND SMOOTH LOADING SYSTEM INTEGRATION
- INDUSTRY APPROVED DESIGNS FOR SOLVENT AND POTENT COMPOUND APPLICATIONS
- DESIGNS THAT MEET THE CHALLENGE OF ATEX REQUIREMENTS.



SYSTEM INTEGRATION

- 20 years experience successfully integrating Lyomax with fixed and flexible automated loading and unloading systems in aseptic applications
- Strength in depth on project management of integration projects
- SCADA systems designed for integrated systems
- Design, documentation and test built from an integrated foundation



ROBUST VACUUM SYSTEMS

The vacuum system of a lyophiliser provides the necessary pressure environment for the lyophilisation process to occur:

- Use of sanitary connections and avoidance of threaded connections
- Two stage, oil sealed rotary pumps
- Roots/rotary combinations
- Dry pump technology
- Capacitance manometer technology
- Modulating vacuum control with capacitance manometer
- Controlled leak of air from the process area
- AISI 316L vacuum pipework.

HIGH PERFORMANCE REFRIGERATION

Lyophilisation requires low temperatures and the demands of biologicals are driving the need for increasingly lower temperatures. IMA LIFE refrigeration expertise has enabled reliable high performance to be achieved:

- Reciprocating compressors, screw compressors or cryogenic (LN₂) solutions
- Canned pumps and magnetic drive fluid circulation pumps
- Use of highest quality components
- Minimised use of threaded connections
- Stainless steel lines used on lines under high working stress
- Electronic expansion valves available to optimise the operation of the refrigeration system
- Ultra low viscosity, non-flammable Safetherm HX heat transfer fluid to improve transfer properties and reduce risk
- Direct expansion or heat transfer fluid cooling of condenser
- Use of environmentally acceptable refrigerant gases
- High efficiency stainless steel plate heat exchangers.

LYOFAST

With the Lyofast range of freeze dryers, IMA LIFE quality is within everyone's reach. Until recently the development of high-end pharmaceutical lyophilisation equipment meant custom engineering with the associated costs and lead-time. However, in recent years Lyofast has broken the mould and rapidly achieved significant global presence with installations in over 25 countries, including many of the world's leading pharmaceutical manufacturers.

The Lyofast concept extends the IMA LIFE range providing support for all your freeze-drying requirements. Lyofast guarantees superior quality, reduced lead-times, lower costs and simplifies the validation process.

The specifications of the base model meet all leading industry standards and the broad range of standard options enable Lyofast freeze dryers to be tuned to your specific requirements. For decades, IMA LIFE has been synonymous with quality, high technology pharmaceutical equipment.

ALL IMA LIFE EXPERIENCE
IN MANUFACTURING AND
SUPPORTING LYOPHILISERS
COMES TOGETHER IN
LYOFAST; THE BENCHMARK
VALUE SOLUTION.
UNCOMPROMISED QUALITY
AT A COMPETITIVE PRICE.



VERSATILE FOUNDATION

A series of standard modules provides the foundation of the Lyofast model concept. Pre-engineering results in time and cost benefits, while a wide range of standard options ensures sufficient flexibility to cover a broad range of configurations. Lyofast is the most versatile standard lyophiliser available.



REDUCED LEAD-TIMES

By constructing from a series of standard modules, IMA LIFE is able to compress project schedules and reduce lead-times even with large capacity equipment. Compared to a custom-built lyophiliser, the lead-time for Lyofast is reduced by up to 50%. This provides users with a competitive edge by reducing time to market.

REDUCED CAPITAL COST

The benefits of our modular standardised approach, combined with our streamlined supply chain, enable cost savings to be passed on to you, the customer.

ENHANCED SALES SUPPORT

The standardisation of Lyofast simplifies and enhances sales support. IMA LIFE puts great importance on providing sales and applications personnel who have an in-depth understanding of pharmaceutical processing. Instead of simply selling individual pieces of equipment, the aim is to provide integrated, validated solutions. This is demonstrated by IMA LIFE laboratory facilities, supporting customers' freeze-drying cycle development requirements and liquid and powder filling evaluation. In recent years, IMA LIFE has promoted preferred supplier agreements with key customers around the world. This has enabled IMA LIFE to better understand customers' cost of ownership issues in order to work together to reduce costs.

COMPREHENSIVE DOCUMENTATION, SWIFT VALIDATION

IMA LIFE internal Quality Management system has, for many years, been accredited with ISO9001-2000. This system provides integrated, comprehensive documentation relating to the manufacture of all products, ensuring the user is provided with full details of the equipment. In order to assist in swift and painless equipment validation, IMA LIFE can also provide a standardised IQ and OQ documentation package.

GLOBAL CONTINUITY

Lyofast is one of IMA LIFE's many Freeze Drying Solutions. Our extensive product portfolio backed by worldwide sales, service and technology centres enables customers with global operations to leverage the benefits of continuity across their sites.

LYOFAST, NOW AND TOMORROW

At IMA LIFE, continuous product development provides the foundation for future growth, including an advanced program that challenges traditional technologies and processes and helps define the direction for future aseptic packaging. This commitment to technology leadership ensures that Lyofast will continue to provide class-leading features.

LYOFAST PRODUCT SOLUTIONS & TECHNICAL FEATURES

PRODUCT SAFETY BY DESIGN

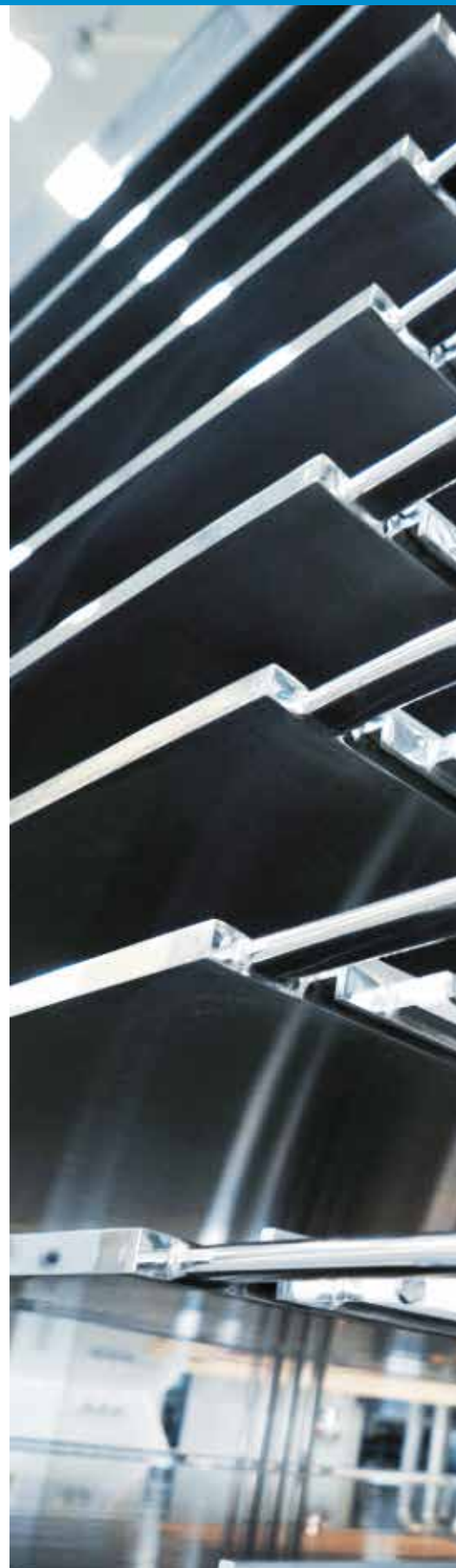
- IMA LIFE PLACES HIGH EMPHASIS ON PRODUCT SAFETY. FOR THIS REASON KEY COMPONENTS OF THE SYSTEM ARE DUPLICATED
- THE CHAMBER AND CONDENSER ARE DESIGNED IN ACCORDANCE WITH THE APPROPRIATE VESSEL CONSTRUCTION CODE AND GOOD VACUUM CONSTRUCTION PRACTICES
- NUMEROUS SAFETY INTERLOCKS TO SAFEGUARD PRODUCT/OPERATOR.

CLEAN AND STERILE

LYOFAST LYOPHILISERS COMPLY WITH INTERNATIONAL cGMP GUIDELINES REGARDING CLEANLINESS AND STERILITY:

- AISI 316L FOR MACHINES WITH SIP AND CIP WITH A SURFACE ROUGHNESS OF $< 0.4\mu\text{m}$ FOR PRODUCT CONTACT PARTS
- EASY ACCESS FOR CLEANING
- FREE DRAINING SURFACES
- COMPATIBILITY WITH COMMON STERILISING & SANITISING CHEMICALS.

LYOFAST MACHINES MAY BE SPECIFIED WITH CLEAN IN PLACE (CIP) AND STERILISATION IN PLACE (SIP) FUNCTIONS. THESE SYSTEMS OPERATE AUTOMATICALLY AND PROVIDE A HIGH LEVEL OF ASSURANCE FOR THE CLEANLINESS AND STERILITY OF THE EQUIPMENT.





CLEAN IN PLACE (CIP)

- 316L stainless steel vessels
- High pressure washing of internal surfaces of chamber and condenser
- High flow rates
- Optional water recirculation system
- Self-draining manifolds with wide angle spray nozzles
- Rotating and/or fixed spray nozzles
- All clean-piping orbitally welded and inspected via boroscope

STERILISATION IN PLACE (SIP)

- 316L stainless steel vessels
- Sterilisation with dry, saturated steam at $>121^{\circ}\text{C}$
- Control and measurement based on equipment "cold spot"
- Automatic door locking system
- Optional hydrophobic filter(s) with filter integrity test connections or embedded integrity testing (WIThin™)*
- Additional insulation of the vessels to retain heat
- Water ring pump for removal of residual water after sterilisation
- Optional water or silicon oil chamber jacket for rapid cooling of the chamber and door after sterilisation

*WIThin is licensed from Sartorius

ROBUST VACUUM SYSTEMS

THE VACUUM SYSTEM OF A LYOPHILISER PROVIDES THE NECESSARY PRESSURE ENVIRONMENT FOR THE LYOPHILISATION PROCESS TO OCCUR. COMPRISED OF VACUUM PUMPS, VALVES, INSTRUMENTATION AND SEALS SUITABLE FOR OPERATING AT HIGH LEVELS OF VACUUM:

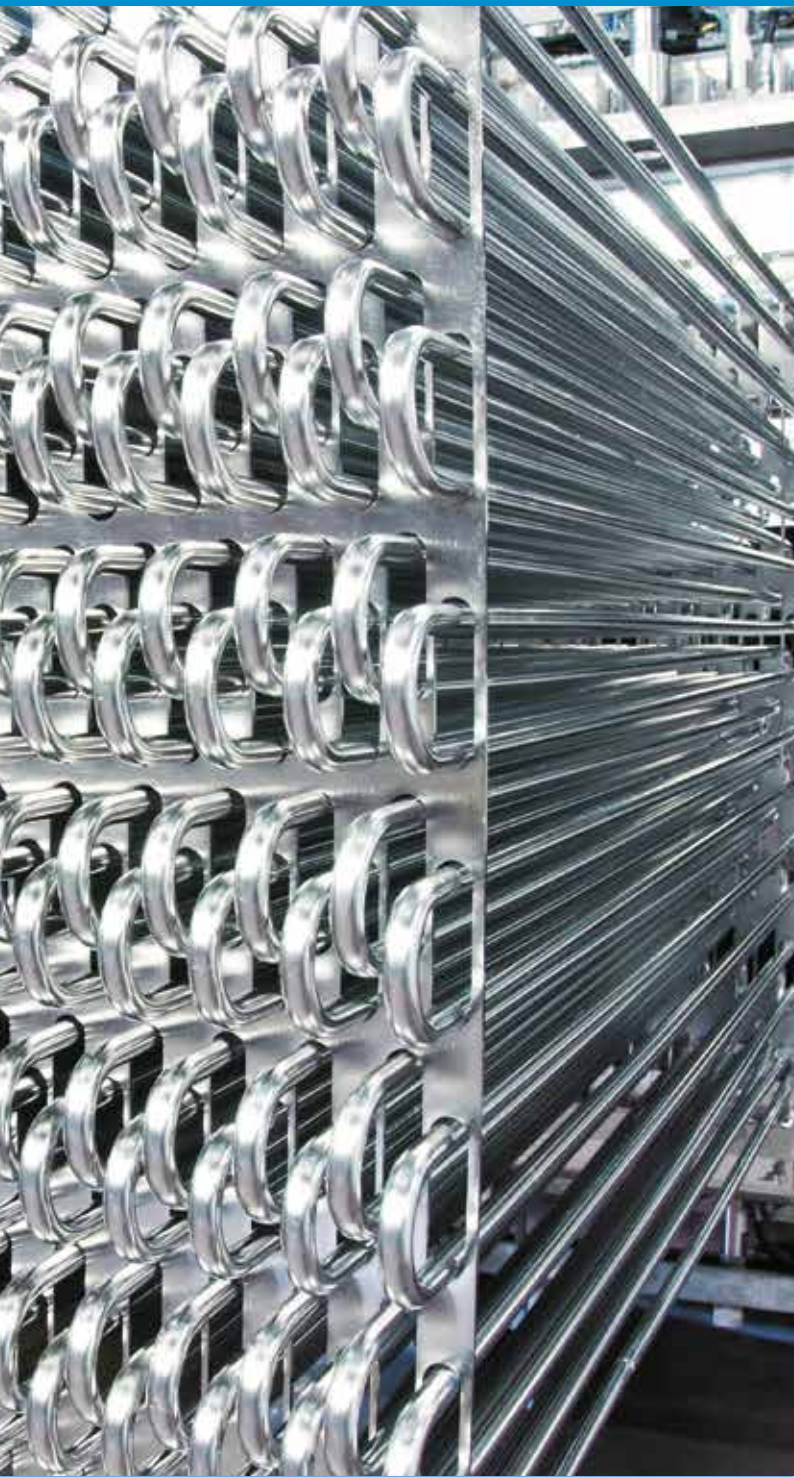
- TWO STAGE, OIL SEALED, ROTARY PUMPS AS STANDARD
- ROOTS/ROTARY COMBINATION ARE AVAILABLE AS AN OPTION
- OPTIONALLY DRY VACUUM PUMPS TO PROVIDE ABSOLUTE SECURITY AGAINST POTENTIAL CONTAMINATION OF THE PRODUCT BY OIL 'BACKSTREAMING', CAN BE PROVIDED
- TWIN ACTIVE PIRANI GAUGES SUPPLIED FOR MEASURING PROCESS AND PUMP VACUUM
- CAPACITANCE MANOMETER GAUGES AVAILABLE AS AN OPTION FOR HIGH ACCURACY VACUUM MEASUREMENT
- MODULATING VACUUM CONTROL
- CONTROLLED LEAK OF AIR FROM THE PROCESS AREA
- MANOMETER.



ADVANCED HEAT EXCHANGE

A heat exchange fluid is used to transfer energy between the shelves and the refrigeration and heating systems. Low viscosity oil is circulated through heat exchangers to adjust the oil to the desired temperature before being circulated through the shelves of the lyophiliser:

- Closed loop system operating at atmospheric pressure
- High efficiency stainless steel plate heat exchangers used for cooling of shelf recirculation fluid
- Electric shell heater with stainless steel heating elements



HIGH PERFORMANCE REFRIGERATION

THE LYOPHILISATION PROCESS REQUIRES LOW TEMPERATURES TO BE MAINTAINED FOR LONG PERIODS, PLACING CONSIDERABLE STRAIN ON THE REFRIGERATION SYSTEM. IMA LIFE REFRIGERATION EXPERTISE HAS ENABLED RELIABLE HIGH PERFORMANCE TO BE ACHIEVED:

- USE OF THE HIGHEST QUALITY COMPONENTS AVAILABLE WORLDWIDE
- STANDARD SYSTEMS EMPLOY DOUBLE STAGE, SEMI-HERMETIC, RECIPROCATING COMPRESSORS
- GENEROUS SYSTEM CAPACITY ENSURES PERFORMANCE CAN BE EASILY ACHIEVED
- MODULAR SYSTEMS PROVIDE BACK-UP SHOULD PROBLEMS ARISE
- SUB-COOLING SYSTEMS MAINTAIN OPTIMUM COMPRESSOR OPERATING TEMPERATURE
- PRESSURE SENSORS PROVIDE PROTECTION IN THE EVENT OF ABNORMAL OPERATING TEMPERATURES AND PRESSURES
- USE OF ENVIRONMENTALLY ACCEPTABLE REFRIGERANT GASES
- SPECIAL SYNTHETIC OILS USED FOR COMPRESSOR LUBRICATION TO ELIMINATE PROBLEMS ENCOUNTERED WITH MINERAL OILS AT EXTREME TEMPERATURES
- SYSTEMS CONSTRUCTED TO ENSURE EASE OF MAINTENANCE.

- Ultra low viscosity silicon oil used as heat exchange medium
- Stainless steel fully welded pipe-work throughout
- Twin pumps for circulating the silicon oil provide security in the case of pump problems (single pumps for Lyofast 1 and 25 and above)
- System fully insulated with closed cell moisture resistant foam.

LYOFAST

IMA LIFE BEST-IN-CLASS IS EPITOMISED BY THE LYOFAST FREEZE DRYING RANGE...
THE BENCHMARK VALUE SOLUTION.



FULLY AUTOMATED CONTROL

The control and recording of the lyophilisation process is a critical factor in ensuring a high level of Quality Assurance. Lyofast freeze dryers are supplied with a fully automated control system.

- Programmable logic controller (PLC) based system
- Windows™ operating system
- Comprehensive graphical user interface to simplify programming
- Flexible configuration enables complex process cycles
- Generous storage capacity for different program cycles and historical data storage
- Operation protected by graduated password levels





- Comprehensive interlocks to prevent misoperation
- Equipment may be manually operated via the control system
- Source code and ladder logic available
- A printer is supplied for process information output
- A range of chart recorder options are available, from 12 to 30 points for monitoring equipment temperatures and pressures, as well as product temperatures.
- Screw compressors may be substituted for reciprocating types. Screw compressors provide greater efficiency and reliability whilst requiring less maintenance
- Electronic expansion valves are available as an option to optimize the operation of the refrigeration system.

INTELLIGENT DESIGN

Lyofast is fully tested according to standardised procedures in order to demonstrate that the performance meets specified requirements. All tests are documented and form the basis of the documentation provided with all equipment.

- Standard AISI 316L (an option for non-SIP and non-CIP machines) stainless steel used for chamber, shelves and condenser
- Full penetration TIG welding avoids difficult to clean crevices and paths of potential leakage
- Documented X-ray weld inspection in accordance with construction codes
- Standard internal surface finish of $<0.4\mu\text{m}$ with mirror appearance
- Satin surfaced shelves to enhance heat transfer
- Surfaces pitched to enhance drainage
- Corners with generous radii to ease cleaning
- Internal structures designed to ensure drainage and accessibility for cleaning
- Pipe-work connections are kept short to ease cleaning
- Orbitally welded sterile pipe-work
- Condensers provide generous capacity

Shelves are designed and manufactured using IMA LIFE patented Fusion™ solution. Fusion™ technology enhances freeze dryer performance and reduces operating costs by providing a lighter, flatter, stronger shelf than conventional freeze dryer shelves. The Fusion™ manufacturing process is highly automated ensuring repeatability of manufacture to reduce risk and increase reliability for your process.

Lyofast is configured to ensure a space efficient layout with adequate access to facilitate maintenance. Typical configurations include:

- Rectangular and cylindrical chambers
- Horizontal and vertical ice condensers
- Integral ice condensers
- Monoblock arrangements for optimum space efficiency

Split arrangements that enable the ancillary components to be located remote from the chamber and condenser.

Further details are provided in separate specification sheets available from your local sales office.

MINIFAST



The product is available in Minifast 04 and Minifast 10 configurations, with shelf areas of 0.4 m² and 1.1 m² respectively. Ice condenser capacities range from 8kg to 20 kg with minimum condenser temperatures of -85°C as standard.

Product shelves are designed and manufactured using the IMA LIFE patented Fusion™ solution to enhance performance, reduce operating costs and increase reliability.

THE MINIFAST RANGE OF LYOPHILISERS PROVIDES THE CONNECTING FACTOR BETWEEN A TYPICAL BENCH-TOP FREEZE DRYER USED IN THE LABORATORIES AND THE INDUSTRIAL LYOFAST OR LYOMAX RANGE OF FREEZE DRYERS. THE MINIFAST PROVIDES A 'DIRECT LINE OF SIGHT' AS REQUIRED BY THE FDA, BETWEEN THE PILOT TYPE FREEZE DRYER WHICH IS SUITABLE FOR SCALE-UP AND THE LARGER FULL PRODUCTION FREEZE DRYERS. THE MINIFAST RANGE IS THE IDEAL SOLUTION FOR PRODUCT DEVELOPMENT AND PROCESS CYCLE OPTIMISATION.



PEAK PERFORMANCE IN PILOT SCALE FREEZE DRYERS.

IMA LIFE MINIFAST RANGE
PROVIDES THE CONNECTION
BETWEEN LABORATORY DEVELOPMENT
AND INDUSTRIALISED PRODUCTION.

The standard shelf inter-distance is 80mm with larger spacing offered as an option (120mm on Minifast 04 and 160mm on Minifast 10).

The Minifast is part of IMA LIFE's wider offering of lyophilisation and aseptic packaging equipment.

The current line-up includes the standard Lyofast range of pre-engineered lyophilisers, the high-end Lyomax range and fully automated loading/unloading systems for single and multiple freeze-dryer installations.

COMPREHENSIVE DOCUMENTATION, SWIFT VALIDATION

IMA LIFE internal Quality Management system has, for many years, been accredited with ISO9001-2000. This system provides integrated, comprehensive documentation relating to the manufacture of all products, ensuring the user is provided with full details of the equipment. In order to assist in swift and painless equipment validation, IMA LIFE can also provide a standardized IQ and OQ documentation package.

GLOBAL CONTINUITY

Minifast is one of IMA LIFE's many Freeze Drying Solutions. Our extensive product portfolio backed by worldwide sales, service and technology centres enables customers with global operations to leverage the benefits of continuity across their sites.



MINIFAST PRODUCT SOLUTIONS & TECHNICAL FEATURES

THE BASIC MACHINE IS SUPPLIED WITHIN A PAINTED CARBON STEEL FRAME FITTED WITH HINGED ACCESS PANELS.



Simple utility connections enable quick installation

CHAMBER

The chamber is a welded fabrication of rectangular section manufactured from AISI 304L stainless steel optimised to provide adequate access to components within the chamber whilst minimising dead volumes. The internal surfaces of the chamber are mechanically polished to $<0.4\mu\text{m Ra}$ with a mirror finish.

CHAMBER DOOR

The door of the chamber is fabricated from clear plexiglass. The door is closed by means of a manual latch.

PRODUCT SHELVES

Within the chamber are mounted product support shelves and one compensation (radiation) shelf mechanically polished to $0.4\mu\text{m Ra} \sim 0.6\mu\text{m Ra}$. Similar to Lyofast and Lyomax, Minifast employs IMA LIFE unique Fusion™ design. The heat exchange fluid is supplied to the shelves via flexible convoluted stainless steel pipes that are welded to the shelves and, in turn, welded to distribution manifolds located outside the chamber. An optional feature enables shelf interdistance to be adjusted to 120 mm (Minifast 04) or 160 mm (Minifast 10) to enable taller containers to be processed.

HEAT EXCHANGE CIRCUIT

Mimicking industrial freeze dryers, the circuit comprises a plate cooling exchanger and electrical heater in series through which a heat exchange medium is circulated by a hermetically sealed pump.

ICE CONDENSER

The cylindrical 304L condenser vessel is mounted vertically behind the chamber. The condensing surface within the condenser body comprises a number of polished 316L stainless steel pipes welded to form helical coil(s). The coil is cooled by the direct expansion of refrigerant supplied by the compressor.



OPTIONS

- CIP
- RABS / ISOLATOR
- CHART RECORDER
- SCADA SYSTEM
- REPORTS PACKAGE
- 21 CFR PACKAGE
- PRE AERATION
- CAPACITANCE MANOMETER PACK
- EUTECTIC MONITOR
- CHAMBER PRESSURE COMPARISON,
DRYING END POINT PACKAGE
- ADDITIONAL GAS SUPPLY POINT

- VERISEQ® CRYOGENIC FOG
- SAMPLE THIEF
- WATER COOLED REFRIGERATION CONDENSER
- STAINLESS STEEL DOOR AND SIGHTGLASS
- THROUGH-WALL INSTALLATION
- AISI316L CHAMBER & CONDENSER
- ALTERNATE SHELF INTER-DISTANCE
- PRODUCT LOADING TRAYS -VIALS
- PRODUCT LOADING TRAYS - BULK
- SPARE PARTS
- IQ/OQ
- DOCUMENTATION PACKAGE
- INSTALLATION & SAT
- IQ/OQ ON-SITE SUPPORT

MAIN VALVE

The chamber and condenser are separate from one another and connected by means of a vapour duct, which is equipped with a large diameter, remotely actuated, valve.

REFRIGERATION SYSTEM

The air cooled refrigeration group comprises two single stage, reciprocating, hermetic compressors installed in a cascade configuration employing R23 and R507 refrigerants. The refrigeration circuit is equipped with the necessary valves, filters, oil separator, suction accumulator, condenser, sight-glasses and expansion valves to enable the system to operate reliably and deliver the required refrigeration performance.

VACUUM SYSTEM

The vacuum necessary for the freeze drying process is created by use of a two stage, oil sealed, rotary vane pump equipped with gas ballast and exhaust filter.

VACUUM MEASUREMENT AND CONTROL

The chamber is provided with a Pirani vacuum gauge. Automatic vacuum control is achieved by a calibrated leak controlled by an on/ off modulated solenoid valve in series with a needle valve.

CONTROLS

The control system employs a PLC with a touch screen user interface panel to display process parameters and enable the user to control the freeze dryer.

VIAL STOPPERING MECHANISM

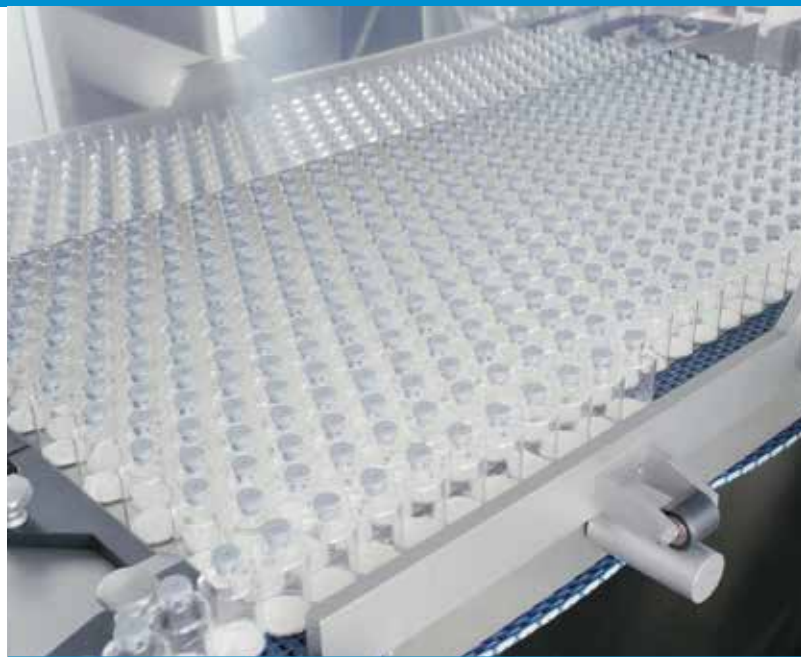
An actuator is fitted to the base of the chamber to raise the shelves and generate a compression force to enable stoppers to be inserted into vials at the end of the drying process.

LOADING SYSTEMS

Automatic loading and unloading systems minimize the risk of contamination through human intervention in the loading and unloading of freeze dryers. The amount of product handled when using an automated loading and unloading process is increased since the time spent for the loading/unloading operation is, of course, much shorter if compared to manual loading.

Operational costs are also reduced since these state-of-the-art systems drastically decrease the number of operators needed to assist the freeze drying process. In some cases, the machine can be left unattended, as well. As a consequence, the SAL levels are greater while temporarily reducing the operating costs.

The protection of operators also when handling potent compounds can be achieved with these automated systems, since they can be installed either under closed RABS or even under a proper isolator.

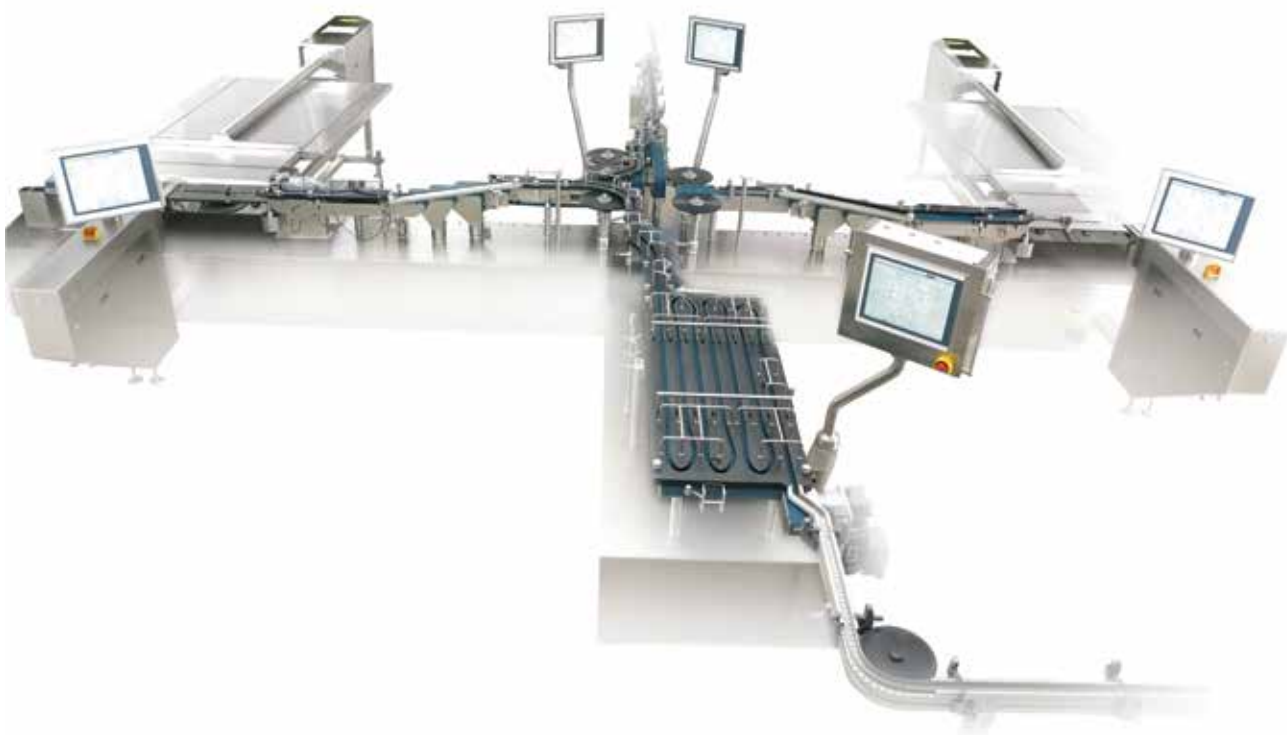


Fixed loading system

KEY FEATURES

THE IMA LIFE AUTOMATIC LOADERS ENSURE EFFICIENT, SAFE AND RELIABLE PERFORMANCES THANKS TO THE FOLLOWING KEY FEATURES:

- EXTREMELY COMPACT FOOTPRINT
- HIGH THROUGHPUT WITH LOADING SPEED UP TO 600 VPM
- HIGH FLEXIBILITY TO HANDLE DIFFERENT VIAL SIZE PARTS
- QUALITY SANITARY DESIGN
 - VHP (VAPORIZED HYDROGEN PEROXIDE) COMPLIANT
- PRE-ARRANGED FOR UAF (UNIDIRECTIONAL AIR FLOW)
- CRABS AND ISOLATOR APPLICATION





Flexible loading system in production area

DA VINCI: THE LATEST GENERATION OF VIAL LOADING AND UNLOADING SYSTEMS

- EXTREMELY COMPACT FOOTPRINT WITH INTEGRATED LOADING AND UNLOADING MODULE
- WI-FI TECHNOLOGY (PATENT PENDING)
- HIGH THROUGHPUT WITH SPEEDS UP TO 600 VPM
- QUALITY SANITARY DESIGN – VHP COMPLIANT
- PRE-ARRANGED FOR ISOLATOR APPLICATION
- EXCELLENT INTEGRATION WITH FREEZE DRYERS



DA VINCI wireless version

FIXED SYSTEMS

These are systems which are built into the individual freeze dryers and can load each shelf one row at a time or in packages of several rows at a time:

- Operating speed: up to 500 vials/min.
- Fixed loading configurations for one, two or four freeze dryers, with more possible depending on cycle times, logistics and process environment
- Choice of type of loading pusher
- Mainly loading and unloading from the same side
- Isolator or cRABS

FLEXIBLE SYSTEMS

These are systems using “transporters” or “robots” to serve multiple freeze dryers on shelf at a time:

- Operating speed
 - Loading: up to 500/600 vials/min.
 - Unloading: up to 900 vials/min.
- This system is primarily used for multiple freeze dryers
- Mainly loading and unloading from same side
- Suitable for pass-through system configurations

MIXED SYSTEMS

These systems offer a combination of fixed and flexible solutions:

- Only pass-through configurations
- Operating speed:
 - Loading: up to 500 vials/min.
 - Unloading: up to 900 vials/min.
- Fixed loading and flexible unloading
- Flexible loading and fixed unloading

Technology has always been at the heart of everything we do. In putting this technology to work and gaining control of development time and the expense of customer engineering, we apply Modular Design Technology (MDT). This provides the opportunity for the well-balanced use of pre-engineered modules in a customer's application.



FUSION™

The Fusion patented shelves bring innovation to the heart of the freeze drying process. Fusion technology enhances freeze dryer performance whilst reducing your operating costs. The Fusion shelves are lighter, flatter and stronger than conventional freeze dryer shelves resulting in improved heat transfer properties and a reduction in volume of required heat transfer fluid. The Fusion manufacturing process is fully automated ensuring higher quality assurance that reduces your risk and increases the reliability for your process.

FUSION™ PLUS

When presented by our customers with the challenge of providing a solution to the problem of stoppered vials “sticking” to the underside of product shelves, we responded with investment in an R&D programme that resulted in a truly innovative solution. Fusion Plus extends the Fusion technology by utilising a patented surface treatment that eliminates the occurrence of “sticking” stoppers. This avoids potential disruption of the vial pack and the associated disruption of automated vial unloading that has become an increasing problem for the industry.

SAFETHERM HX™

With SafeTherm HX we can now provide an inert, non-flammable, ultra-low viscosity heat transfer fluid for freeze dryer applications. This industry leading development is a further example of intelligent technological evolution in our products that results in an improved freeze drying process combined with reduced risk for our customers.



IMA LIFE HAS BEEN
CONSISTENTLY
AT THE LEADING EDGE
OF FREEZE DRYING
AND LOADING SYSTEMS
INNOVATION... PUTTING
NEW TECHNOLOGY
TO WORK FOR OUR
CUSTOMERS.

VERISEQ® NUCLEATION

During freeze drying, the freezing step is considered the foundation to a repeatable and efficient process. A good freezing process can produce a consistent product and enable faster primary and secondary drying cycles.

Ice fog nucleation is a means to control ice nucleation using a sterile cryogenic fog that is applicable to laboratory, pilot and production scale lyophilizers.

This technology is highly adaptable and can be retrofitted to most freeze dryers with minimal impact on established lyophilization protocols.

To provide improved process control to its customers, IMA LIFE has joined forces with Linde Gases (a Linde Group division) for the implementation of Linde's proven VERISEQ® technology.

ENABLING PAT

The goal of the FDA's Process Analytical Technology (PAT) initiative is to understand and better control the manufacturing process. Quality cannot be tested into products...it should be built-in or should be by-design.

IMA LIFE is committed to research and engineer in-house and in partnership with specialist technology providers and customers to develop solutions aligned with the PAT initiative: pharmaceutical and biological drugs which are produced through safe, consistent, repeatable, reproducible processes.

PROCESS OPTIMISATION

Our laboratory facilities and equipment, including Lyoflux, as well as our on-site experts can offer customised cycle development studies with the ultimate goal to optimise the freeze drying process.

WITH OUR WORLDWIDE PRESENCE AND HIGHLY TALENTED AND PROACTIVE STAFF, WE CAN HELP YOU ANY TIME.

- WE TAKE PRIDE IN OUR RESPONSIVE APPROACH
- WE CAN OFFER YOU SERVICE CONTRACTS TAILORED TO YOUR INDIVIDUAL NEEDS
- WE CAN GUARANTEE OPTIMAL PERFORMANCE OF YOUR SYSTEMS AT ANY POINT IN TIME
- ON TOP OF OUR COMPREHENSIVE SPARE PARTS PROGRAMMES, WE OFFER A WIDE RANGE OF VALUE-ADDING SERVICES... WHEREVER YOU ARE.



PREVENTATIVE MAINTENANCE PROGRAMMES

These are an integral part of our cGMP approach. All maintenance will be properly documented to support you during corporate audits and regulatory inspections. The preventative maintenance programme will:

- Assure compliance and continuity of your validated equipment status
- Make the operation of your equipment reliable
- Minimise downtime
- Considerably extend your equipment LIFE-span.



VALIDATION SUPPORT

IMA LIFE can provide you with an omni-comprehensive package of documentation for on-site validation. The package can include DQ, IQ, OQ and PQ protocols and support by specialists for execution. We can support your equipment qualification with a variety of different approaches:

- Integration between commissioning and qualification. Based on written procedures, approved by you, we define rules (deviation management, project change control, etc.) to limit the duplication of effort between FAT/SAT and IQ/OQ/PQ
- Risk analysis-Through the analysis of the critical process parameters and written rationale, we support you in defining the scope of the qualification, setting up initial and periodic qualification programmes, and integrating the commissioning and qualification efforts.

CONTROL SYSTEMS UPGRADES

WE CAN SUPPORT YOU IN ASSESSING YOUR CONTROL SYSTEM WITH RESPECT TO COMPLIANCE WITH CURRENT REGULATIONS, INCLUDING GAMP IV AND V AND 21 CFR PART 11. UPGRADES ARE AVAILABLE FOR SCADA, PLC, AND FIELD INSTRUMENTATION AND ARE FULLY DEBUGGED AND BENCH TESTED IN A SIMULATION ENVIRONMENT THROUGH TO FAT AND SAT. THEY INCLUDE A FULLY COMPLIANT DOCUMENTATION PACKAGE AND CAN INCLUDE:

- VALIDATION MASTER PLAN
- USER REQUIREMENTS SPECIFICATION
- DESIGN QUALIFICATION/TRACEABILITY MATRIX
- FUNCTIONAL DESIGN SPECIFICATION FOR PLC
 - BLOCK DIAGRAMS
 - PIN CHART
- FUNCTIONAL DESIGN SPECIFICATION FOR SCADA
- HARDWARE DESIGN SPECIFICATION
- SOFTWARE DESIGN SPECIFICATION FOR PLC AND SCADA
- FAT (FACTORY ACCEPTANCE TESTS) AND
- SAT (SITE ACCEPTANCE TESTS)
- TEST PROTOCOLS.

FREEZE DRYING CYCLE DEVELOPMENT

OUR LABORATORY FACILITIES CAN OFFER A COMPLETE SET OF EQUIPMENT AND FACILITIES FOR CYCLE DEVELOPMENT STUDY, ENABLING FOCUS ON:

- OPTIMISING THE FREEZING TEMPERATURE AND COOLING TIME
- VACUUM TO OPTIMISE THE HEAT TRANSFER FROM SHELVES TO PRODUCT AVOIDING UNDESIRABLE MELTING
- PRODUCT TEMPERATURE TO OPTIMISE THE PRIMARY AND SECONDARY DRYING TIME MODIFYING THE SHELF TEMPERATURE AND VACUUM WITH CALIBRATED LEAK (NITROGEN GAS BLEEDING)
- THE SECONDARY DRYING PHASE USING CALIBRATED LEAK AND SHELF TEMPERATURE TO REDUCE TIME AND MEET THE CUSTOMER REQUEST FOR RESIDUAL MOISTURE
- MEASUREMENT OF THE RESIDUAL MOISTURE
- KARL FISCHER ANALYSER TO VERIFY THE RESIDUAL MOISTURE AFTER LYOPHILISATION
- DSC ANALYSER TO VERIFY THE EUTECTIC POINT AND PHASE TRANSITIONS.



CALIBRATION SERVICES

Calibration must fulfill both maintenance and compliance requirements. We can develop a comprehensive programme for you using our extensive experience. Gain direction for classifying instruments and setting appropriate limits to ensure product quality. Avoid unnecessary deviation investigations. We can also provide you with calibration procedures and perform calibration of your instruments with highly qualified technicians and fully traceable primary instruments.

TRAINING SERVICES

We offer a variety of training programmes for Machine operators, Electrical and Mechanical engineers, Maintenance engineers, and Supervisory personnel.

Our programmes are designed not only to improve the participants' overall understanding of the production equipment, but also to enhance their confidence and performance levels to provide you with a beneficial return for your business.

Training programme options:

- Level 1: System fundamentals, operation and error recovery
- Level 2: Preventative maintenance techniques
- Level 3: Corrective maintenance techniques
- Train the trainer: Course development and material delivery.



WE CAN ASSESS THE MECHANICAL SET UP AND PERFORMANCE OF YOUR FREEZE DRYING SYSTEMS:

- EQUIPMENT INTEGRITY
- PERFORMANCE IMPROVEMENT
- REGULATORY COMPLIANCE
- EXTENSION OF LIFE SPAN.

UPGRADES & REFURBISHMENT

Following a customised investigation programme, we can provide tailored maintenance and/or replacement programmes as part of your assessment, including items such as:

- Piping/valves
- Sterile filter rack
- In-line automatic and non-automatic filter integrity test
- Hydraulic unit
- Shelf stack
- Vacuum line
- Vacuum pumps.

All are normally covered by our investigation and can be implemented with customer specific/equipment specific checks.

IMA LIFE has a long experience with various compressors and refrigeration technology and is able to review and optimise the performance of your refrigeration skid, including:

- Reciprocating compressors
- Screw compressors
- Liquid nitrogen
- Variable speed drive
- Electronic expansion valves
- Pressure transducers .

DESIGNING OUR SERVICES TO MATCH OUR CUSTOMERS' ON-GOING NEEDS THROUGH THE PRODUCT LIFE CYCLE.

IMA LIFE IN THE WORLD



Group Headquarter:

IMA LIFE division

ASEPTIC PROCESSING & FREEZE DRYING SOLUTIONS

Via Emilia, 428/442

40064 Ozzano Emilia - Bologna - Italy

Phone +39 051 6514111

Fax + 39 051 6514821

Calenzano Production Facility:

Via Petrarca, 34/38/40

50041 Calenzano - Firenze - Italy

Phone +39 051 883231

Fax + 39 051 8879745

mktg.life@ima.it



North American Regional Headquarters:

2175 Military Road

Tonawanda, NY 14150 USA

Phone +1 716 6956354



European Service Centre:

De Leest 3

Dongen, 5107 RC, The Netherlands

Phone +31 162383500



European Service Centre:

IMA LIFE division

Via Piero della Francesca, 26

20090 Trezzano sul Naviglio - Milano - Italy

Phone +39 02 36566993



Asian Regional Headquarters:

No.3 JianAn Street, BDA - Yizhuang,

100176 Beijing,

People's Republic of China

Phone: +86 10 59623866 899



IMA LIFE Japan K.K.:

Kuramae Sanyo Bldg. 7F 2-42-5

Kameido - Koto-ku - Tokyo 136-0071 -

Phone: +81 (0) 3 5626 9151

Fax: +81 (0) 3 5626 9158

sales@imalife.com

services@imalife.com

Lyomax, Lyofast, Minifast, Fusion™ - Fusion Plus™, SafeTherm HX™
are registered trademarks of IMA LIFE.

FOR INFORMATION ON THE IMA SUBSIDIARIES

AND SALES OFFICES, VISIT OUR WEBSITE:

WWW.IMA-PHARMA.COM (CONTACTS SECTION)

www.ima-pharma.com



IMA S.p.A.
IMA LIFE division
Via Emilia 428-442 - 40064 Ozzano dell'Emilia (Bologna) - Italy
Tel. +39 051 6514111 - Fax +39 051 6514666
mktg.LIFE@ima.it - www.ima.it

