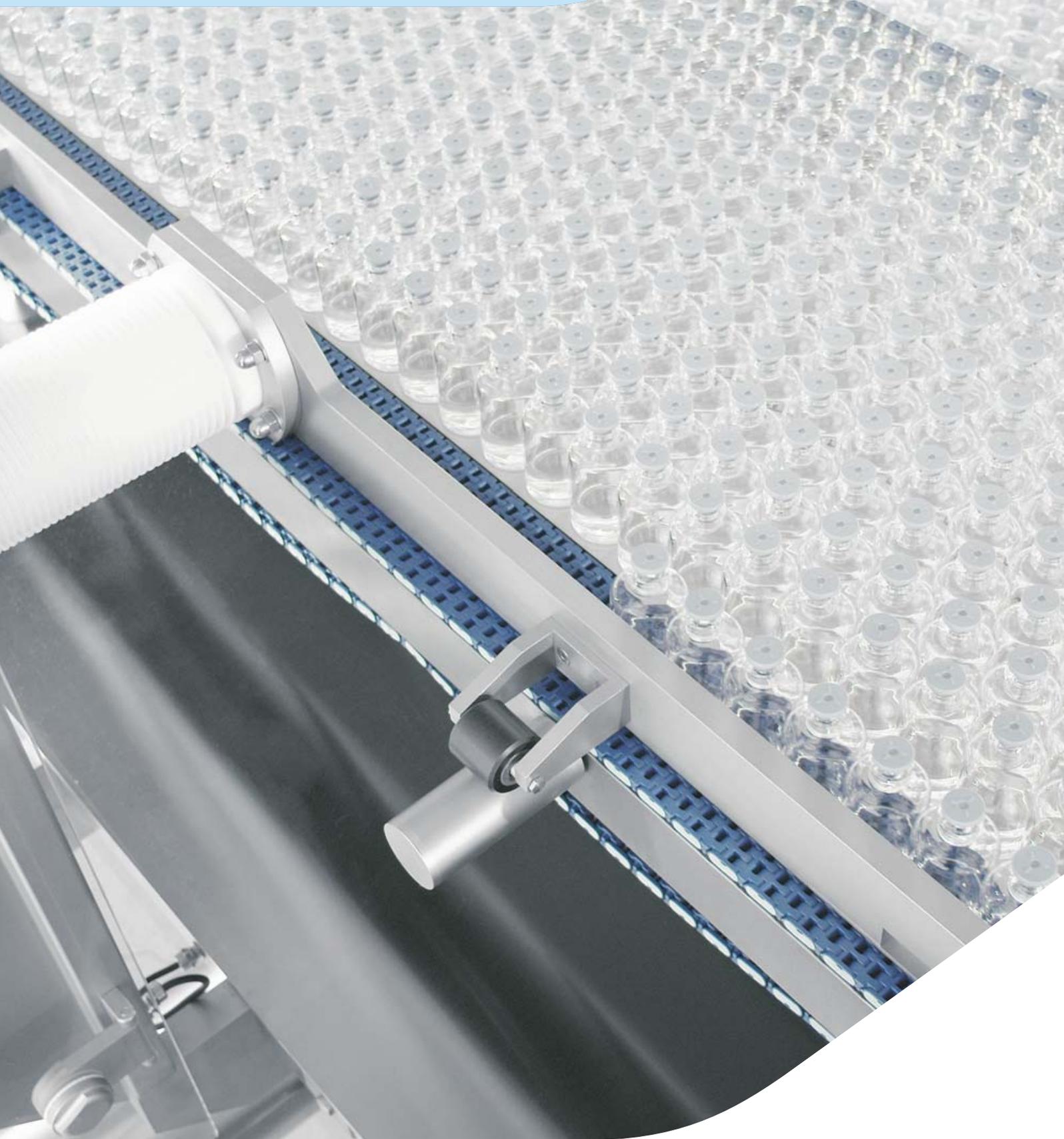


LOADING SYSTEMS

LOADING AND UNLOADING SYSTEMS FOR FREEZE DRYERS



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.

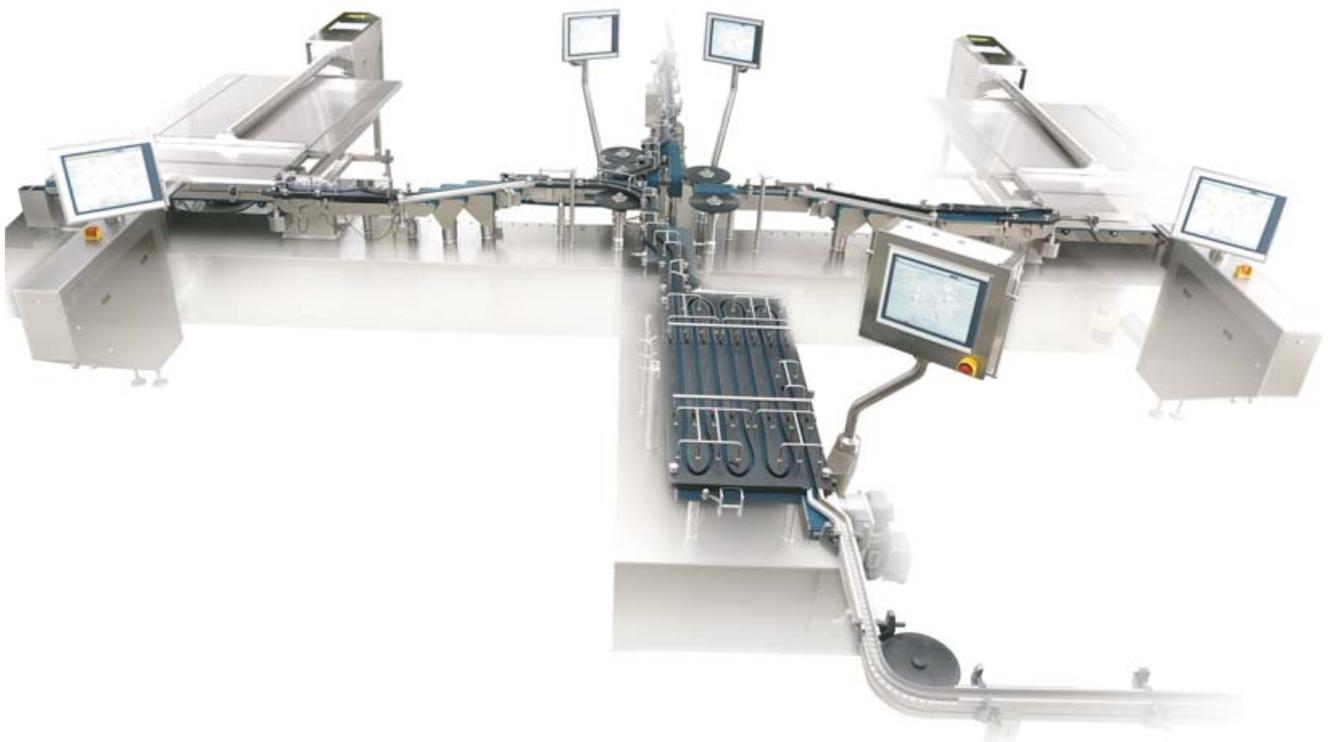
The protection of operators also when handling potent compounds can be achieved with these automated systems, since they can be installed either under closed RABS or even under a proper isolator.



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





IN SUPPORTING CUSTOMERS AND ADDRESSING EVER-CHANGING MARKET REQUIREMENTS, IMA LIFE HAS CONSISTENTLY LED THE DEVELOPMENT OF AUTOMATIC LOADING AND UNLOADING SYSTEMS FOR MINIMISING HUMAN INTERVENTION IN CLEAN ROOMS, THEREBY REDUCING CONTAMINATION EXPOSURES.

AUTOMATION DRIVERS

- GREATER SAL (STERILITY ASSURANCE LEVEL)
- BIO-BURDEN REDUCTION
- INCREASED OUTPUT
- REDUCED OPERATING COSTS
- HIGHER PRODUCT & OPERATOR PROTECTION
- REPEATABLE STANDARDS
- REDUCTION IN ROOM AIR CLASSIFICATION
- PROCESS TIME DRASTICALLY REDUCED

A major driver of our design is the performance criteria of the application. Productivity is vital and so speed of operation. Short lead-times between batches is a must. We have proven systems which can load up to 600 vials per minute and unload up to 900 vials per minute. Flexibility for the application is also a big influence with IMA LIFE systems supporting vial formats from 14.25 mm to 51 mm vial diameters and from 2 ml to 100 ml vial sizes. We offer fixed and flexible systems, compact designs, single or multiple-row loading, and on to complete shelves across multiple handling requirements.



Fixed system integrated with a complete aseptic filling line under isolator.

PROCESS ENVIRONMENT

The production environment being served at the customer facility means we develop flexible sequencing programmes to meet diverse process requirements. From ambient to cold-shelf loading, even via cryogenically pre-frozen product.

From conventional UAF (Unidirectional Air Flow) to cRABS or Isolator systems with designs optimizing unidirectional airflow at the vial level to ensure there are no static or moving objects above the vials.

LOADING SYSTEMS PRODUCT SOLUTIONS

NATURE OF LOADING

The Freeze Dryer is loaded or unloaded one shelf, or one row or several rows at a time, with vials at constant level. All systems are frameless and can be FLEXIBLE, FIXED or MIXED in nature.



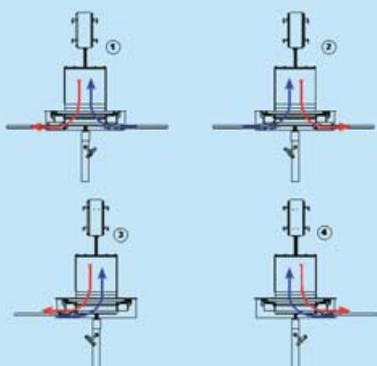
NUMEROUS DESIGN CRITERIA HAVE BEEN USED AS THE BASIS FOR OUR SYSTEM SOLUTIONS, INCLUDING THE FOLLOWING:

- FULL MODULAR DESIGN TECHNOLOGY (MDT) APPROACH
- MINIMAL FOOTPRINT WITH COMPACT SOLUTION AND OPTIMUM ERGONOMICS
- SHELVES BASED ON SUNKEN RAIL PRINCIPLE
- AMBIENT AND COLD SHELF LOADING
- HIGH LEVEL ERROR RECOVERY SYSTEM (VIA SCADA OR MANUAL INTERVENTION) AND FULLY GMP COMPLIANT
- DIFFERENT PUSHER CONFIGURATIONS AVAILABLE
- COMPACT FOOTPRINT WITH DEDICATED LOADING AND UNLOADING PUSHER.

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:

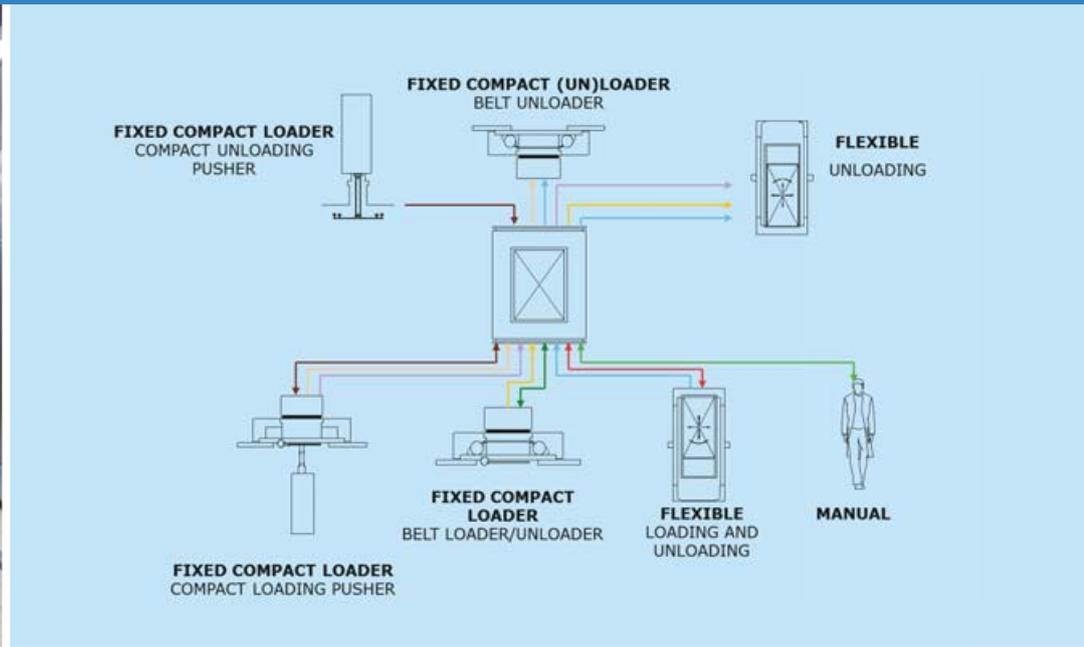
- Operating speed: up to 500 vials/min.
- Fixed loading configurations for one, two or four freeze dryers, with more possible depending on cycle times, logistics and process environment
- Choice of type of loading pusher
- Mainly loading and unloading from the same side
- Isolator or cRABS



LOADING CONFIGURATIONS

THE FIXED AUTOMATED LOADING AND UNLOADING SYSTEM IS AVAILABLE IN THE UNDERNEATH STANDARD CONFIGURATIONS:

1. LOADING FROM RIGHT & UNLOADING TO LEFT
2. LOADING FROM LEFT & UNLOADING TO RIGHT
3. LOADING FROM LEFT & UNLOADING TO LEFT
4. LOADING FORM RIGHT & UNLOADING TO RIGHT



Flexible loading system in production area

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



LOADING SYSTEMS DA VINCI: THE LATEST GENERATION

- 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



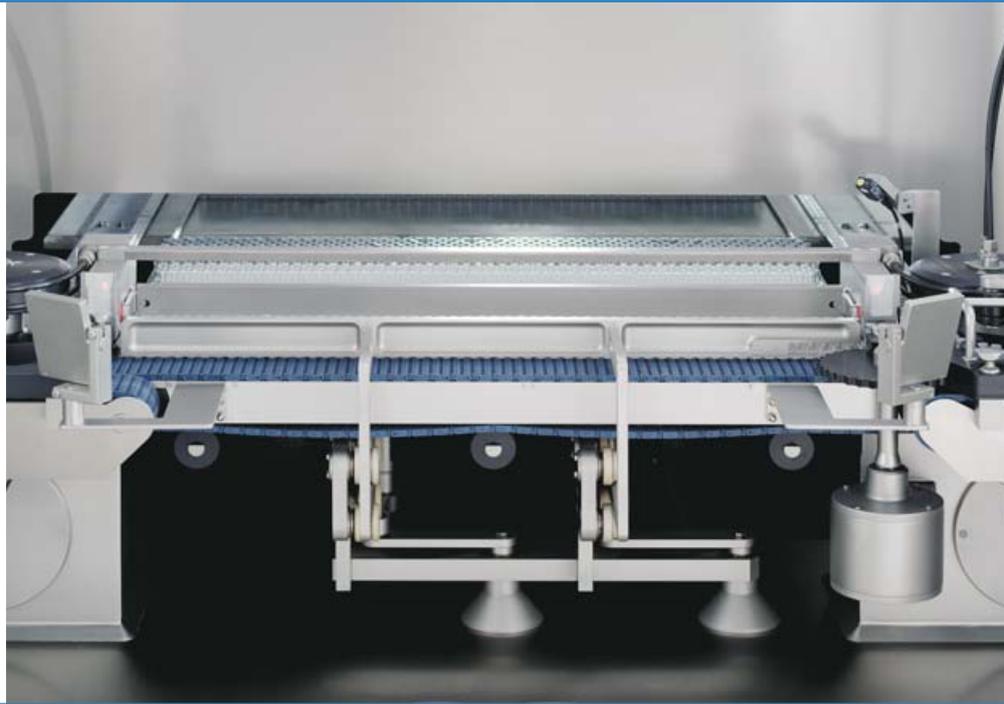
A state of the art design coupled with innovative wireless technology makes the DA VINCI the latest cutting edge breakthrough in the field of loading system automation.

DA VINCI is the latest example of IMA LIFE's ability to capitalize on in-depth application experience to deliver simple design concepts for improved automation resulting in enhanced performance and lower operating costs for the end user.

- 2 VERSIONS AVAILABLE:
 - WIRELESS
 - WITH CABLES
- COMPLETE ABSENCE OF FRONT AND BACK PUSHER
- ONE-SIDED LOADING AND UNLOADING OF FREEZE DRYER
- SELF-DRIVEN MODULE INSTALLED ON A TRANSFER BAR

OF VIAL LOADING AND UNLOADING SYSTEMS

THE EXTREMELY CLEAN AND NEAT DESIGN OF THE NEW LOADER IS BASED ON THE COMPLETE ABSENCE OF ACTUATING MECHANISM INSTALLED IN FRONT OR BACK OF THE SYSTEM GIVING BIRTH TO AN EXTREMELY COMPACT FOOTPRINT



DA VINCI loader with cables

The design of the new DA VINCI loader is based on the complete absence of any overhanging actuating mechanism installed at front of at back of the freeze dryer. This mechanism used to move vial packs into and out of the freeze dryer is based on the unique concept of a stand-alone battery driven transfer module. Communication with the machine is fully wireless.

Designed according to the latest international guidelines, DA VINCI loaders can be configured under RABS or fully isolated working environments.

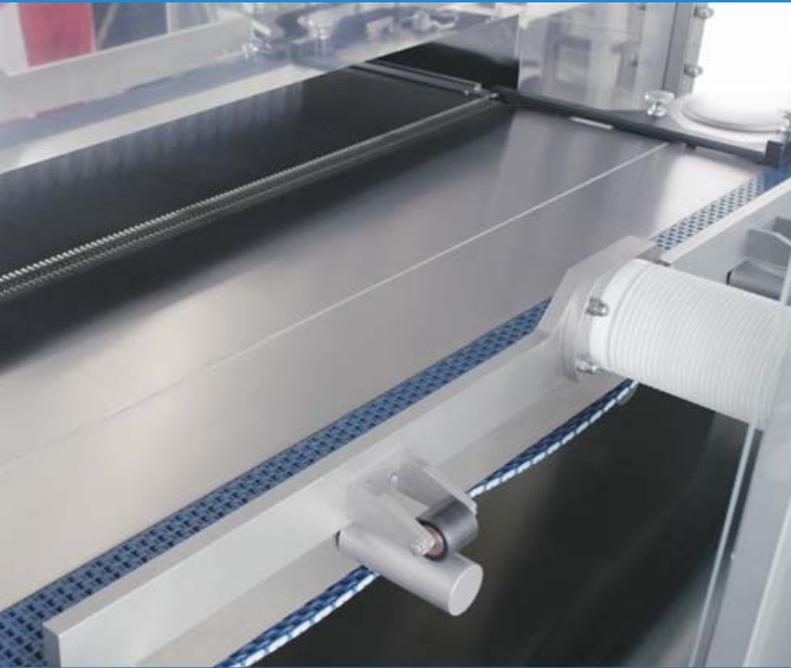
DA VINCI's revolutionary technology results in an extremely compact footprint, which considerably increases the level of flexibility towards possible lyo configurations and cleanroom layout. DA VINCI can be used with lyo's which are loaded and unloaded on same side or opposite sides in a pass through configuration.

The new system combines leading-edge technology and innovation with IMA LIFE's proven ability to meet the latest market demands for class-leading aseptic processing. Speed and efficiency are matched with reliability and control to provide a winning combination for the customer.

KEY FEATURES

- LASER MEASURING SYSTEM TO DETECT WHETHER THE TWO
- DRIVING MODULES ARE ALIGNED; IN THE NEGATIVE, THE COMPLETE TRANSFER UNIT NEEDS TO BE RETURNED (AUTO OR MANUAL) TO HOME POSITION FOR RESETTING
- CONTACT FREE RECHARGEABLE BATTERY
- SHORT STROKE PUSHER WITH OR WITHOUT BELLOWS
- THE SYSTEM NEVER STOPS DURING UNLOADING PROCESS
- MINIMUM NEED FOR FIFO

LOADING SYSTEMS INTEGRATION



SYSTEM INTEGRATION

- More than 20 years' experience successfully integrating freeze dryers 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
- Conveyors up and down-stream always part of loading system supply
- Conveyors based on fifo principle with single or serpentine designs
- Manage all interfacing with filling and capping equipment

IMA LIFE HAS ALL THE NECESSARY EXPERTISE AND FACILITIES IN-HOUSE TO ENSURE THE HIGHEST QUALITY STANDARD ACROSS THE ENTIRE SOLUTION.



INDEED, IMA LIFE LOADING SYSTEMS ARE DESIGNED TO BE FLEXIBLE ENOUGH TO MEET MANY INTEGRATION AND INTERFACE REQUIREMENTS AND CAN EVEN SUPPORT NON-IMA LIFE FREEZE DRYERS



INTEGRATION WITH FREEZE DRYER

- Integrated design
- Flexible docking plate
- Vertical sliding slot door
 - Minimum opening
 - Two-seal (vacuum + steam) design
 - Minimises access from outside (UAF or Isolator) into FD
 - Cleanable backside
 - Fast acting design
- Sunken rail principle

INTEGRATION WITH FILLING & CAPPING MACHINE

- Upstream and downstream conveyors of loading system are always part of system supply
- Conveyors based on FIFO (First In First Out) principle (single conveyors or serpentine system)

Loading system in-feed from filling machine

Conveyor length is determined by:

- Speed of filler & loading system (according to vial size): the loading system needs to run slightly faster than filler
- Position of back-up switch at filler's out-feed
- Type of IPC (In Process Control) on filler
- Loading sequence type on loader

Unloading system for vial transport to capping machine

Conveyor length is determined by:

- Position of in-feed switch on capper
- Speed of unloading system & capper (according to vial size)





TECHNICAL DATA

STANDARDIZED SHELF DIMENSIONS FOR FIXED SYSTEMS

Gross Shelf (mm)	Fixed Net (mm)	Manual Net (mm)
942 x 916	914 x 837	916 x 916 (tray: 454 x 300)
942 x 1220	914 x 1141	916 x 1220 (tray: 454 x 300)
942 x 1524	914 x 1445	916 x 1524 (tray: 454 x 300)
1248 x 1220	1220 x 1141	1222 x 1220 (tray: 404 x 300)
1248 x 1524	1220 x 1445	1222 x 1524 (tray: 404 x 300)
1552 x 1524	1524 x 1445	1526 x 1524 (tray: 506 x 300)
1248 x 1830	1220 x 1751	1222 x 1830 (tray: 405 x 300)
1552 x 1830	1524 x 1751	1526 x 1830 (tray: 506 x 300)

STANDARDIZED SHELF DIMENSIONS FOR FLEXIBLE SYSTEMS

Gross Shelf (mm)	Fixed Net (mm)	Manual Net (mm)
1328 x 1524	1214 x 1445	1222 x 1524
1632 x 1524	1524 x 1445	1526 x 1524
1632 x 1830	1524 X 1751	1526 x 1830

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



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N. IT00/0415