# Aseptic Processing & Freeze Drying Solutions

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IMA Life, in the field of liquid, powder, aseptic and non-aseptic processing, can today offer a wide range of machinery, particularly designed to meet the most stringent pharmaceutical requirements, from traditional filling and closing machines to the most advanced machinery and applications.

Combining the role of machinery supplier with the added ability of being a solution provider for its customers, IMA Life can satisfy even the most demanding requirements of the aseptic and pharmaceutical markets, offering products which represent, not only consolidated technology, gained during many years of experience, but which also derive from a continuous partnership with pharmaceutical multinationals worldwide.

IMA Life can in fact be considered a true partner to the pharmaceutical industry, offering a wide range of technologically advanced equipment. The production range includes machines for vial blowing, washing and de-pyrogenating, filling and stoppering machines for aseptic environments, filling and closing machines for pharmaceuticals, microdosing machines for aseptic powders, labellers depackers and tray loaders.

Thanks to the acquisition of the former BOC EDWARDS, renamed IMA Life and offering lyophilizers and loading/unloading systems IMA Life can be considered the world’s leading name in one-stop aseptic processing and filling solutions for the pharmaceutical and biotechnology industries.

Production cross-over together with the joint design capabilities will offer improved lead times, management of large-scale projects and a more comprehensive product portfolio to answer the ever more demanding requirements of the pharmaceutical industry.

Producing almost 200 machines a year in the field of filling, most of which are integrated in complete processing lines, due to an intimate knowledge of machine integration and line functioning logic, guaranteed by dedicated facilities and staff know-how for equipment assembly and integration.

IMA Life has two production sites, one located in the outskirts of Bologna and one in Calenzano near Florence.

IMA Life Freeze Drying Solutions operates through three production plants, one in Dongen (The Netherlands), one in Tonawanda (USA) and one in Beijing (China).
OUR CORE BUSINESS

UNDERSTANDING needs and RESPONDING to our customers is our REAL CORE BUSINESS, not only the production of one piece of equipment, but rather the comprehension of the whole CUSTOMER production SCENARIO.

REAL ADDED VALUE

From the very beginning of User Requirement Specifications definition through to final drug production: to supply the pharmaceutical industry with the SERVICE and SUPPORT necessary to CREATE REAL ADDED VALUE throughout the entire supply chain.

CUSTOMER RELATIONSHIP

The RELATIONSHIP WITH OUR CUSTOMERS: this is what guides the way we design and develop machinery and services to the pharmaceutical industry.

EXPERIENCE ON-THE-FIELD

At IMA Life, we envision a real partnership with our clientele, through the exchange of experiences on both sides of the pharmaceutical production process. Only through the “on the field” practice of its customers, IMA Life can keep the pace with the highest technology standards developing innovative and intelligent packaging solutions.
Cleaning and washing of containers in drug processing lines is becoming a crucial path in pharmaceutical production, when a strict decontamination of vials is required. IMA Life is a world leader in the production of equipment for blowing and washing pharmaceutical type containers such as ampoules, vials and bottles. These specifically designed machines meet the most stringent regulatory standards requirements followed by the pharmaceutical industry.

HYDRA SERIES
Specially designed linear washing machines are the result of years of research and experience dedicated to the decontamination of containers for injectable use.
- From 2 to 500 ml vials
- From 8,000 to 34,000 vials/hour
- Equipped with 8-13 washing stations
- Automatic drainage system
- SIP - Steam In Place with temperature recording

VEGA SERIES
Rotary washing machines for small vials and ampoules, with gentle mechanical handling of containers.
- From 2 to 50 ml vials
- From 6,000 to 24,000 vials/hour
- Equipped with 8 washing stations
- Pre-washing in an ultrasonic bath
- Water recycling station, siliconizing station
HYDRA 100/300 SERIES

The importance of decontaminating the filled and capped vials coming out from a processing line is becoming increasingly popular in the world of sterile applications. The possibility to reduce or even avoid cross contamination of vials is satisfied with the external washers of the HYDRA 100/300 Series.

- From 2 to 500 ml vials
- Up to 18,000 vials/hour
- Quick and easy size change over
- Automatic drainage and drying system

MISTRAL SERIES

Rotary blowing machines for dry cleaning of glass and plastic containers in general, that do not need washing with water or detergents but rather the removal of solid granular or dusty solids by means of a sterile air jet.

- From 6,000 to 25,000 vials/hour
- Simultaneous suction of impurities
DEPYROGENATING

IMA Life laminar flow sterilization tunnels of the BLUE GALAXY series are the result of years of research and experience in the field of sterilization and depyrogenation, and are designed to be inserted in production lines that require continuous depyrogenation by means of dry heat.

HIGH TECHNOLOGY FOR THE SAFETY OF DEPYROGENATION PROCESS.

BLUE GALAXY SERIES

Precise construction of the chambers (in particular the hot chamber) guarantees perfect distribution and penetration of heat by means of a flow of hot air treated with HEPA or ULPA filters, which strikes the bottles with vertical laminar flow. Air quality is ISO 5 as per ISO 14644.

- AUTOMATIC BALANCING
- AUTOMATIC ADJUSTMENT OF AIR SPEED
- AIR FLOW MEASURING SYSTEM INSIDE THE HOT AREA
- CALIBRATION SYSTEM
- OVER-KILL FUNCTION DURING LOADING AND UNLOADING
- VHP (PATENT PENDING) OR DRY HEAT STERILIZATION OF TUNNEL COOLING ZONE
STERILIZATION OF COOLING ZONE

DRY HEAT
The cooling zone can be sterilized with dry heat. Double electrical heaters are installed in the return ducts with all electrical connections outside the heated area. Before the sterilization cycle the cooling system is drained to avoid water pressurization or additive’s coating if present. The cycle guarantees that all points reach at least 170°C or more temperature and time adjustable.

The system guarantees 6 log of spore reduction.
The chamber is insulated to avoid external surface temperature.

HYDROGEN PEROXIDE IN VAPOUR PHASE
Equipping the tunnel with this exclusive patent sterilization system, it is possible not only to have an aseptic cooling zone, but also all tunnel’s internal surfaces sterilization.

This system allows to sterilize the tunnel at the same time of the isolator sterilization or during the room gasification. The simple and efficient design permits a very optimal gas distribution within all the tree zones of the tunnel. The particularly cycles guarantee a very high hydrogen peroxide concentration and easy and fast aeration.

When isolator or room are sterilized at the same time, the gas can move from the isolator or room inside the tunnel sterilizing all transfer area.
The cycle guarantees 6 log of spore reduction.

The wide range of manufactured tunnels gives the possibility of satisfying any production need; in the same way the high technology allows the use of these tunnels for any kind of application and this is why they can be easily integrated in lines to handle high toxic products and/or in lines with isolators.
IMA Life machines for aseptic filling in vials are distinguished by their rigorous detail design and are the result of careful research in fluid dynamics, to guarantee maximum product protection for all aseptic filling environments, such as traditional clean rooms or isolation technology.

**SMART SERIES**
Medium to high-speed filling and stoppering machines for vials from 0.25 to 500 ml, for SVP and LVP.
- Output up to 120 vials/min
- 100% IPC or statistical checkweighing systems
- All types of filling systems available
- Pre-arranged for R.A.B.S. or ISOLATOR
- CIP-SIP systems

**XTREMA SERIES**
Top of the range filling and stoppering machines for SVP vials and for LVP vials.
- Output up to 600 vpm
- Innovative design & extreme adaptability
- 100% IPC at 400 vpm - Dual vial transport motion
- All types of filling systems available
- Pre-arranged for R.A.B.S. or ISOLATOR
- CIP-SIP systems
STERIFILL SYRINGE SERIES

Small batch filling and stoppering machines for pre-sterilized syringes in nest from 0.25 to 20 ml.

- Output up to 200 syringes/min
- Automatic nest handling system available
- All types of filling systems available
- CIP-SIP systems
- Vacuum filling & plunger insertion systems
- Pre-arranged for cRABS integration or isolator

STERIFILL AMPOULE SERIES

High-speed filling and sealing machines for ampoules from 1 to 25 ml.

- Output up to 400 ampoules/min
- All types of filling systems available
- CIP-SIP systems
- LAF Hoods system or cRABS
- Statistical IPC for vials
- High versatility and quick configuration change over
- Combi version for vials and ampoules also available
BARRIER TECHNOLOGY

Although interest on the part of the pharmaceutical industry in the use of isolators is relatively recent, IMA Life has already acquired a solid experience, producing aseptic filling lines for dosing liquids and powders using various types of isolators and creating highly flexible mechanical interfaces. Several FDA approved lines are running successfully worldwide.

The very compact size of IMA Life Series of machines allow the implementation under isolator, without changing the basic design.

The vial transport systems are completely exposed to the laminar air flow and therefore sterilizable through VHP (Vapour Phase Hydrogen Peroxide) without the need of complicated air recirculation systems.

XTREMA PWD

High-speed aseptic powder microdosing and stoppering machine with positive, in-line transport system for processing at once up to three different powder drugs inside the same vial.

- Up to three powder dosing units
- Filling volume from 0.50 mg
- Set output up to 400 vials/min
- 100% IPC checkweighing system
- Innovative "Smartplate" device for the assembly/disassembly of the dosing units preserving class continuity
- 90° dosing unit left-right rotation allowing a precise and trouble-free changeover
- Vacuum pressure/Auger dosing systems
- HMI friendly interface with PC touch-screen
- Suitable for installation inside conventional sterile room or integration with any type of RABS or isolators, as well.
RABS also process in an ISO 5 environment, with varying degrees of contact with the surrounding room, which is generally classified ISO 7 or better. Bio-decontamination is performed manually in a RABS. Although doors can be opened, this is a rare occurrence, after which the system must be appropriately sanitized, a necessary line clearance performed, and the intervention documented. IMA Life has already gained a wide experience on the application of RABS systems on top of their aseptic filling machines.

**SL SERIES**
Medium to high-speed filling and sealing machines for plastic unit dose containers.
- From 1 to 10 ml
- Up to 375 pcs/min
- 5-15 dosing heads

**ALU SERIES**
Medium to high-speed alu-capping machines for sterile applications.
- From 5 to 100 ml - up to 600 vials/min
- Low particle generation capping system
- 100% measurement and control of vertical compression force
- Pre-arranged for R.A.B.S. or isolator attachment
Almost 2000 machines for more than 100 different applications: this is the experience and background that IMA Life makes available to its pharmaceutical customers in the field of multipurpose liquid filling and closing machines.

Either intermittent or continuous motion the IMA Life fillers for pharmaceuticals can dose different types of product applying different types of closures (injectables, infusions, ophthalmics preparations, intranasal products, suspensions, oral drops, drinkables, sugary syrups, detergent/disinfectant solutions etc.).

THE SERIES OF FLEXIFILL MACHINES REPRESENT IMA LIFE’S ANSWER TO THE FLEXIBILITY AND RELIABILITY DEMAND OF THE PHARMACEUTICAL MARKET NOWADAYS.

FLEXIFILL SERIES

In-line filling machines, for medium speed.

- Intermittent or continuous motion version
- Electronically or mechanically driven
- From 120-250 bottles/min
- From 5 to 1000 ml filling volume
- All types of filling systems available
- CIP-SIP systems
MULTIFILL SERIES

High differentiation of technical solutions coupled with years of consolidated experience make of the Multifill Series a milestone in drugs processing assuring flexibility and reliability at the same time.

- Intermittent or continuous rotary motion version
- From medium to high speed machines: 60-500 bottles/min
- From 0.25 to 1000 ml filling volume
- All types of filling systems available
- All types of pharma closures possible
- CIP-SIP systems

IDEAL FOR BIG BATCH PRODUCTION, F800 SERIES OF MACHINES CAN BE EQUIPPED WITH THE LATEST GENERATION OF COMPLETELY AUTOMATED CIP-SIP SYSTEMS.
For more than half a century, IMA Life Freeze Drying Solutions has provided the benchmark for freeze drying solutions to the pharmaceutical and biotech industry. With a truly global presence with main facilities well positioned to serve customers in all corners of the world. With over 1000 freeze dryers installed in over 50 different countries, IMA Life is ready to leverage this experience to better serve its customers needs.

IMA LIFE FREEZE DRYING SOLUTIONS PRODUCTION RANGE:
- INDUSTRIAL FREEZE DRYERS
- PILOT FREEZE DRYERS
- LOADING SYSTEMS.

THE LYOFAST AND LYOMAX RANGES COVER ANYTHING FROM PILOT MODELS UP TO LARGE PRODUCTION UNITS. PRODUCTS CAN BE CONDITIONED IN BULK, VIALS, AMPOULES OR OTHER TYPE OF CONTAINERS SUCH AS CARTRIDGES OR SYRINGES.

LYOMAX
Lyomax comprises the most comprehensive range of custom-built freeze dryers for those who require more than a standard solution. Lyomax can provide the solution from 1 m² to 100 m² 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.

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.
LYOFAST MINI

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

LYOFAST

A series of standard modules provide the foundation of the Lyofast model concept. Pre-engineering results in time and cost benefits, while a wide range of standard options ensure sufficient flexibility over a broad range of configurations.

By constructing from a series of standard modules, IMA Life Freeze Drying Solutions 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 the customer with a competitive edge by reducing the time to market.
The new Da Vinci loader is based on a self-driven module installed on the transfer bar. Communication between battery and PLC control is wireless. Positioning control is based on laser technology.

Designed according to the latest international guidelines, Da Vinci loaders can be configured under RABS (Restricted Access Barrier System) or fully isolated working environment, as well. Its revolutionary design results in an extreme compact footprint and in the absence of any protruding mechanism in front or at the rear side of LYO, which considerably increases the level of flexibility towards possible line configurations and cleanroom layout.
IMA LIFE IS ONE OF THE FEW SUPPLIERS IN THE WORLD THAT DESIGNS, MANUFACTURES AND TESTS A FULL RANGE OF PROVEN SYSTEMS FOR FULLY AUTOMATIC LOADING AND UNLOADING VIALS INTO INDUSTRIAL FREEZE DRYERS.

**FIXED SYSTEMS**
The Fixed system consists of a conveyor integrated with the out-feed of the filling line, which transports vials to a loading/unloading station installed in front of the freeze dryer.

**FLEXIBLE SYSTEMS**
Loading systems consist of a loading accumulation table (LAT), integrated with the out-feed of the fill line, which collects and moves vials in a vial pack equivalent in shape and size to each freeze dryer shelf. Once a vial pack is created on the LAT, a Transfer Cart (TCAR) collects the vial pack and transfers the pack onto the designated freeze dryer shelf. At the end of the freeze drying process, the TCAR collects the vial packs from the designated freeze dryer shelf and transfers the vial pack to an unloading accumulation table (UAT) or Unloading Accumulation Buffer (UAB), where the vials are de-scrambled for single lining to the alu-capper.

**MIXED SYSTEMS**
These systems offer a combination using fixed and flexible solutions:
- Only pass-through configurations, loading operating up to 450 vials per minute and unloading up to 900
- Fixed loading and Flexible unloading
- Flexible loading and Fixed unloading
IMA Life production range includes a wide range of labelling machines which can be an integral part of complete packaging lines or serve as stand-alone machines. To complete the panorama of packaging lines, IMA Life manufactures a range of equipment primarily dedicated to automate the traditional manual operations for loading of containers.

**SENSITIVE SERIES**

- Highly flexible and high performance self-adhesive labelers
- Suitable for glass and plastic bottles vials, ampoules, cartridges, syringes and containers with irregular shapes
- Front and rear labelling
- Vignette labels and self-adhesive tamper evident seals on cartons
- Overprinting units (hot foil, ink-jet, thermal transfer, laser)
- Bar-code readers - 2D code readers - Datamatrix, Printing systems and control camera systems, vision systems and camera pixel counters
- Semi automatic splicing of label reel without machine stop

**SELF-ADHESIVE TECHNOLOGY FOR LABELLING OF AMPOULES, SYRINGES, VIALS, BOTTLES AND CARTONS WITH FLEXIBILITY, VERSATILITY AT HIGH SPEED.**
STARPACK SERIES
Semi-automatic and automatic de-packers offer the possibility to further enhance the performances of complete processing lines.
- Suitable to handle bundles with vials and bottles up to 500 ml
- Up to 240 vials/min

V & VL SERIES
V & VL are automatic tray-loaders for loading vials onto plastic, metal or paperboard trays, designed for installation in aseptic production lines, where the minimum operator intervention is required.
Following the increasing demand in automation of lyophilization processes, IMA Life has designed and developed a range of special traying facilities to ease the loading/unloading operations typical of lyophilization lines, facilitating transfer operations of vials to and from the freeze-dryers.
- Up to 600 vials/min
- Up to 2 loading positions for 2 trays each
- Ray capacity optimization
- Minimal operator intervention
- Ideal for classified environments
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