IMA LIFE
Aseptic Processing & Freeze Drying Solutions

INJECTA

7 MOVES CHECKMATE

ADVANCED ROBOTIC DRIVEN

As the pharmaceutical industry faces a growing demand for tailored solutions such as parenteral targeted medicines, or even a critical need to reduce time to market and ensure high volumes at high speeds, aseptic processing equipment manufacturers are required to address new issues. Compliance with stringent guidelines, on one hand, plus the flexibility needed to maximise efficiency for small -medium size production, or high performance on the other.

The trend towards personalised therapies is accelerating, involving the need to produce biologic sterile injectable drugs and increasingly smaller volumes of drugs for genome-specific therapies. On the other hand, high-speed processing for products necessitating high volumes is another growing concern and priority. To keep pace with a variety of evolving scenarios, pharmaceutical companies and CDMOs must be able to handle a broad variety of product types and packaging formats, such as vials, syringes and cartridges. Flexibility within an aseptic environment helps reduce time-to-market, and manufacturing flexibility also means the ability to scale up and down without process re-qualification. Some companies will need to integrate a lyophilisation process, others will count on modularity to meet layout constraints. All companies will aim for the highest achievable sterility assurance levels and in many cases, especially those handling high potent compounds, require containment solutions. Gloveless aseptic processing is also a primary target for the industry, compliance with Annex 1 guidelines and the ability to monitor viable airborne particles **INJECTA** is the result of four years of design and development carried out by a team of **IMA Life** experts, the first of its kind built around a fully robotised concept. Addressing one by one the critical issues facing the pharmaceutical industry, **INJECTA** adopts a combined strategy to provide a winning solution that will answer today's market demands and ensure that companies who adopt **INJECTA** will play a key role in tomorrow's dynamic marketplace.


MOVE | 1
- FLEXIBILITY -

INJECTA drives multi-product, fill-finish operations into a new realm of flexibility. With its ability to handle so many different product types and formats, and the speed with which processing can switch from one specification to another, INJECTA is the queen of superior versatility.

One of the needs today is the ability to stay flexible and keep up with changing, patient-centric demands for new drug-delivery systems that can better fit patient lifestyles. If the primary goal in the injectable market is to achieve flexible production in an aseptic environment, implementing cost-saving solutions to reduce time-to-market, INJECTA has the ideal characteristics to answer those demands.

MULTI-PRODUCT, MULTI-FORMAT FLEXIBILITY

INJECTA is born to be flexible. Superior agility for multi-product manufacturing catering for multiple formats is fundamental. The filling system accommodates a broad range of containers like tubs, nests, trays and pre-sterilised RTU components such as vials, syringes and pre-capped cartridges, pre-oriented vials in trays as well as sterilised vials from the depyrogenation tunnel. No need to change the filling module and minimal changeover is required.

ADVANCED ROBOTIC TECHNOLOGIES

INJECTA uses the full potential of its robots. Whereas conventionally confined to just one step of production, INJECTA exploits advanced robotic capabilities in an integrated solution.

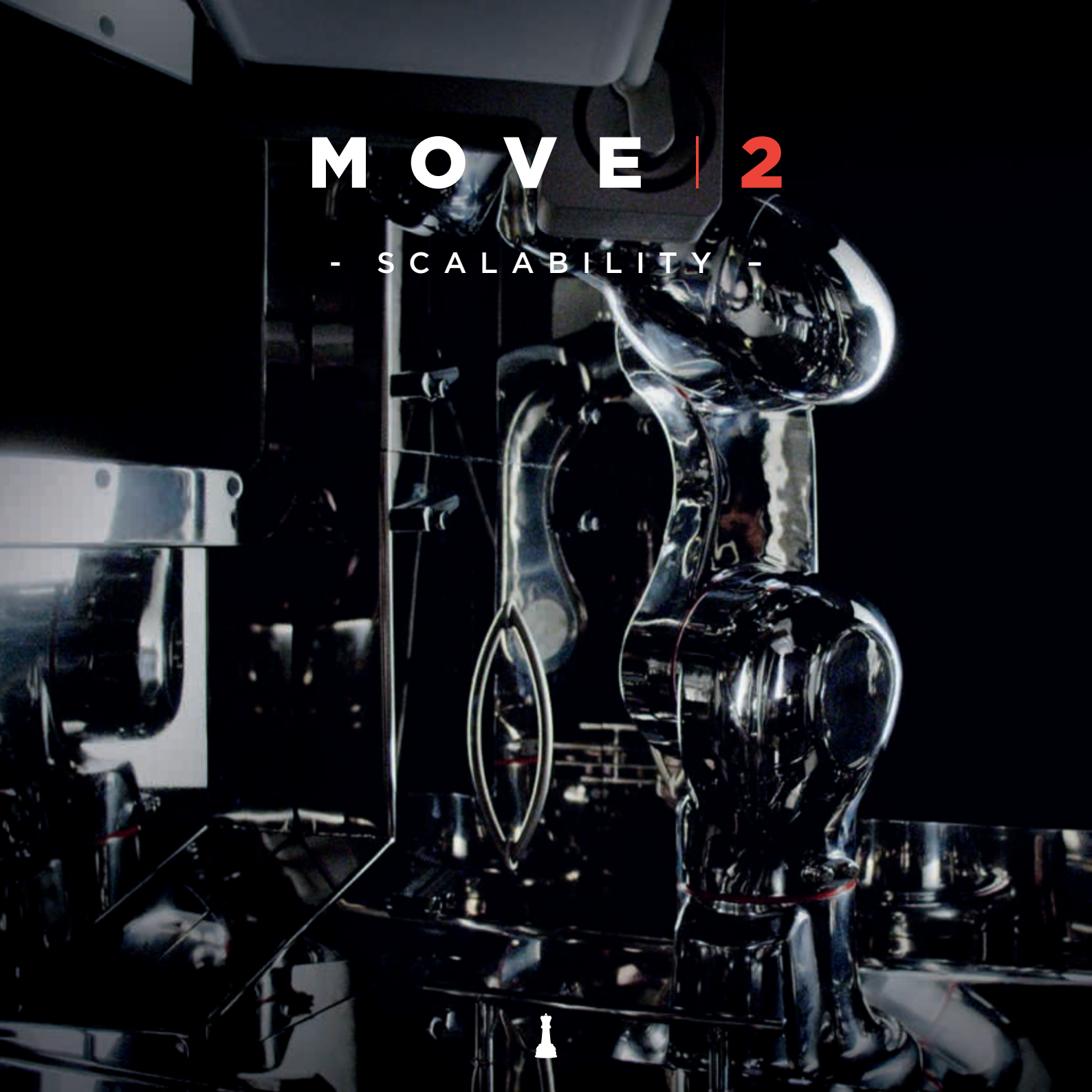
The use of robotically driven manipulations at all stages, from outer/inner bag opening to the stoppering station, allows for the smoothest production process, drastically reducing human intervention and cross-contamination.

Not only do the robots provide precise, consistent handling activities, they also offer a high level of flexibility and are digitally controlled with Industry 4.0 capability.

FLEXIBLE CONFIGURATION

INJECTA fills and closes RTU components in a nest or with de-nesting and easily performs fully robotized 100% check-weighing for either configuration.

De-nesting operations are available for high-level quality control, with individual component handling by a robot. All processed RTU components are individually check-weighed in the case of de-nesting or check-weighed all together while in nest, with single rejection of each individual non-conformity, safeguarding the nest.


MOVE | 2
- SCALABILITY -

Measuring up to demands for targeted medicine and scaling up and down to accommodate all batch sizes, even the smallest, requires unprecedented processing agility. INJECTA performs the same identical filling, check-weighing and stoppering operations without a need for process re-qualification thanks to its unique process platform.

Biologic sterile injectable drugs are one of the fastest growing trends facing the pharma and biopharma industries, alongside an increase in parenteral targeted medicine. This generates a need to adopt versatile solutions for smaller batch sizes and ensure minimal product loss. INJECTA provides outstanding scalability through a unique platform from the early phases of drug development and clinical trials up to full production scale.

SUPERIOR AGILITY IN ASEPTIC PROCESSING

Manufacturing targeted biologics requires the ability to handle small numbers of high-value batches at an increased frequency, often producing multiple therapies in parallel. All of this means that sterile injectable manufacturing capabilitieshave to meet the need for improved scalability. INJECTA enables flexible, multi-product, small batch production, minimising product waste and cross-contamination between drugs.

STANDARDISED DESIGN FOR SMOOTH HANDLING

Having the same supports and transfer devices for all types of RTU components, plus unique robotised pick & place procedures, INJECTA boasts built-in scalability. When switching from one container type to another (in nest or with de-nesting), INJECTA overcomes the complexity of performing aseptic processing with high sterility assurance levels. The container handling system provides consistency and repeatability, simplifying set-up and material transfer without any glass-to-glass contact.

IDENTICAL, REPEATABLE PROCESS PATTERNS

INJECTA's robotic multi-format filling system design meets multiple requirements, ranging from small-scale clinical trial batches up to medium-high production levels. Its unique platform, which implements any number of filling pumps between one and six, performs the same identical filling, check-weighing and stoppering operations avoiding re-qualification of the production process, thereby enhancing production efficiency.


MOVE | 3
- MODULARITY -

Modular solutions are the smart way to support your strategy from all angles, multiplying your opportunities to achieve production targets in the smoothest possible way. INJECTA ensures both physical modularity by adapting to multiple layout needs, and operational modularity to cope with demands for different volumes and formats.

Modularity as a key aspect of facility design is an increasingly important issue. Building modular units according to single process steps ensures advantages such as reduced costs and faster time-to-market. INJECTA is intrinsically modular and meets multiple requirements: machine functions can be assembled in different configurations to fit an unlimited number of layout solutions, starting from the handling of primary packaging components. Moreover, robotic technologies maximise operational modularity.

LAYOUT OPTIMISATION

INJECTA provides unlimited possibilities for layout design, either for new parenteral manufacturing lines or brand new facilities. In the case of existing plants, thanks to its superior adaptability, INJECTA fits perfectly into configurations with an upstream depyrogenating tunnel, downstream alu-capping and external washing. Even lines with freeze-drying requirements and complete high potent lines under isolation. Thanks to its modular approach, INJECTA models itself to any kind of production context.

Layout configurations include solutions to process: RTU components pre-arranged in nest and tub; RTU vials from bulk with de-nesting; RTU vials upside down from trays with de-nesting; RTU vials lyophilised in a nest and special solutions for handling plastic press-fit vial closures (snap caps) for lyo vials.

ROBOTIC HANDLING MODULES

Forward-looking facilities will benefit from modularity to ensure flexible use of space when faced with future requirements for new processes performed in existing environments, or a need to scale up or down without excessive investments.

Designed not only for INJECTA, the robotic handling modules can be integrated with conventional aseptic lines handling RTU vials pre-arranged in trays.

LYO PROCESS INTEGRATION

INJECTA easily integrates with a lyophilisation process, where an automated vial loading and unloading system handles products in and out of the freeze dryer. A robotic arm places the nested vials into the process ensuring no product losses, no vial falls or breakages.

INJECTA fits into in-line and T-shape configurations as well as all-in-one integrated fill-finish solutions with combined (double lane) lyo process and capping operations.

To maximise space efficiency, custom-built configurations are also possible.

The final aim is to combine intelligent facility layout, cutting-edge technologies and innovative processes.

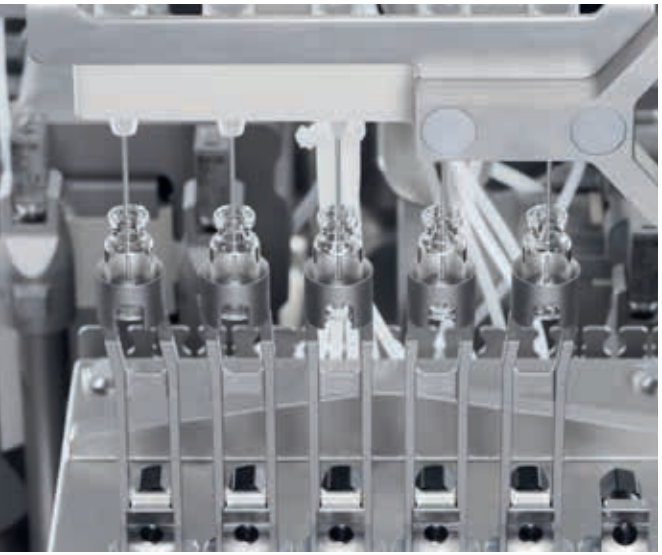

MOVE | 4
- QUALITY ENHANCEMENT -

Managing risks to avoid particle generation in aseptic processes ultimately enhances the quality of the product and ensures safety, vital for patients. INJECTA implements a host of technologies such as widespread use of robotic handling techniques, and is designed to ensure maximum quality through full in-line process control and single rejection capabilities.

Quality risk management in aseptic processing should determine where particulates are most likely to enter the process, identifying the most critical steps. Managing these risks means implementing advanced technologies and effective containment solutions. INJECTA responds with appropriate innovations and process automation to prioritise both quality and efficiency.

STERILE OUTER BAG HANDLING

Robotic technology is key to preserving tub sterility and helps complete routine tasks swiftly and accurately. Controlled barriers, containment measures of pressure differentials and protective airflow together with advanced robotics help preserve sterility during outer bag opening. To meet the regulatory requirements, the tub-opening unit is completely robotized and under containment. Bag opening is performed at a point where airflow and pressure difference between the two sections ensure the tub remains sterile. After cutting the bag, the primary package is instantly transferred by an internal transfer port to the isolated, processing area. Bag flaps are opened by suction cups, only when the tub is physically transferred to the isolated area. This pass-through solution minimises exposure to undesirable particles, thereby improving process quality. Alternatively, NEBULA, the latest IMA Life decontamination solution, enables the tub to enter INJECTA having undergone 6-log decontamination, thus avoiding the need for a bag-opening module.



IN-LINE PROCESS CONTROL WITH SINGLE NON-CONFORMITY REJECTION

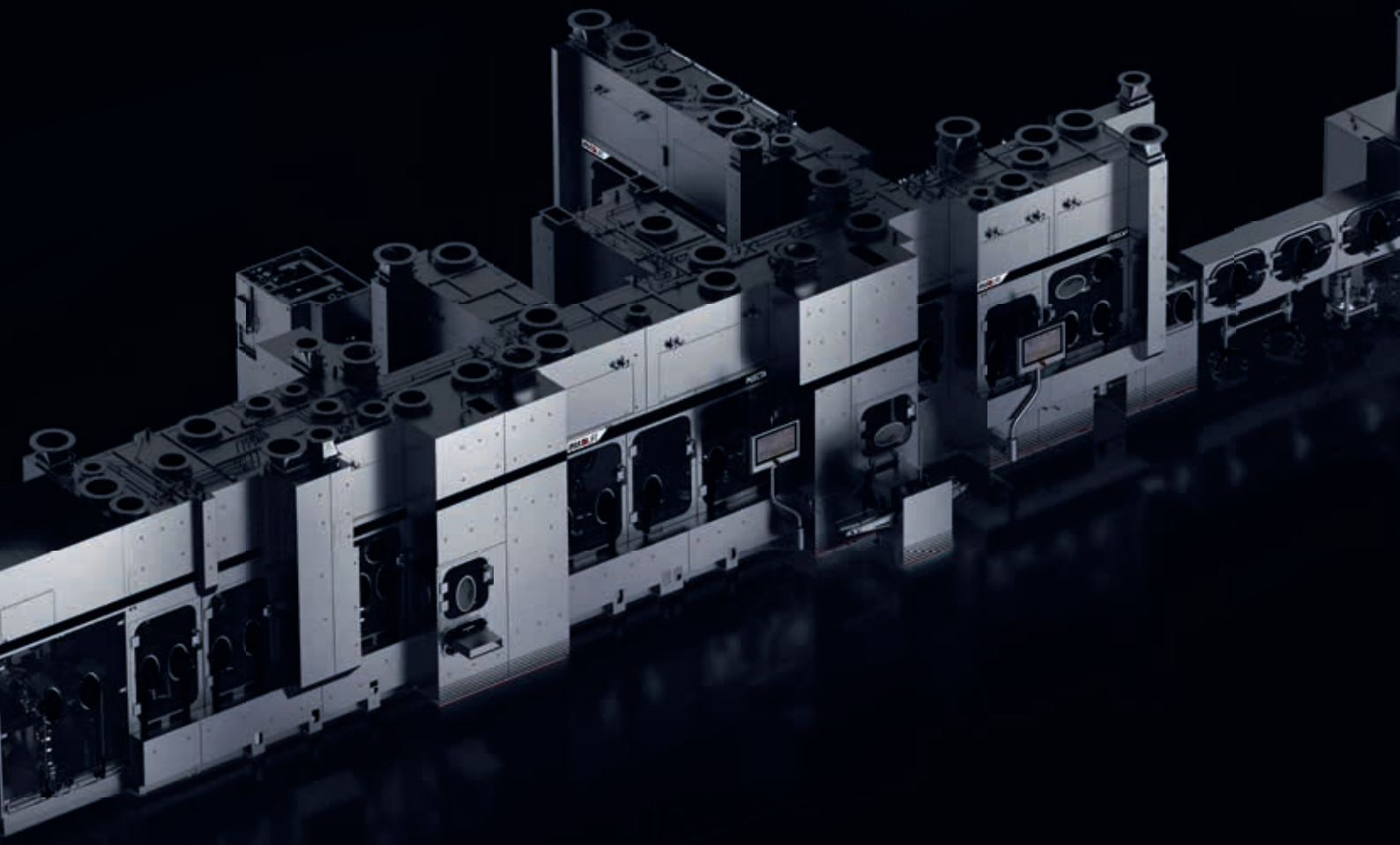
Fully robotized 100% check-weighing, together with single rejection capabilities – both from the nest or with de-nesting - enhance process quality. A patented device eliminates the electrostatic charge in the nest for more accurate weighing. The handling system also minimises interference caused by airflow. Individual de-nested components are filled, check-weighed and immediately stoppered, reducing sterile drug exposure times. Weigh-cell block design allows for tolerance required to manage different RTU component formats.

MAXIMUM CLEANSABILITY

Overall design of INJECTA facilitates proper wash-in-place procedures, which are mandatory when handling potent compounds. The overwhelming presence of robots entails the total absence of transfer combs or conveyor belts, facilitating unidirectional airflow. Ensuring potential contamination is kept to a strict minimum means greater protection for the product, the equipment itself and staff.

MOVE | 5

- HIGH CONTAINMENT -



INJECTA combines design, decontamination and isolation strategies, resulting in a high containment concept to satisfy the most stringent demands. Robotic technologies, which minimise intervention, and seamless co-implementation of an IMA Life isolator set the seal on the most efficient solution in the industry. INJECTA is high containment and low concerns.

Facilities handling high potent compounds must be equipped with appropriate methods for high containment. For injectable liquid products, specific strategies should be applied to the production line configuration. These may involve isolation technology, air handling systems, coupled with cleaning and bio-decontamination procedures, as well as GMP validation at each manufacturing stage.

ISOLATOR

IMA Life isolators are a perfect match for INJECTA. Seamless integration, without gaskets between isolator and air plenum, is ideal for multiple small batch capabilities. Interfacing with a single machine, the isolator is able to exploit INJECTA's potential for switching frequently between production cycles and formats, enabling fast replacement of machine parts. Based on its extensive experience in isolation technology, IMA Life has developed a solution which meets EU GMP requirements for product quality, efficacy and patient safety.

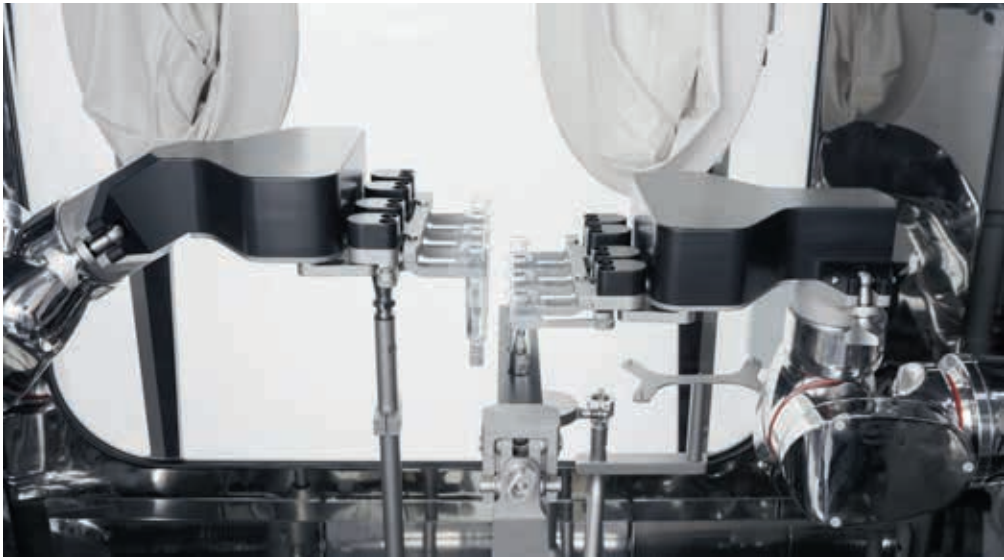
DESIGN OPTIMISATION

Mock-up testing procedures are performed to check INJECTA's upstream and downstream interactions. Thanks to the flexibility of the concept, the best suited configurations can be implemented case by case. Electrical connections and positioning of the utilities inside the isolator are also defined based on the mock-up testing and will be defined to avoid affecting line ergonomics.

REGULAR IN-PLACE DECONTAMINATION

Unidirectional Air Flow in Grade A filling environments suppresses release of contaminant to a lower level zone, enabling in-place decontamination. The containment barrier is closed for the WIP cycle which ensures removal of surface contaminants. Improved isolator design plus easily cleanable robots optimise the WIP cycle, making it sufficient to validate a single washing cycle. Developing a single decontamination cycle with VPHP is possible with the INJECTA-plus-isolator set-up.

The set-points for the decontamination process, once validated, do not require adjustment or re-testing since this is a dedicated cycle for a single line. A single VPHP cycle for all possible INJECTA configurations saves time, both for the first and for periodic validations.

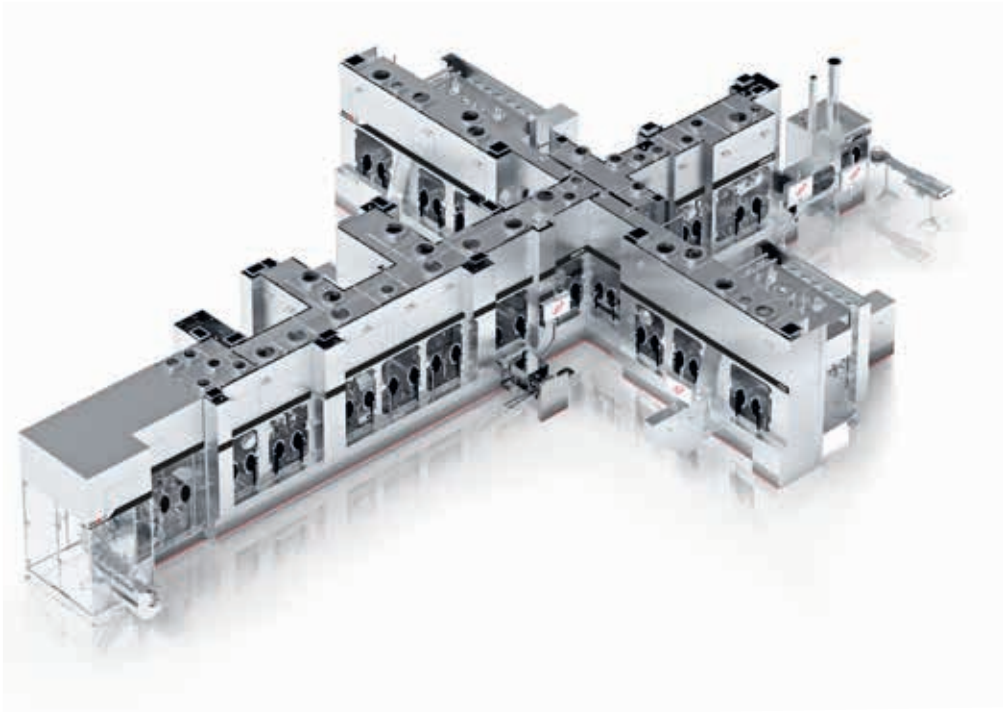


MOVE | 6

- ADVANCED COMPLIANCE -

INJECTA rises to the challenge of advanced compliance through implementation of towards gloveless solutions, isolation technology, fully automated robotics and real-time viable particle monitoring. Assuring strict compliance with Annex 1 guidelines and implementing the latest aseptic processing technologies, INJECTA provides the most effective way of achieving advanced compliance.

Strict procedures must be followed when manufacturing sterile products to lessen risks of microbiological and particulate contamination. The aim is to achieve the highest possible Sterility Assurance Level by acting on several factors, favouring compliance with the regulatory requirements of FDA/EMA pharmaceutical authorities.



TOWARDS GLOVELESS SOLUTIONS

INJECTA is designed to run without human intervention. No mouse holes, conveyors, glass-to-glass contact or vibrating bowls which could place the batch at risk. Robotic systems operating in an isolator system ensure outstanding sterility assurance as well as reliable product outcome in full-scale production. Robotic arms safely accomplish uncompromised movements and will flexibly adapt to a new process or container type. In absence of traditional, mechanical components, decontamination cycles are much shorter too. INJECTA is leading the way towards fully automated aseptic processing, towards a gloveless system, resulting in savings, safety and quality.

MEETING ANNEX 1 GUIDELINES

The new Annex 1 draft of the EU GMP takes into account several critical factors. INJECTA's robots handle all RTU container types in the same way, limiting change parts. Stoppering is performed using a linear stopper feeding system, featuring small components ideal for RTP transfer without breaking SAL. INJECTA ensures automated assembly of the stopper feeding unit and of the filling group. Autoclaved stoppering/filling components enter the isolator automatically, handled by robotic arms. This allows sterile parts to be transferred to the stoppering/filling station inside the barrier system, without breaking containment. INJECTA's isolated robotic technology is a step ahead in the evolution of the fill-finish process, as it allows for superior contamination control.

REAL-TIME VIABLE PARTICLE MONITORING

Whereas optical particle counters are unable to determine particle viability, INJECTA goes a step further by implementing real-time airborne viable particle counting technologies to quickly react to possible microbial excursions. Based on Laser Induced Fluorescence technology, viable microbial counts are obtained in real time. The potential to instantly respond to an airborne microbiological event when it happens is exciting and beneficial and results in an increase in product quality, a safer product, and risk reduction.

MOVE | 7

- THE CHECKMATE -

Building a strategy that addresses major issues and provides a single solution is the goal that has been achieved with INJECTA. Each move evaluates a specific demand facing pharmaceutical and biopharma companies today, answering it with an eye to the future. INJECTA implements advanced technologies, patented devices and relies on the wealth of experience IMA Life has in the field of aseptic processing to say checkmate. One future-looking concept paving the way towards product quality, processing efficiency and production safety.

INJECTA redefines **flexibility** and exploits robotic technologies to handle multiple packaging formats. Digitally controlled, the robots manage all processing steps, including fully robotized 100% check-weighing. Low-to-medium volume production or high-speed processing with INJECTA 36, conceived to process up to 36,000 syringes or cartridges per hour, underpin the versatility of the solution.

Ensuring operational **modularity,** robots easily adapt to new processing requirements allowing companies to react fast to changing demands. A step further in terms of modularity enables integration with freeze-drying sections or even lines under isolation.

Enhanced **product quality** and minimal product losses are obtained thanks to factors such as sterile outer bag handling, airflow and pressure controlled through key design features, patented devices for high-precision weighing and robotized handling under containment. In fact the massive presence of robots eliminates the use of transfer combs and other mechanical elements. This facilitates unidirectional airflow and enables extremely effective wash-in-place procedures.

Pharmaceutical companies needing to modulate output volumes will benefit from INJECTA's unique platform offering unprecedented **scalability,** adapting to clinical trials or full production. Activating between one and six filling pumps capable of repeating identical processing operations removes the need for re-qualification. **High containment** capabilities are a must for facilities handling high potent compounds and IMA Life, with its extensive experience in isolation technology, has succeeded in matching its isolator with INJECTA. This leads to more efficient and effective in-place decontamination to the point where a single cycle using VPHP is totally adequate.

Addressing each of these aspects gains in value for the pharmaceutical company or CMO only when **advanced compliance** is assured. Today's strict guidelines herald the increasingly stringent regulations we can expect in the future. This is the competitive advantage INJECTA delivers: compliance with Annex 1 guidelines, robotics used to avoid human intervention, sophisticated automation leading the way towards a gloveless reality.

Only a series of coordinated moves leads the Queen to declare Checkmate. Only INJECTA has the power to deliver the outcome required for tomorrow's world of aseptic processing.

INJECTA36

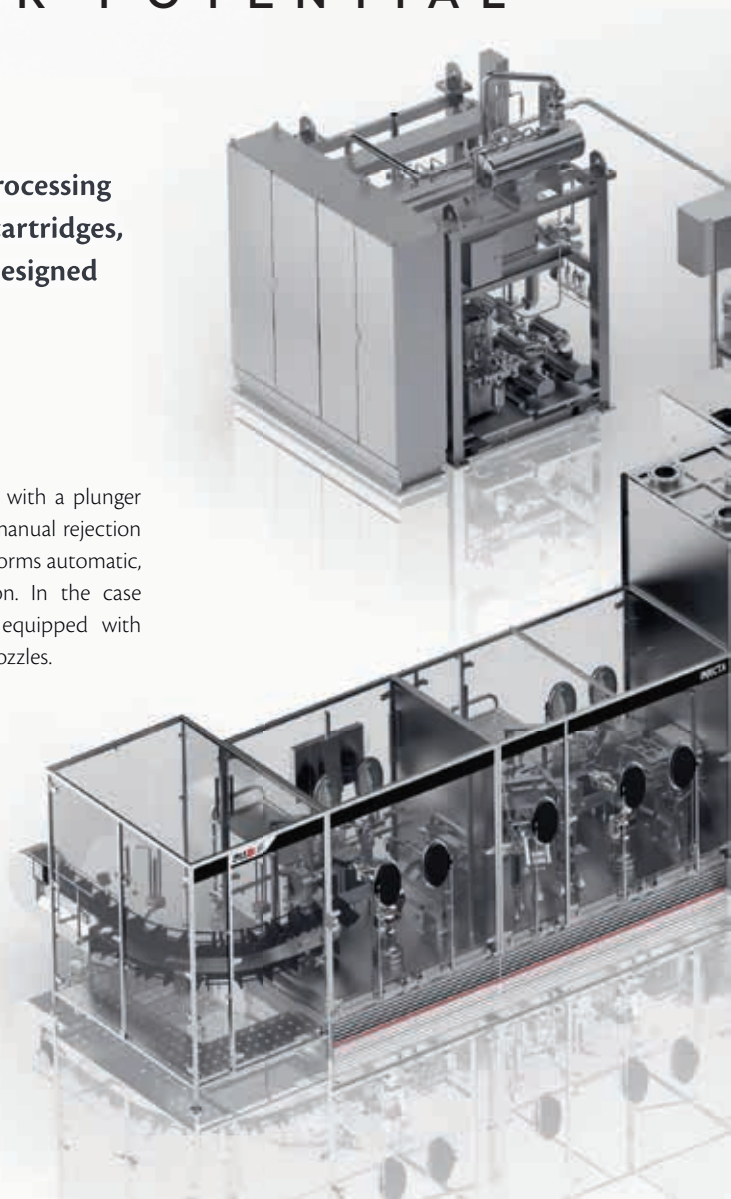
- INCREASING YOUR POTENTIAL -

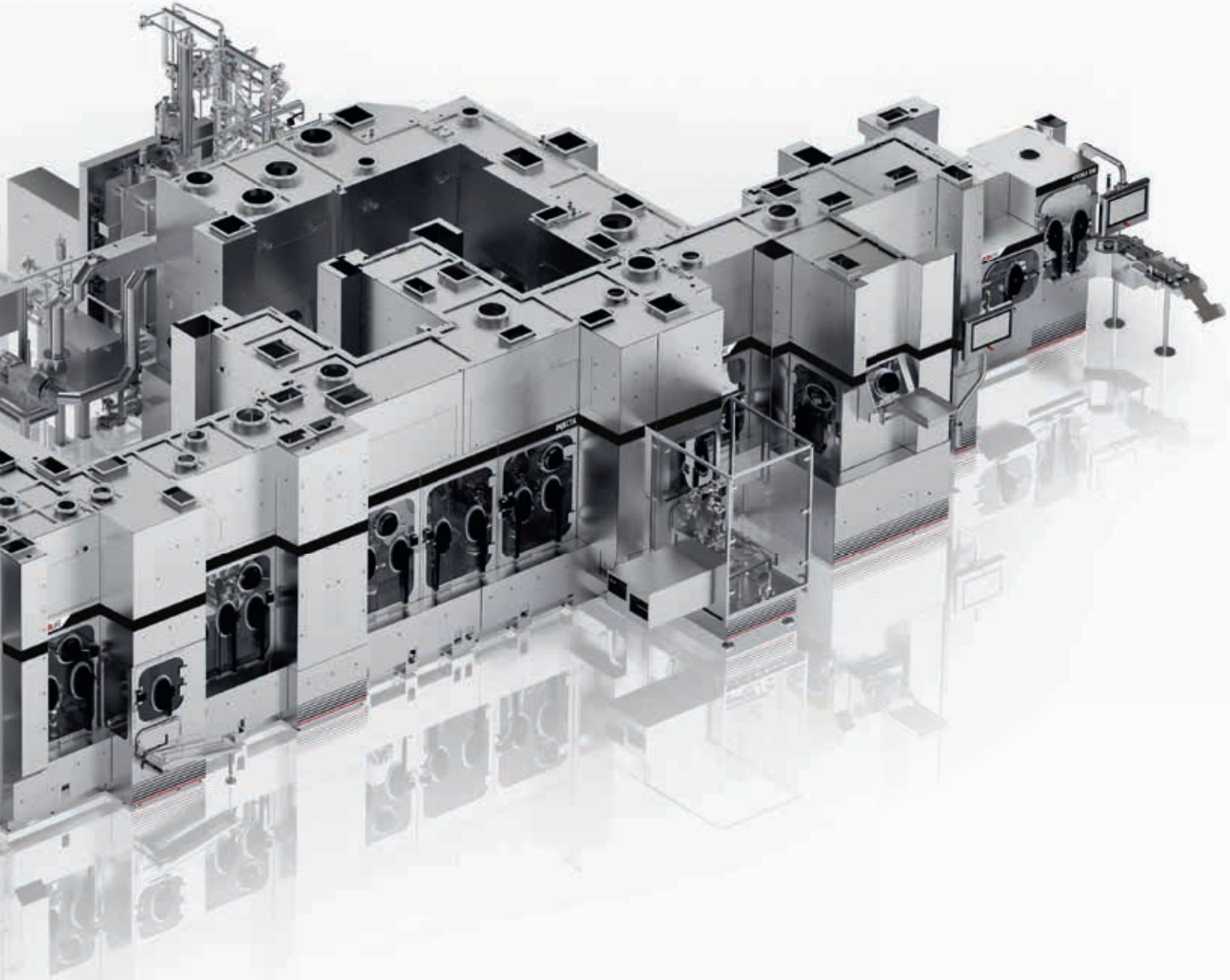
INJECTA 36 is the world's most efficient, high-speed processing solution for RTU components, especially syringes and cartridges, using the very latest robotic handling technologies, designed specifically for an aseptic environment.

Broadening IMA Life's innovative fill-finish concept with a high-volume version able to handle up to 36,000 nested syringes/hour, INJECTA 36 increases production capacity without compromising any of the concept's key characteristics.

The same processing accuracy is maintained with statistical weight control or 100% IPC for up to 6,500 pcs/hr, and satisfies the growing need to accelerate the time to market of vaccines and key pharmaceuticals.

INJECTA 36 can be equipped with a plunger presence check to allow the manual rejection of non- conformities, and performs automatic, robotic weight cell calibration. In the case of CIP SIP, the machine is equipped with automatic insertion of filling nozzles.





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IMA LIFE division
marketing.life.it@ima.it • ima.it/pharma/Injecta
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