

# MEDICAL DEVICES ASSEMBLY SOLUTIONS





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# IMA AUTOMATION YOUR STRATEGIC PARTNER

IMA AUTOMATION DESIGNS AND MANUFACTURES ADVANCED TECHNOLOGY SOLUTIONS FOR ASSEMBLING COMPONENTS TO BE USED IN DIFFERENT FIELDS OF AUTOMATION, SUCH AS THE PHARMACEUTICAL AND DIAGNOSTIC INDUSTRIES, AS WELL AS FOR THE VISION CARE MARKET.

WE DEVELOP ASSEMBLY SOLUTIONS FOR THE FOLLOWING PRODUCTS:

- INHALERS
- INJECTION SYSTEMS
- DIAGNOSTIC DEVICES
- INFUSION PRODUCTS
- OPHTHALMIC PRODUCTS



# FOR MEDICAL DEVICE ASSEMBLY

Each device has its own unique challenges. With a range of standard platforms, linear and rotary, along with indexing and continuous motion assembly capabilities at our disposal, we are able to optimize the design to suit the individual needs of the assembly process, taking into account production requirements and at the same time optimising the available floor space in your clean room.



Inhalers



Injection systems



Diagnostic devices



Contact lenses



Infusion products

# INHALERS



## INHALER ASSEMBLY

Our company's knowledge and experience inhaler assembly is unrivaled. We offer a highly versatile inhaler assembly line, with a flexible dedicated platform and the possibility to choose between Automatic or Semi-Automatic running mode.

100% Weight check, in addition all of our platforms are easy to clean and made according to the highest standards for reduced footprints, allowing Inhalers to be manufactured efficiently, reliably and cost-effectively.



Ageing population and record levels of air pollution are high-risk factors for the development of conditions such as Asthma and COPD. Medical research aims to tackle this issue, commercializing new high-tech solutions that can considerably improve patients' quality of life. While Metered-Dose Inhalers are widely popular and frequently used, Dry-Powder Inhalers are a less known and more complex subject. Both of these, together with dose counters, are at the center of our quest for the perfect medical device platform. IMA Automation's expertise ranges from pre-assembly phases to the product's final assembly stage, including drug manipulation and all of the challenges that come with the developing and manufacturing of such products. Turnkey solutions are also part of our comprehensive offer, including packaging equipment if necessary.



## MDI

Our Metered-Dose Inhaler assembly solutions are available for both plastic and metal parts; including springs and the final assembly inclusive of aluminum canister.



## DPI

Our Dry Powder Inhaler line ensures the best design and performances, thanks to the platforms' workflow inclusive of powder dosing, capping, up-to-vision packaging, orientation and welding.



## DOSE COUNTER

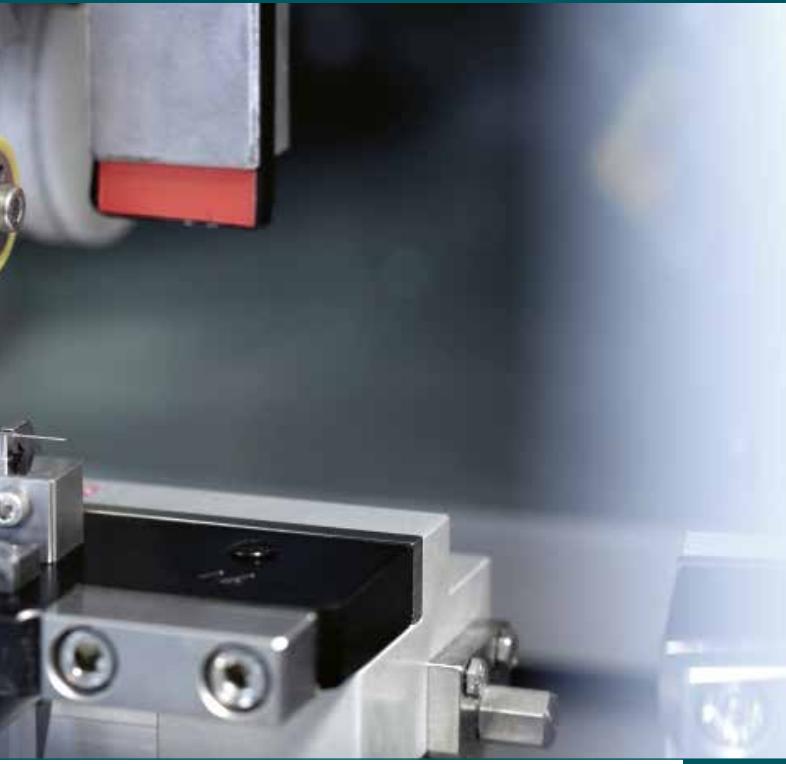
Dose Counter assembly is also part of our offer thanks to our reliable equipment, also providing dial printing, arming and functional checks.

# INJECTION SYSTEMS



## INJECTION SYSTEM ASSEMBLY

IMA Automation is deeply experienced in the assembly of pens and auto-injectors: from automatic denesting systems for pre-filled syringes to dosing mechanisms, in addition to power-pack assembly and final product assembly including drug manipulation. Turnkey solutions are also offered, together with packaging equipment, if required.



Injection systems allow for drugs to be effortlessly injected or even self-injected; it's a precise and effective way to administrate medications.

There are many treatments that can benefit from the use of injection systems other than diabetes care, especially when dealing with biosimilar products.



## PEN SYSTEMS (PENS, AUTO-INJECTORS)

Robust, accurate and standardized solutions for both pre & final assembly of pens and auto-injectors. Includes assembly & test of electronic components in latest generation devices.

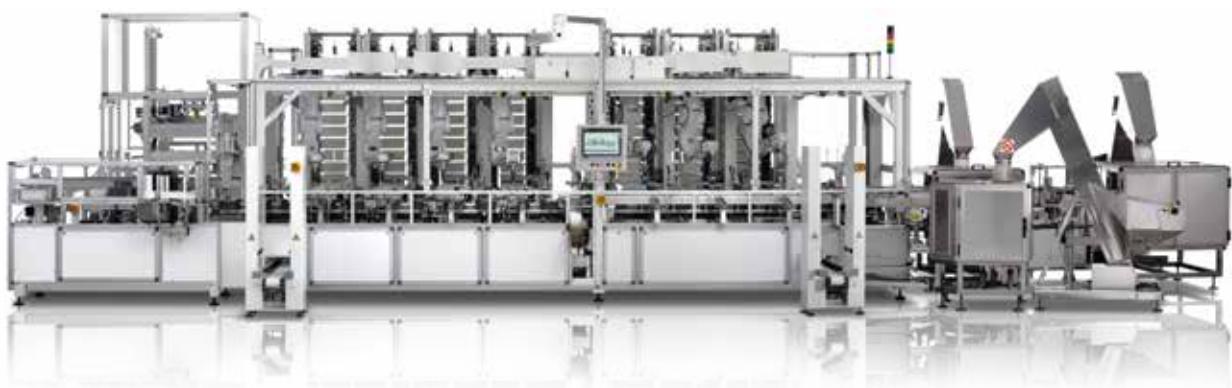
## SYRINGES

Assembly and marking systems for traditional syringes. Pre and final assembly solutions for safety devices.

## PATCH PUMP

Complex, flexible and precise assembly systems for patch pumps, including micro-assembly, needle bending and PCB assembly.

# DIAGNOSTIC DEVICES



## DIAGNOSTIC CARTRIDGE ASSEMBLY

Our assembly units are made of linear transfer platforms capable of loading and assembling diagnostic cartridges. Both square and round vials may be loaded individually, through buffers of 12 trays each. All of the cartridges are then unloaded and stored in a dedicated rack or diverted to downstream equipment, according to your needs. Our camera inspection system ensures everything is impeccable, from codes, to liquid levels and color, while our label printing device guarantees a product distinguishable by code and lot handling.



Automation has reached impressive results and become a predominant force in the field of blood exams and laboratory analysis.

IMA Automation has led the revolution by providing machinery for the assembly of reagent cartridges needed by various diagnostic devices.



## DIAGNOSTIC DEVICES

Providing flexible and highly efficient production systems for diagnostic and POC (Point Of Care) processing. From initial spotting processes to final packaging.



# OPHTHALMIC PRODUCTS



## CONTACT LENS ASSEMBLY

Our contact lens processing equipment has 5 integrated modules dedicated to different tasks such as: lens inspection, lens hydration, packaging, sealing, laser marking and the automatic inspection of packaging materials. Lot traceability has also been a primary focus in designing our machinery according to the highest medical industry standards.



Thanks to the study and optimization of existing platforms, IMA Automation has developed fully customized process lines for the Handling of contact lens and blister packaging. Lines are designed to implement robotizing, filling, laser and inspection systems, in order to duly execute lens releasing, washing and packaging operations. This also ensures high versatility in the handling of different sizes of lenses, thanks to quick mechanical & control changeovers.



## CONTACT LENSES

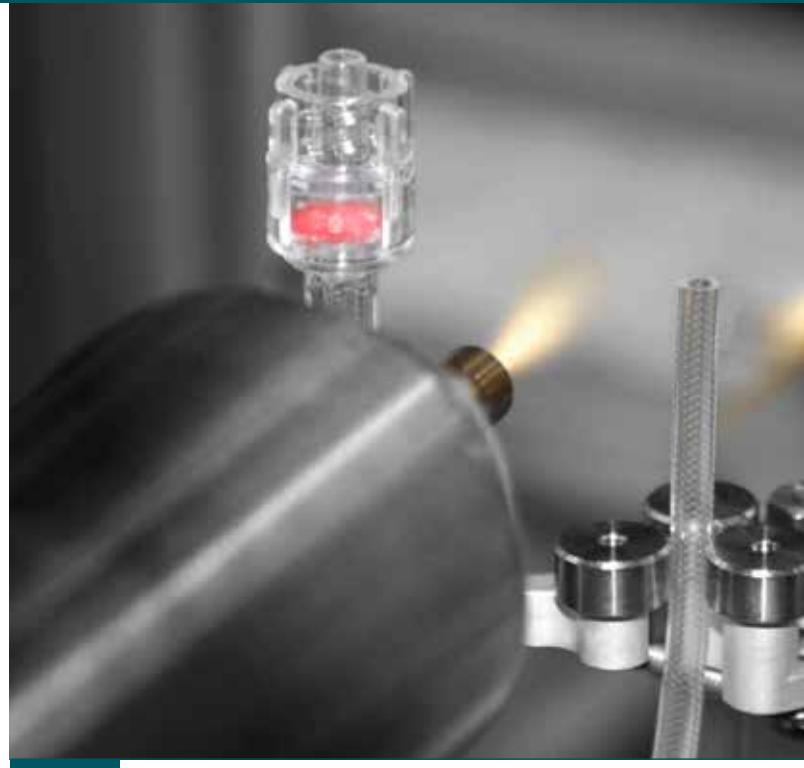
Designing space saving and high performance contact lens manufacturing lines, IMA Automation provides total control of the contact lens manufacturing process for coloured, daily or semi-permanent contact lenses.

## LENS INSERTER

Complete assembly and functional testing of lens inserters, lens processing and final device with all necessary coatings in place.

# INFUSION PRODUCTS

IMA AUTOMATION INFUSION SET SYSTEMS ARE ABLE OF ASSEMBLING MULTIPLE VARIANTS OF INFUSION SET. DEPENDING ON PRODUCT COMPLEXITY, MACHINE OUTPUTS UP TO 2300 INFUSION SETS PER HOUR ARE POSSIBLE.



## COILING MODULE

Tube coiling and handling system with 25 parts per minute output. Consisting of two rotary dial tables, a twenty-four and a twelve position one, and one antry pick & place for packaging unload.



## INFUSION PRODUCTS

IMA Automation can provide production solutions for IV catheter, Urinary Catheter as well as infusion port and drip chamber assembly.

# ASSEMBLY PLATFORMS AND KEY PROCESSES

## KEY PROCESSES

Developing a new medical device can be challenging. Your assembly processes have been tested manually. However, taking this to the next stage through automation poses a number of risks.

In this early stage of the medical device development our competent team of process engineers provide needed support in terms of proof of principles as well as design for manufacturing studies. We support you in designing your device from early stage development right through to high speed fully automated assembly lines to find the optimal solution. Our de-risking approach from an early stage eliminates costly redesigns and delays later in the product's transition from low speed to high speed automation.



### PILOT MED LOW VOLUME

Outstanding flexibility for cost-effective assembly operations.

An entry point for assembly automation, the PILOT MED Low Volume platform is the highly flexible answer for customers seeking efficiency and cost-effective assembly operations, with the chance to merge manual, semi and fully automatic work stations. The key reason behind this platform's ultimate flexibility is its ability to integrate manual work stations and/or feeding positions, as well as semi and/or fully automatic stations. Tooling can be manually operated, cam-driven, pneumatic and/or servo-controlled, and can operate at speeds identical to those required for high-volume production, thus transferring de-risked validated technology directly to high-speed lines.

- PILOT MED



### IQ FLEX HIGH VOLUME

An innovative, modular approach for automation.

iQ FLEX is the latest modular platform for the automation industry, based on pallet transfer technology. It provides today's future-focused solutions and meets the need for speed and flexibility in manufacturing.

Intelligent conveyor technology allows this platform to be expanded, adding or removing process stations as the product evolves, thus adapting to product and volume changes. This solution is the next step in motion control, replacing mechanics with simple, effective software profiles, redefining speed and flexibility in automation.

- IQ FLEX



Each assembly system consists of a platform that forms the basis for a made-to-measure solution to satisfy specific needs. Stations and assembly technologies are added in accordance with customer requirements.

All technological platforms designed by IMA Automation are a step up from the most advanced electronic and mechanical automation technologies available on the market. This is why we call our technology "Advanced Assembly Technology".



### ROTARY MED HIGH VOLUME

Unending Assembly Opportunities.

The ROTARY MED machine is comprised of a servo-driven dial table unit designed to allow complete flexibility of the system configuration, including servo-controlled pick and place mechanisms.

Assembly of between 2 and 5 components can be achieved through basic machine configuration. The unit can be merged with a second one by adding a specific transfer module which allows the pre-assembled parts to be transferred from one module to the other. On board, the electrical cabinet enables fast dismantling and installation of the system.

- ROTARY MED
- EVO FLEX ROTARY



### LINEAR MED HIGH VOLUME

Smooth assembly, fully compliant, for medical devices.

A flexible platform for countless assembly requirements, the Linear MED indexing platform is a modular concept conceived for medical device assembly, compliant with the strictest norms and manufacturing standards.

With its unique, modular design enabling easy fixture access from 3 sides, the Linear MED indexing platform is based on one-metre modules, allowing the chassis to be set up with 2, 3 or 4 sections. Reconfigurable and easy to maintain, the assembly platform complies with all applicable GMP and GAMP5 norms, as well as manufacturing standards for ISO 7 clean room environments.

- LINEAR MED

# TRAYS & COMPONENTS HANDLING

IMA BFB Division develops robotized solutions for the smooth handling of different devices, such as medical inhalers, injection pens or similar sub-assemblies.

Here's a better look at the concepts behind our products and processes:

- Robotized de-palletization system for different devices and components, positioned in heat-formed plastic trays. All the depalletizers have safe and easy access, while incoming and outgoing expulsion is managed by a controlled-speed conveyor system.
- Robotized palletization system, capable of picking up devices from pucks and gently placing them into heat-formed plastic trays. The stacks of empty/filled trays are completely accessible to operators.



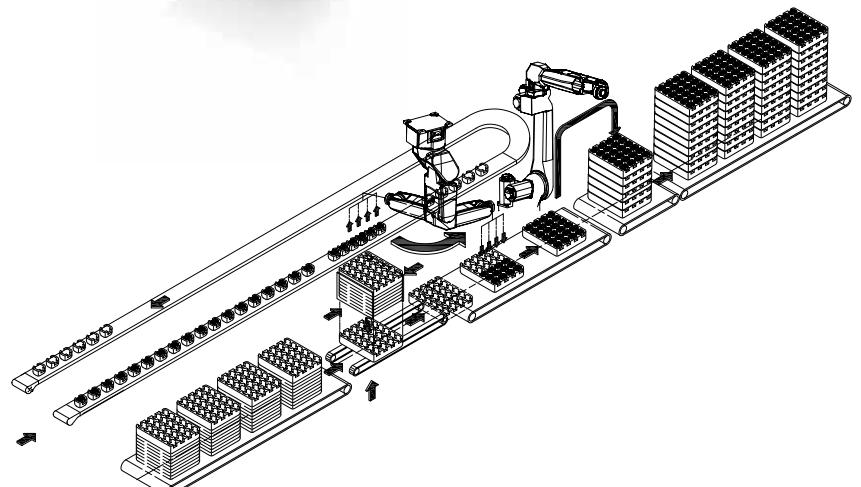
## TLS TRAY LOADING SYSTEM

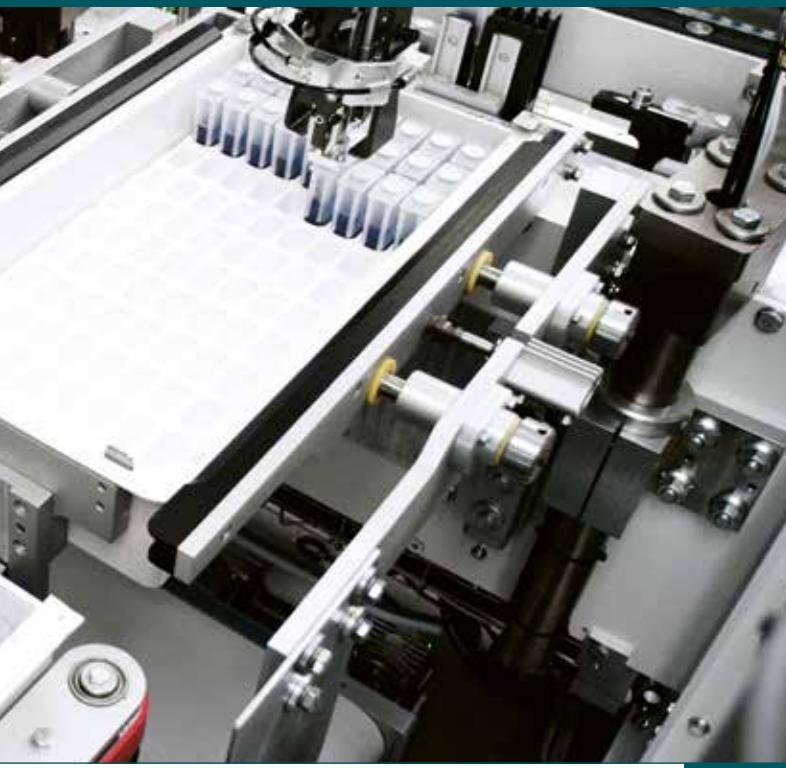
Robotized Tray Loading System which fits for different devices and components that are to be positioned in heat-formed trays. The devices are sent from assembly machines into pucks, and are then directly picked by a robot and carefully placed in empty trays. Empty tray magazines can be designed according to the customer's requirements of high or medium capacity.

Robot grippers are tailor-made, according to the objects they need to handle. The grippers' materials are carefully selected so to avoid damaging the device.

Filled trays are then palletized by another robot and placed in the exit magazine where all stacks are accumulated for the operator to handle. A sampling conveyor is included in the equipment and can be activated when needed.

The same concept can be inverted, and TLSs transformed into de-palletizers, simply by using them backwards: starting with stacks of filled trays, de-nesting them, and emptying them one by one, robotically placing devices into incoming empty pucks.





ALL THESE SOLUTIONS ARE BASED ON HIGH MODULARITY, IN ORDER TO BE ADAPTED TO ALL POSSIBLE CUSTOMER SPACE-RELATED NEEDS.

- ONE-STOP SUPPLIER
- SMART LAYOUT MANAGEMENT
- FLEXIBILITY
- TAILOR-MADE AND CUSTOMIZED SOLUTIONS.

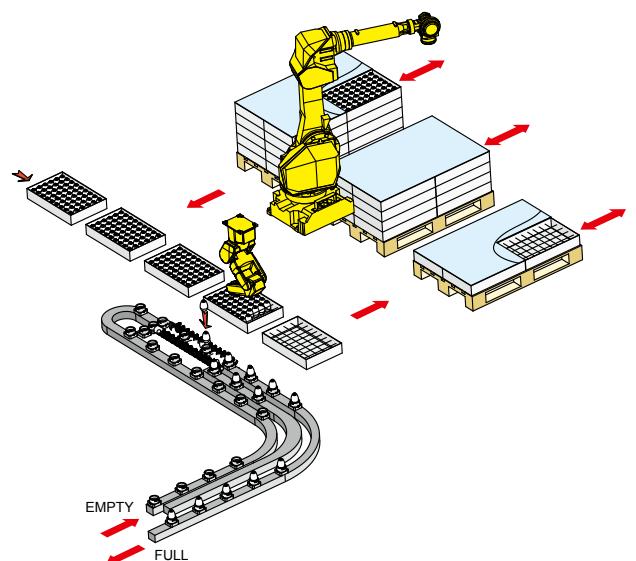


## DEPACKER DEPALLETIZING SYSTEM

Robotized de-palletization system for different devices and components that are to be positioned in heat-formed trays.

All the de-palletizers have safe and easy access, while incoming and outgoing expulsion is managed by a controlled-speed conveyor system. De-palletization is managed by an integrated vision system able to recognize the trays' position and the overlapping/direction of both trays and devices. During the transfer, the devices can be precisely angled, rotated 90° and adjusted up to 45°.

The system is based on 2 robots: the first one picks filled trays from pallets, or re-palletizes empty trays into final pallets; the second one is responsible for the emptying of incoming trays from devices, placing the devices into incoming pucks or a dedicated exit conveyor.



# TURNKEY SOLUTIONS



## SOLID DOSE PROCESSING

IMA's experience gained in the field of solid dose processing and manufacturing, combined with the constant commitment to innovation, makes IMA Active division a leading supplier able to find the most suitable solution to your requirements.

With thousands of installations worldwide for dispensing, handling, granulation, tableting, capsule filling and coating of category IV and V products, IMA Active is able to supply a wide range of solutions to work with HAPI (Highly Active Pharmaceutical Ingredients).

## ASEPTIC PROCESSING AND FREEZE DRYING SOLUTIONS

IMA Life division, leader in the field of aseptic processing and filling technology, can be considered a true partner to the pharmaceutical industry, offering a wide range of technologically advanced machines. IMA Life's product range includes blowing and washing equipment, depyrogenating tunnels, liquid and powder filling machines, labelling machines, isolation systems and freeze dryers for industrial, pilot and laboratory applications which can be combined together with automated loading and unloading systems.

## BLISTER AND TRAY PACKAGING

IMA Safe division designs and realizes a complete range of primary and secondary packaging machines for the pharmaceutical, nutraceutical and cosmetic industries. Blister machines, cartoners, counting machines and tube fillers are the four kinds of products powered by IMA Safe, which offers complete tailor-made lines.

## END-OF-LINE SOLUTIONS

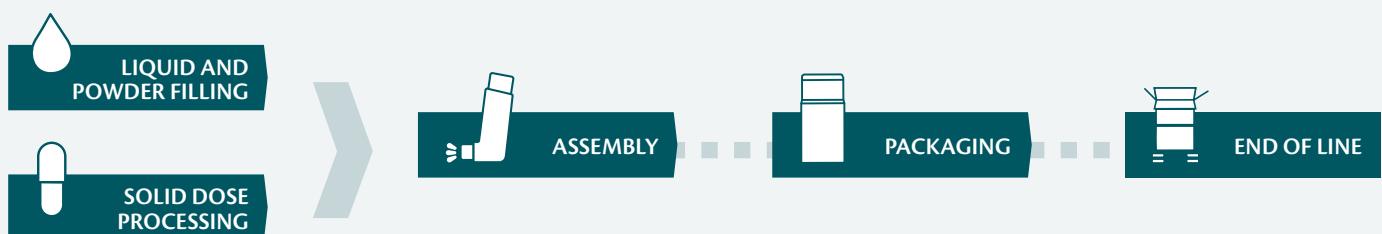
IMA BFB has been designing and manufacturing end-of-line equipment and today it has the most comprehensive range of secondary packaging machines currently available on the market. The machine range includes shrink-wrapping, overwrapping, tray packing, case packing and palletizing machines.



IMA AUTOMATION HUB IS A PERFECT COMPLEMENT TO THE CONSOLIDATED PACKAGING EXPERTISE OF THE IMA GROUP, ALLOWING THE SHARING OF CUSTOMERS INSTEAD OF CLIENTS AND, MOST IMPORTANTLY, OF ROLES IN PROVIDING TECHNOLOGICAL SOLUTIONS AND INTEGRATED LINES.



Example of an IMA integrated line



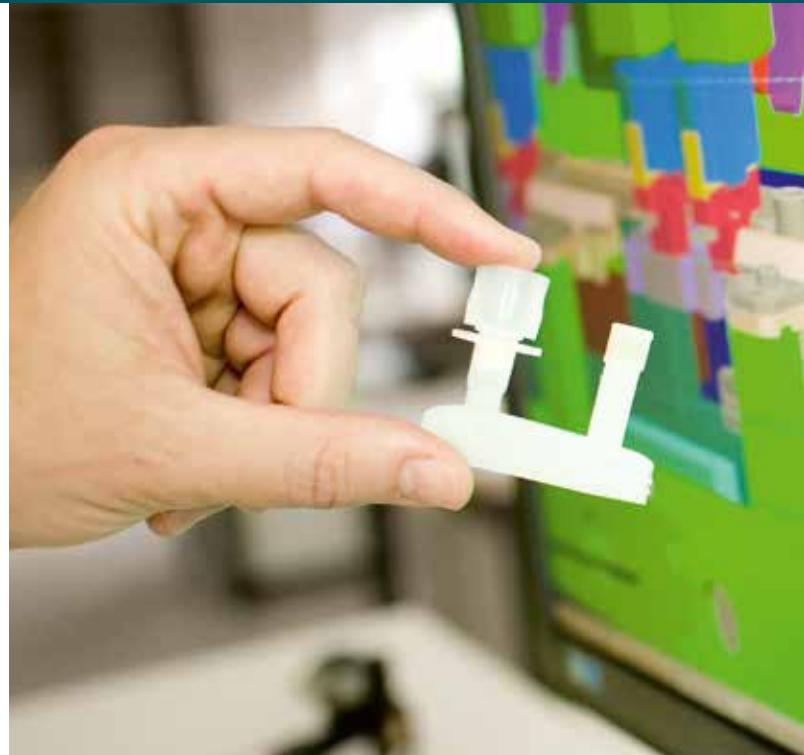
# SCIENCE-BASED MANUFACTURING PROCESSES

IN ADDITION TO DESIGNING AND MANUFACTURING INNOVATIVE AND EFFICIENT MACHINES, IMA MEDTECH HAS DEVELOPED A FULLY COMPREHENSIVE PROCESS OPTIMIZATION SERVICE.

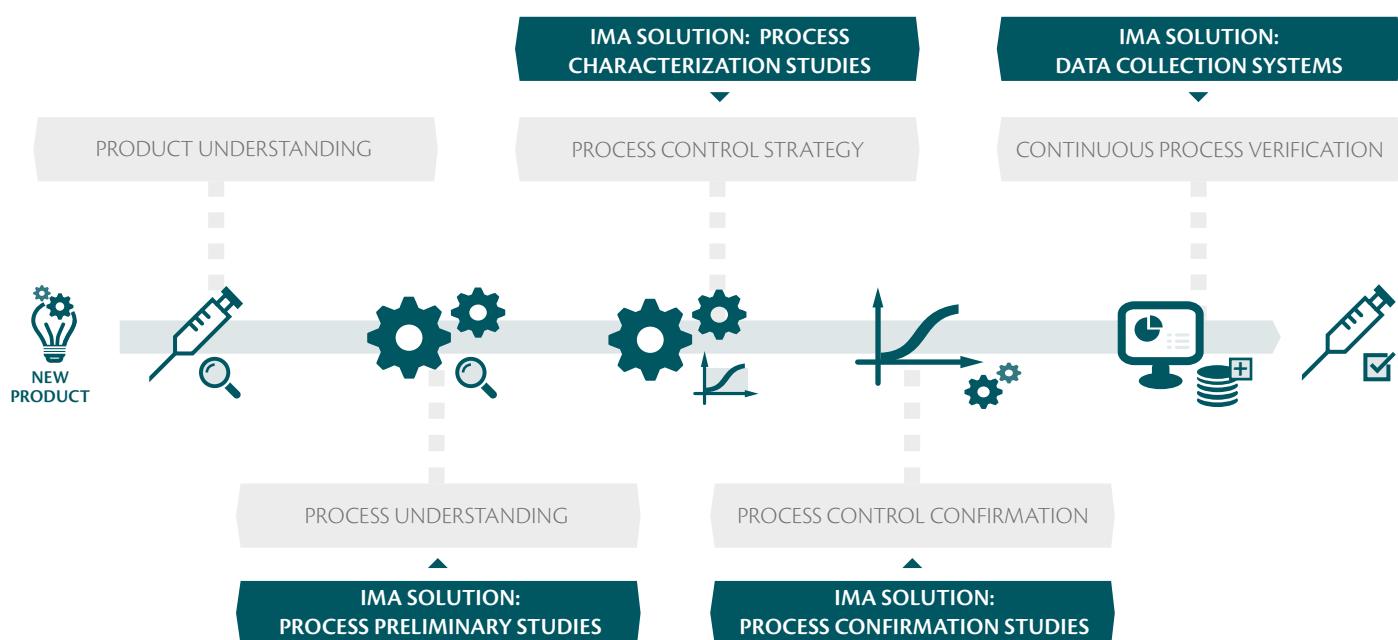
With its experienced and highly skilled engineers, this service is specialized on measurement processes and complex mechatronics processes.

Our goal is to develop with you a **comprehensive manufacturing science** of your medical device by following principles of Quality by Design (QbD).

Together we understand the impact of process variability on your device and put in process controls in place to meet your expected device quality.



IMA MEDTECH HAS SUPPORT SOLUTIONS FOR EACH STEP OF YOUR DEVICE DEVELOPMENT FROM PROCESS UNDERSTANDING TO OPERATION.



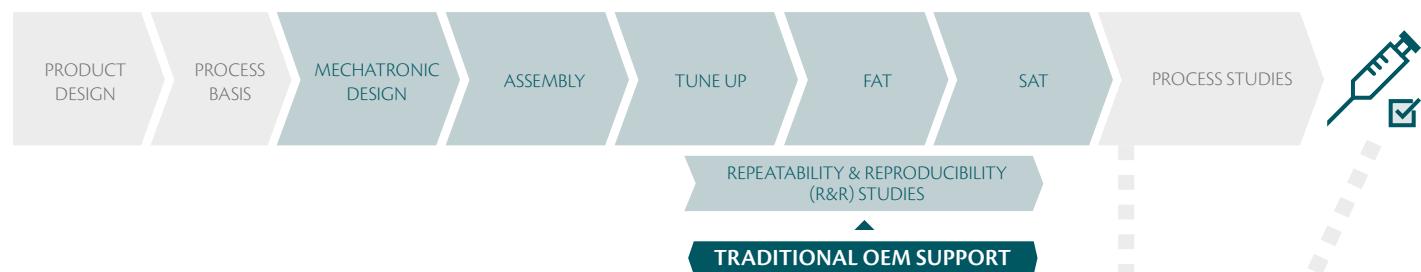


## IMA MEDTECH SUPPORT FOR **QUALITY BY DESIGN (QbD)** APPROACH MEANS:

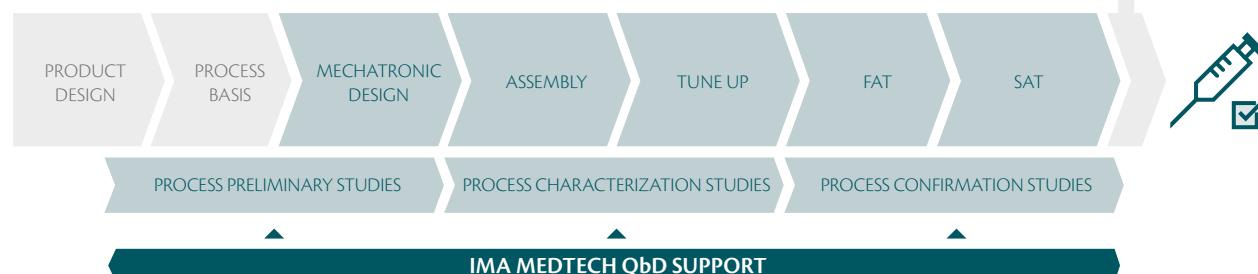
- BETTER PROCESS UNDERSTANDING
- BETTER EXPERTISE FOR YOUR ENGINEERS
- REDUCED TIME TO MARKET
- PROCESS ROBUSTNESS AND MASTERING IN OPERATION

**YOUR PROCESS STUDIES ARE ANTICIPATED AND CONDUCTED DURING THE EQUIPMENT REALIZATION WITH OUR ENGINEERS TO OPTIMIZE YOUR OVERALL TIME TO MARKET.**

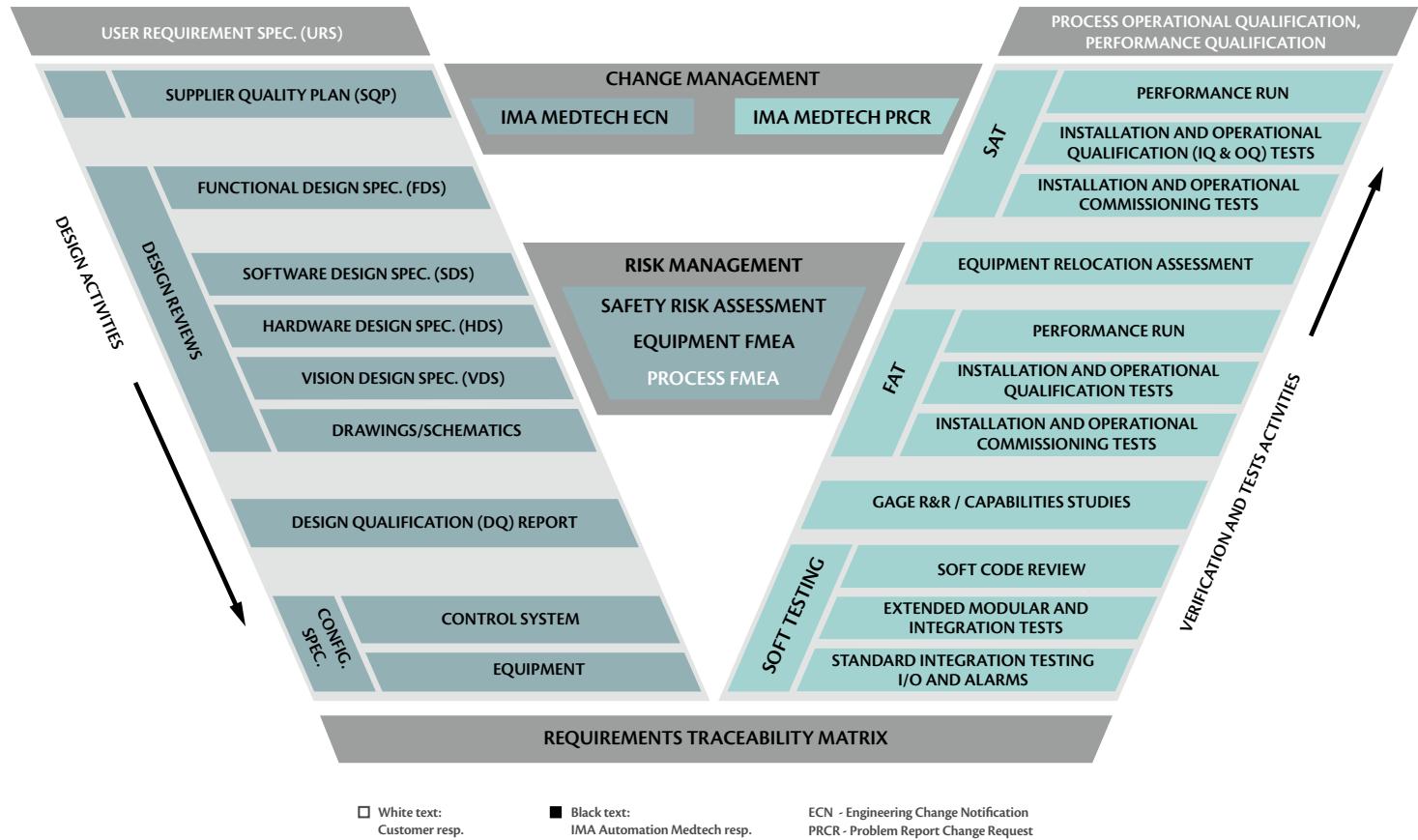
TRADITIONAL APPROACH:



IMA MEDTECH PROCESS ENGINEERING APPROACH:



# OUR SERVICES



## VALIDATION TAILORED PACKAGE

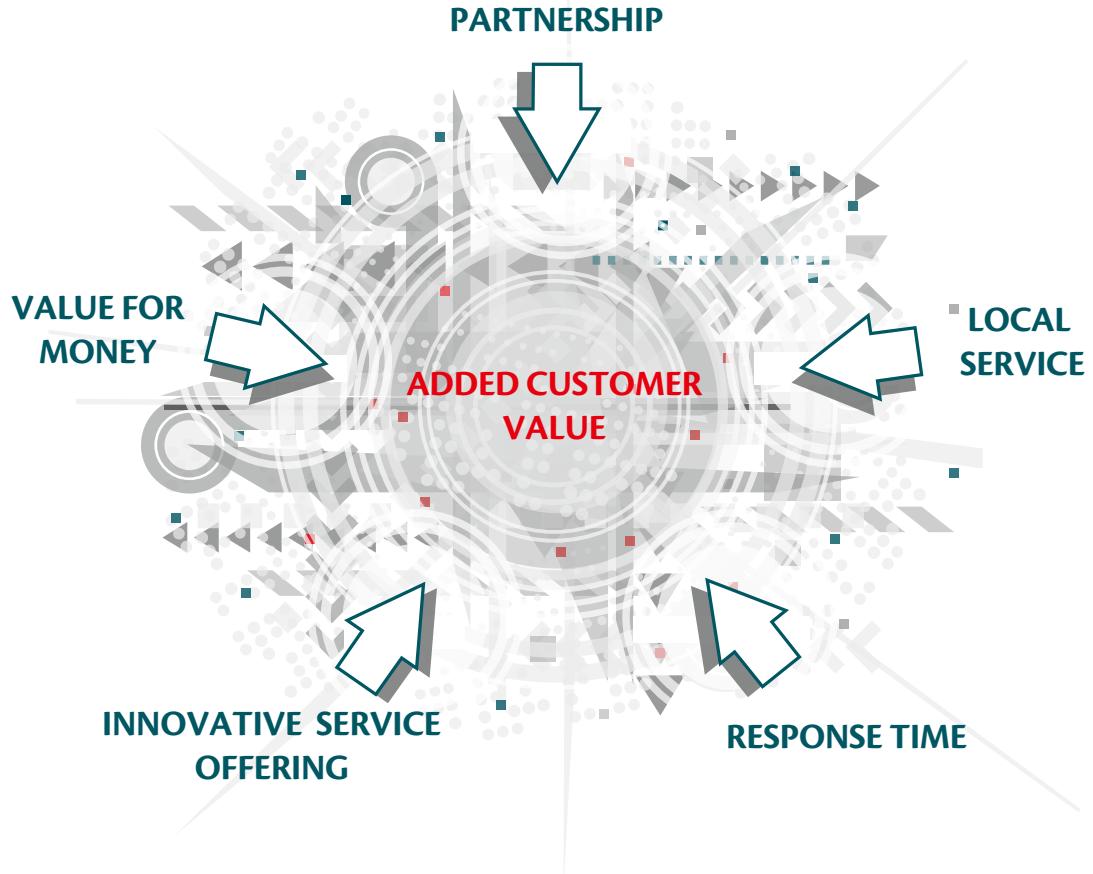
Validation is a must-do and being aware of the demanding requirements of the medical industry ensures the safety, purity and effectiveness of your medical device and enables you to complete all the necessary documentation requirements.

Our **flexible modular approach**, fully compatible with the **GAMP 5** methodology, is carefully designed to fit each customer validation strategy and specific needs, minimizing time while efficiently placing **"your device to market"**.

## AIM FOR PROJECT MANAGEMENT EXCELLENCE

IMA Automation Medtech based its project monitoring approach on the **Earn Value Management (EVM)** and **Critical Path Management (CPM)** methods. Our system delivers accurate and reliable information on every project in order to reach our four key goals:

- Compliance and Safety
- Delivery Time & Cost Control
- Risk Mitigation
- Equipment Robustness



## INTEGRATED SERVICE SOLUTIONS CUSTOMER SERVICE

The lifespan of a machine designed by IMA Automation Medtech and its customer, regardless of its complexity, is marked by numerous key stages that we share together. The resulting production operation is the perfect expression of a **flawless partnership**. We deeply commit to each and every task we undertake. To us, it is not just about the development and manufacturing of our products: our efforts continue as we strive to provide the best support and assistance, including delivery and **customer service**, to swiftly meet all your needs and requests.

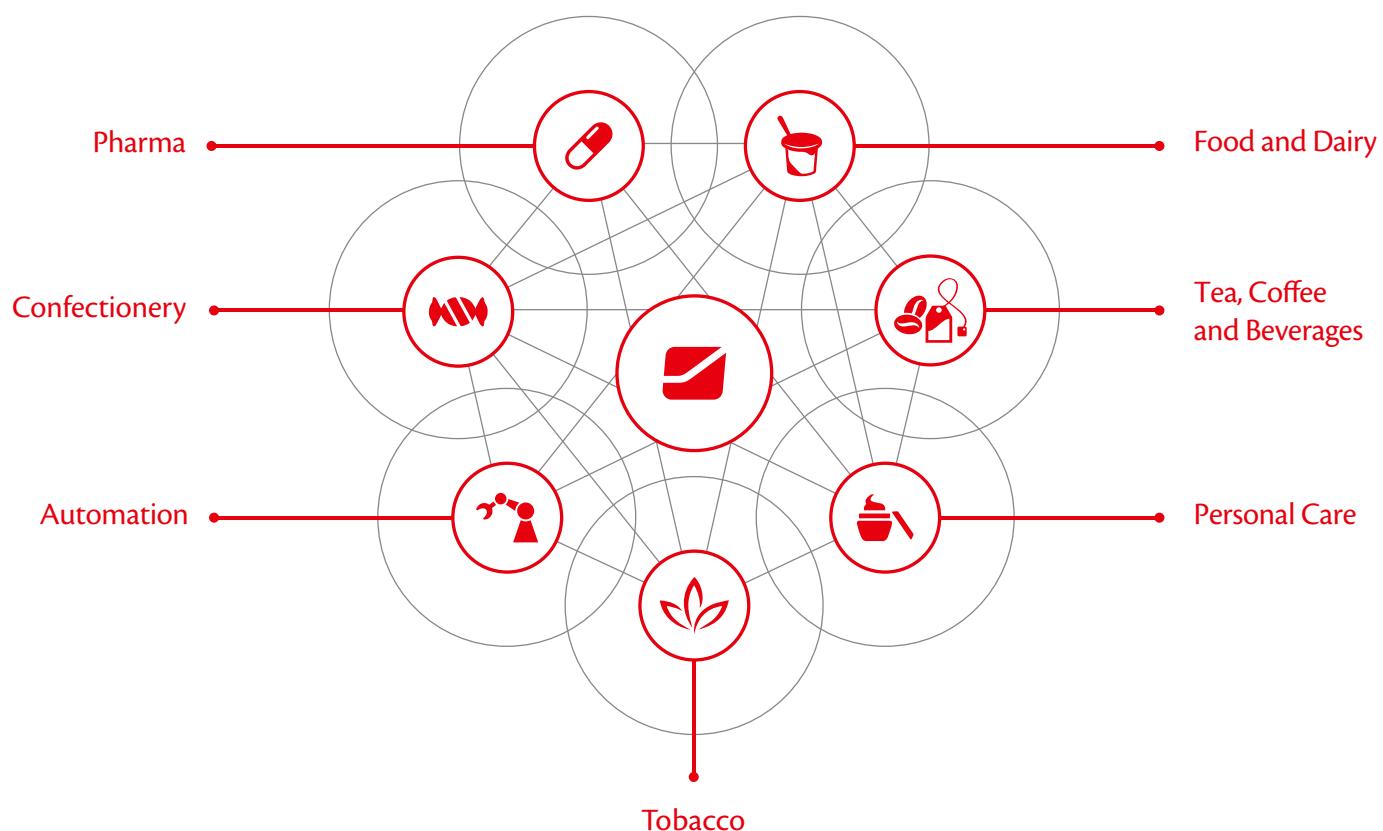
While working with you, we will share all our knowledge, acquired through **years of experience**, in order to increase and improve your **production output** while enhancing the performance of your new equipment.

Witness how our passion and attention to detail results in **better products**, greater satisfaction and **reduced costs**, thanks to our skillful specialists.

# IMA GROUP VAST EXPERIENCE IN ASSEMBLY AND

IMA GROUP IS WORLD LEADER IN THE DESIGN AND MANUFACTURE OF AUTOMATIC MACHINERY FOR THE PACKAGING OF PHARMACEUTICALS, COSMETICS, FOOD, TEA AND COFFEE, AS WELL AS FOR THE ASSEMBLY OF COMPONENTS TO BE USED IN ALL FIELDS OF THE AUTOMATION INDUSTRY, SUCH AS MEDICAL DEVICES AND CAPS & CLOSURES.

IMA manufactures equipment in 43 production plants, and has a worldwide after sales service and a sales network covering more than 80 countries.



# PACKAGING TECHNOLOGIES



## IMA AUTOMATION

### THE SPECIALISTS IN ASSEMBLY SOLUTIONS

IMA has a recently established business hub composed of leading companies in the automation industry, dedicated to offering its customers a wide range of technological solutions for assembling of components to be used in several fields of the automation industry. The companies that make up the IMA Automation world have earned their success being driven by "passion" for their work and by the great dedication of their technical and commercial teams in pursuing their ultimate objective of fully satisfying their customers.

Many years of experience in the industry, designing and building assembly systems for a great variety of plastic components for various industries, have helped our companies develop top-of-the-line technical skills, earning excellent market reputations and positioning themselves as leaders among those offering specialized technological solutions.

The newly established Automation hub is also a perfect complement to the already consolidated IMA Packaging line, allowing the sharing of customers and, most importantly, of roles in providing technological solutions.



[www.ima.it](http://www.ima.it)

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