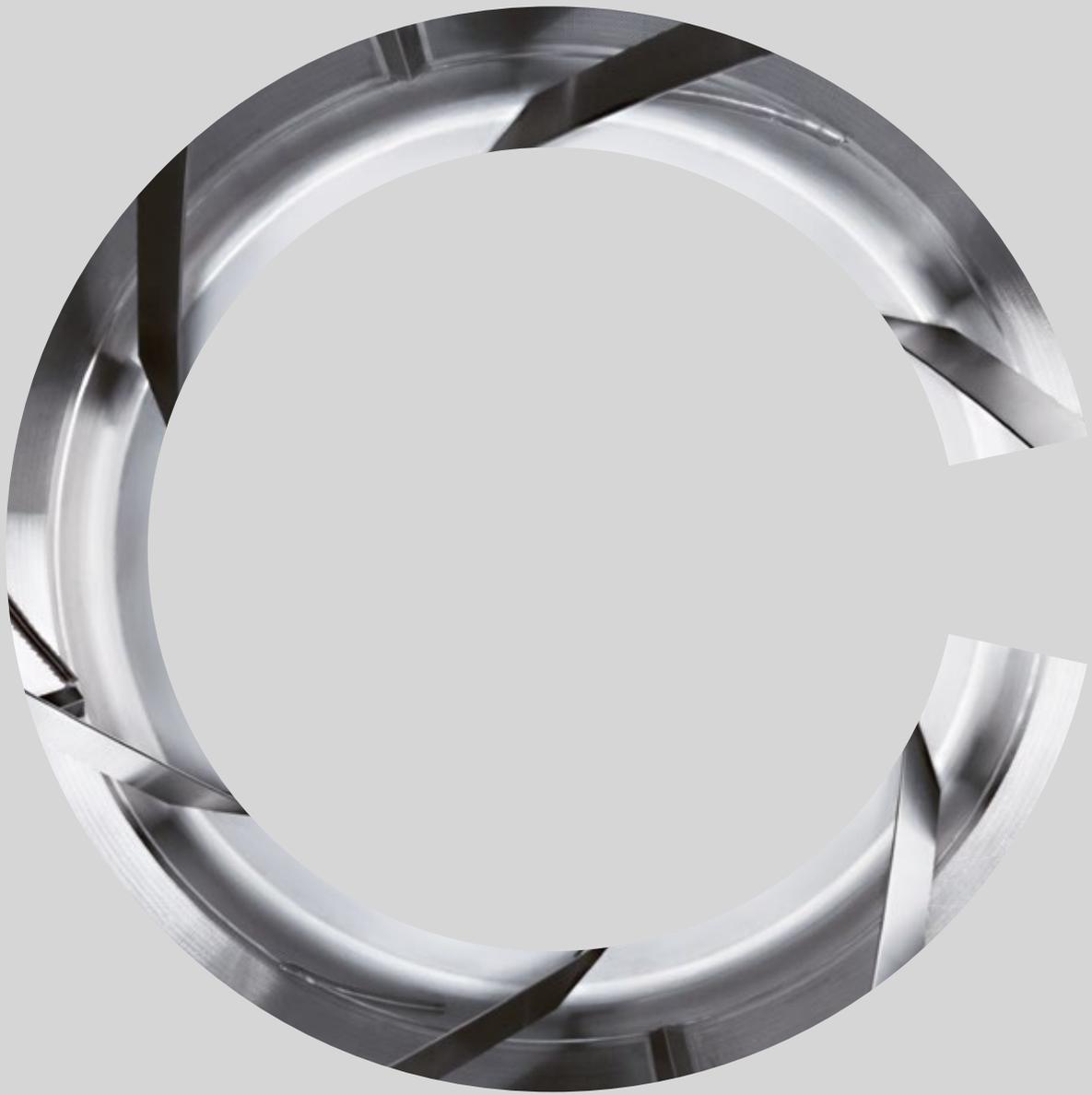




THE COATING BOOK





COATING
SYSTEMS





COATING SYSTEMS

A SHIELD OF QUALITY

PIONEERING EXCELLENCE IN TABLET COATING TECHNOLOGY

For more than six decades, Thomas Engineering has been at the forefront of innovation in the pharmaceutical processing industry. Since our establishment in 1959, we have introduced groundbreaking technologies that set new standards for efficiency, quality, and performance in tablet coating.

HISTORICAL LEGACY OF INNOVATION

Thomas Engineering began its rich history of pioneering advancements in 1968 with the development of Pharma's first fully perforated tablet coating drum. This innovation, known as the ACCELA COTA, significantly improved coating efficiency and film quality, setting a new industry standard. The perforated drum technology also created an entirely new industry, specializing in development and commercial manufacture of pre-formulated aqueous film coating materials.

VISION AND BREAKTHROUGH TECHNOLOGIES

In 1997, we further revolutionized the industry with the introduction of our CTC, the first Continuous Tablet Coater designed specifically for pharmaceutical applications. This advancement provided unmatched efficiency and consistency in the coating process, with features and enhancements to produce tablets of better quality than many batch coating processes.

Thomas maintained its presence at the

forefront of pharmaceutical innovation, introducing the revolutionary Thomas Spray Bar technology to the market in 2002.

This cutting-edge design features internal porting for both air and liquid channels, eliminating the need for solution and pneumatic lines crossing through the process environment. The advanced spray bar not only enhances GMP but also streamlines cleaning and changeover processes, making it a game-changer for the industry.

Building on these successes, in 2010 we launched the FLEX 500, the first production scale coater with exchangeable drums, offering unprecedented batch size flexibility, process versatility, and reductions in downtime for cleaning, setup, and material handling. This model was quickly followed by several smaller production class models along with the FLEX 100 pilot scale unit and even a benchtop unit for R&D, the FLEX 05.

CREATING OPPORTUNITIES AND PRESERVING VALUE

Our customers find value in their partnership with Thomas, the market leader fully dedicated to tablet coating systems. These customers know their investment extends beyond a system of machinery and controls: they benefit from our expertise and competency resulting from more than sixty years of innovation and field experience with tablet coating systems. The dividend is their assurance that a Thomas coating system will always deliver reliable performance and consistently excellent finished products.

TOTAL QUALITY: IMA APPROACH

MEETING EVERY REQUIREMENT, CONSIDERING EVERY DETAIL.
NOT JUST A BELIEF, BUT QUALITY AT OUR VERY CORE.

QUALITY

- Quality by design (QbD) approach bringing reduced time for quality control and test release.
- Reduced risk of human errors due to high level of automation.

SAFETY

- Coating equipment designed to meet the highest safety requirements and standards.
- Automation and minimal human intervention minimize risks for operators.
- High containment design helps reduce risk of exposure, enhancing safety for operators and potentially lowering needs for PPE.
- Precise controls and process repeatability reduce risk of product deviations, ensuring patient safety.

GMP AND CLEANABILITY

- Thomas coaters are designed to meet strict GMP requirements and guarantee the highest final product quality.
- WIP (Wash-In-Place) systems with full validation support.
- Automatic and optimized washing recipe and water recirculation system to save up to 30% to traditional washing systems.

SUSTAINABILITY

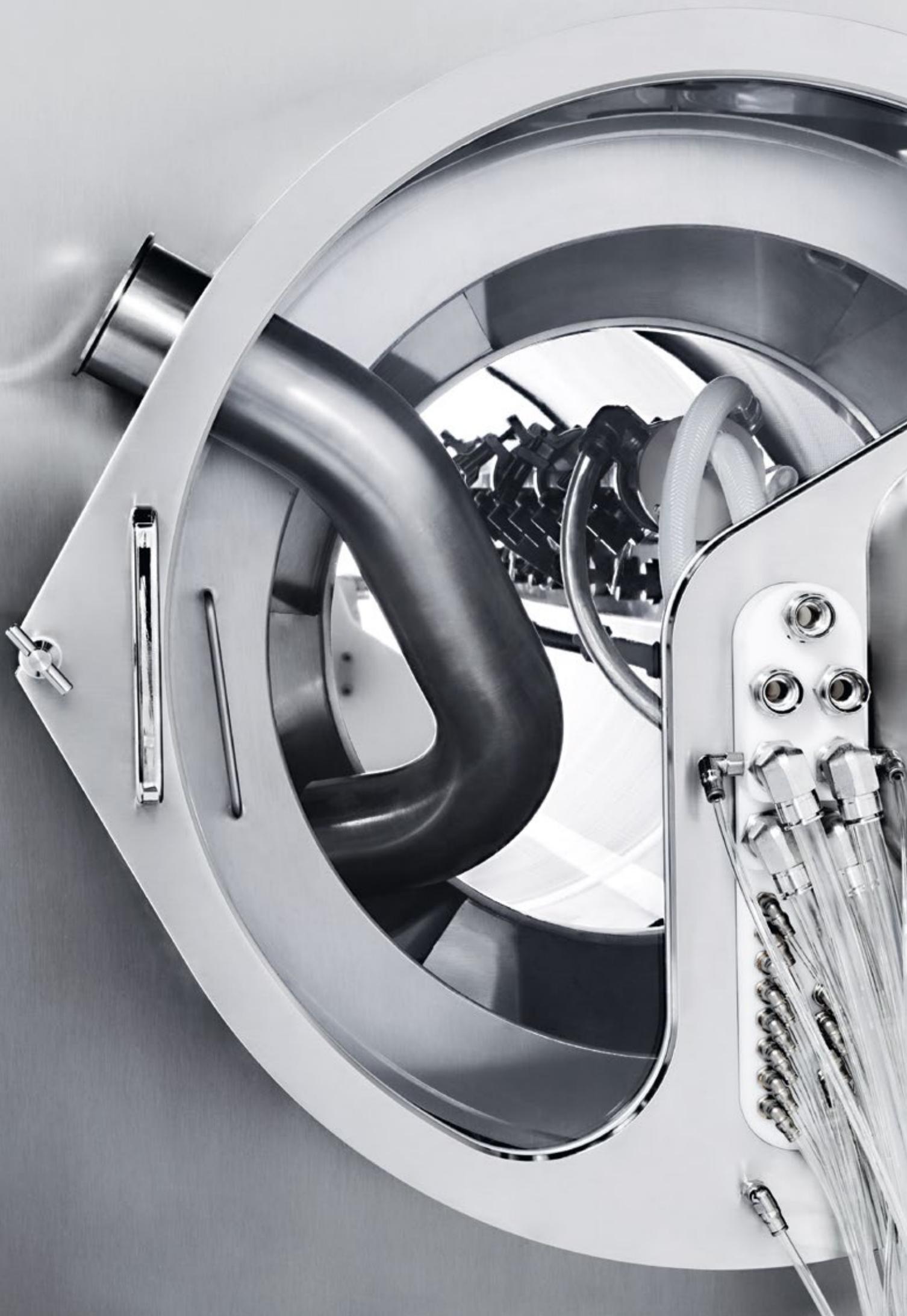
- We are committed to environmental sustainability through sensible design practices and process optimization, aiming to minimize utility consumption.
- Engineering services and support for plant footprint and material handling optimization.
- Thoughtfully designed systems to reduce downtime, supporting timely production and delivery of drug products to market.

PROCESS CONTROL AND SCALE-UP

- Shorter time to market due to quicker product and process development, minimization of process scale-up.
- Optimization of process coating parameters using process modeling tools.
- Fully automatic process control.

PROCESS FLEXIBILITY AND EFFICIENCY

- All core sizes from small pellets to large tablets can be processed.
- Different machine sizes available, from lab scale to large production scale coaters.
- 25%-100% in-drum batch size range.
- Easy switch between different setups.



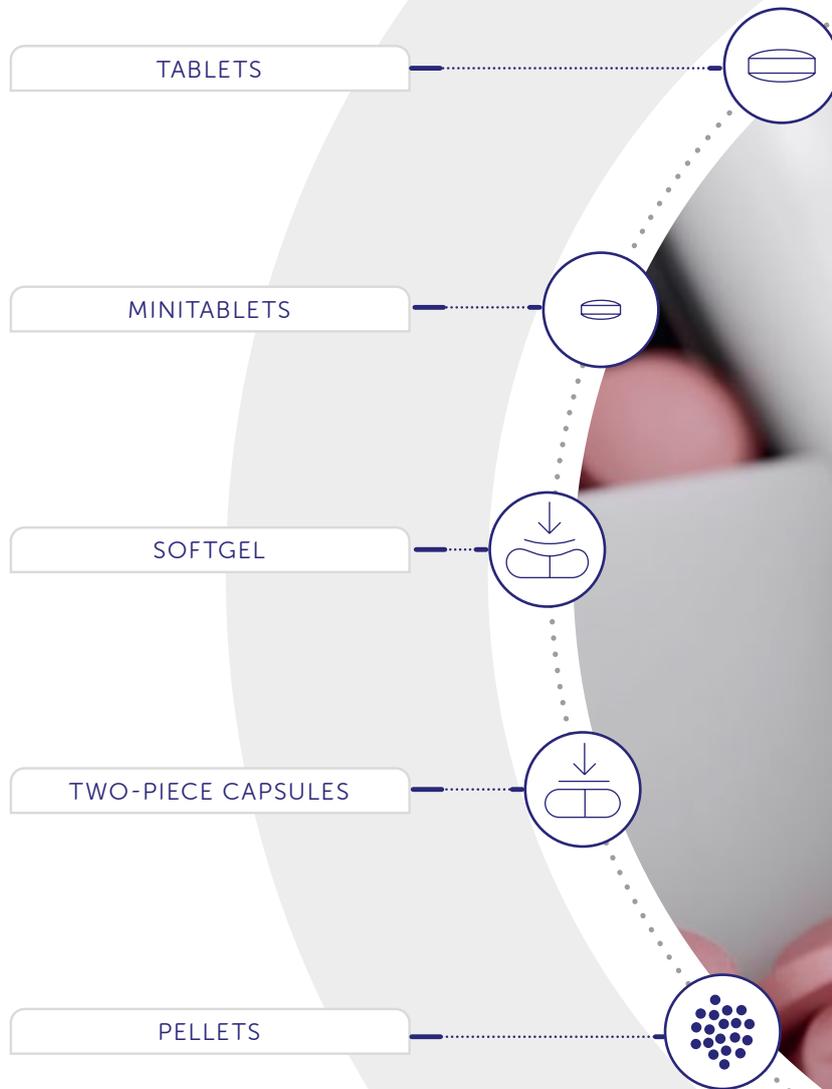




PROCESSES
AND
TECHNOLOGIES

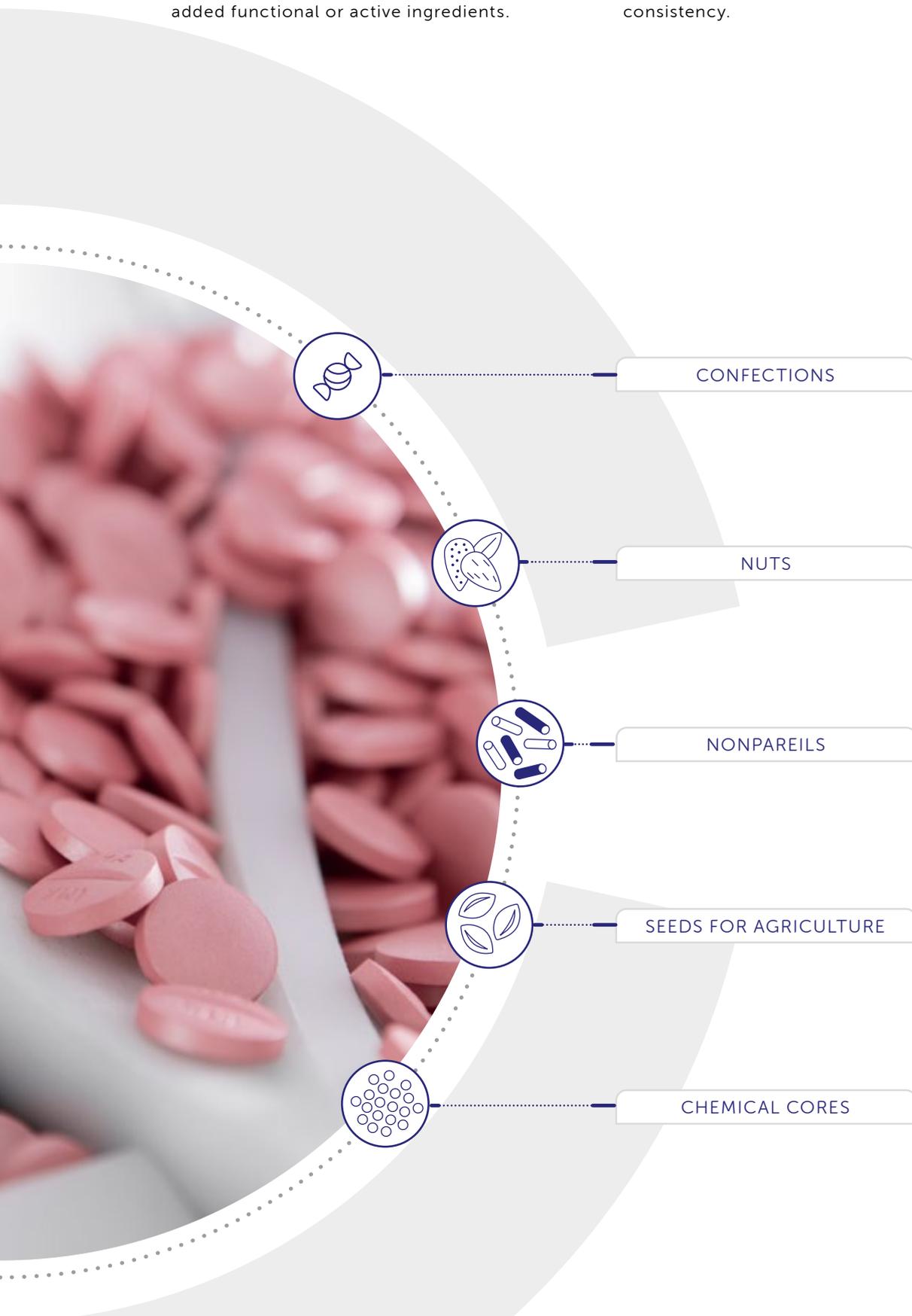
BEYOND PROCESSES, DELIVERING EXCELLENCE

IMA COATING SOLUTIONS CAN
PROCESS A WIDE RANGE OF CORES



Coating processes are widely used in industries such as pharmaceuticals, nutraceuticals, food, confectionery, agriculture, and chemicals. Coated cores offer benefits including enhanced appearance, taste masking, protection, and added functional or active ingredients.

The process involves spraying a water or solvent-based solution onto cores in a rotating perforated drum. As hot air flows through, the coating dries to form a solid layer on each core, ensuring desired quality and excellent consistency.



FILM COATING PROCESS

Film coating applies a thin layer (weight increase 2-16%) of a polymeric substance onto solid dosage forms, commonly used in the pharma



and nutraceutical sectors. Ideal for both batch and continuous coating technology.

NON-FUNCTIONAL COATING low weight gain (2-4% w/w)

- AESTHETIC
- PROTECTION
- EASE OF SWALLOWING
- TASTE AND ODOR MASKING

FUNCTIONAL COATING high weight gain (6-12% w/w)

- GASTRO-RESISTANT RELEASE
- CONTROLLED RELEASE

ACTIVE INGREDIENT COATING high weight gain (8-16% w/w)



SUGAR COATING PROCESS

Sugar coating applies layer upon layer of colored, flavored sugar solutions onto the core surface. This forms a thick sugar-based coating

(weight increase 50-100%). Nowadays less common in the pharmaceutical sector. Process phases include:

- **CORE INSULATION:**
protection of tablets against humidity during subsequent phases.
- **BUILD-UP:**
rapid increase of tablet weight using viscous sugar solutions rich in gum, thickening powder, and anti-adhesives to cover edges.
- **SMOOTHING:**
correction of surface imperfections created during previous process, using diluted sugar solutions.

- **COLORING:**
important for product identification and to improve appearance.
- **POLISHING:**
to obtain final tablet finish using various wax products or PEG.
- **FINAL COOLING AND CURING:**
enables total crystallization of sugar coating and ensures more consistent and harder coating.

FILM POWDER LAYERING PROCESS

Film powder layering is performed in pharmaceutical manufacturing and other industries to create layered particles or pellets. It involves applying layer upon layer of coating onto a pellet to achieve specific characteristics such as controlled release, taste masking, improved stability or altered drug dissolution profiles. Process phases include:



● CORE PREPARATION:

cores can be drug particles, sugar spheres, inert microcrystalline cellulose spheres or other suitable materials.

● SPRAYING:

the core particles are introduced into a coating chamber. The binder solution is then sprayed onto the core particles.

● POWDER DOSING:

powder is added to the pellets manually or with the help of an auger screw.

● DRYING:

layer after layer, the coated particles are dried to remove solvent, leaving a solid coating. Drying is done using controlled temperature and airflow.

● REPEATING THE PROCESS:

the layering and drying steps are repeated multiple times to build up the desired number of layers.

● FINISHING:

final drying ensures that the coating is fully dry and adheres to the core particles. Final cores can also be film-coated for taste masking or retard properties.





COATING DRUM
TECHNOLOGIES
AND SPRAY BAR

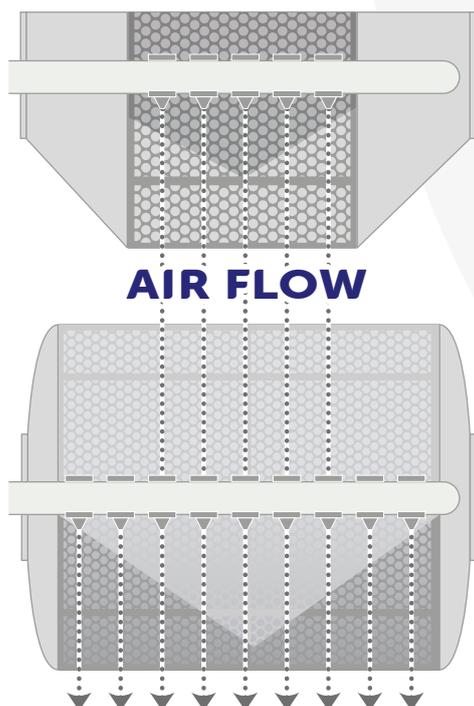
PERFORATED DRUM TECHNOLOGY

Perforated drum is the most common and widely adopted technology used in coating equipment due to its high efficiency and optimal air distribution throughout the core bed.

BICONICAL DRUM

Biconical drums have been a coating industry mainstay for more than fifty years. As a well proven and deeply understood technology, coaters with biconical drums continue in widespread use for manufacturing legacy pharmaceuticals, along with line extension products and even for new drugs. Their distinctive shape aids in the efficient mixing of tablets front-to-back and back-to-front, ensuring uniform coating application across all tablets.

Though they do not provide as much perforated surface area as cylindrical drums, biconical drums excel in applications requiring gentle handling of fragile tablet cores, thereby minimizing product loss due to breakage. Thomas offers biconical drums with legacy plough-type baffles and advanced helical baffles. These are removable and interchangeable, making it possible to select the baffles best suited to a product.

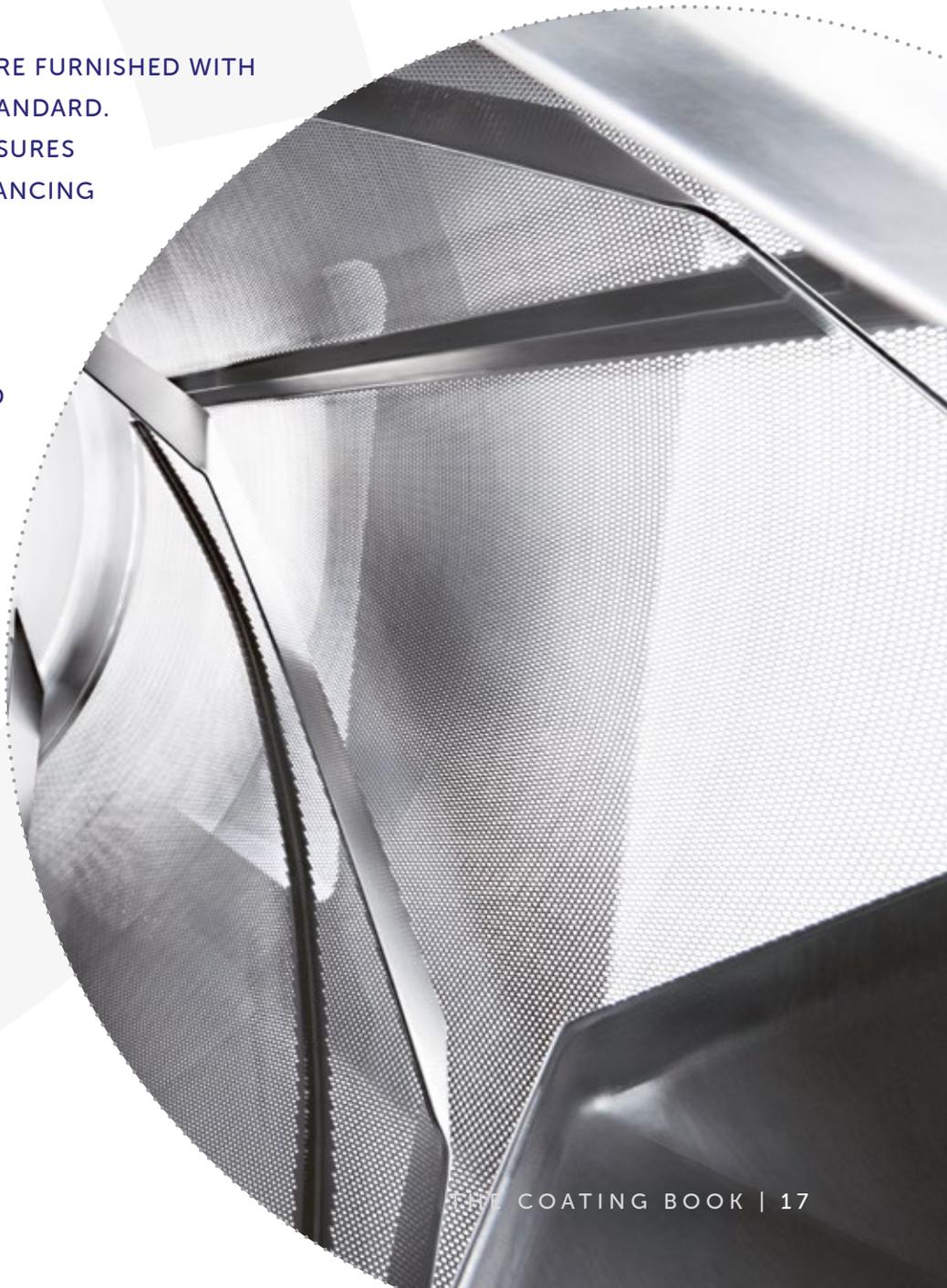


CYLINDRICAL DRUM

Cylindrical drums maximize the usable space within the coater and within the coating suite. This design allows for more tablets to be coated simultaneously, increasing productivity without expanding the equipment's footprint. This configuration provides additional perforation along the drum's length, allowing greater airflow and accommodating more spray guns. More guns, more air, faster coating mean outstanding productivity.

Stability of the coating process is another benefit provided by cylindrical drums. The increased length of the perforated section offers a greater area for air to be drawn through the bed. The correspondingly larger exhaust plenum area correlates to a lower velocity of air passing through the tablet bed, which has several benefits: reduced turbulence within the drum, higher spray efficiency, and lower pressure drop across the tablet bed.

CYLINDRICAL DRUMS ARE FURNISHED WITH HELICAL BAFFLES AS STANDARD. THIS COMBINATION ENSURES DYNAMIC MIXING, ENHANCING COATING UNIFORMITY AND SUPPORTING BETTER OUTCOMES IN SOPHISTICATED MODIFIED RELEASE AND DRUG LAYERING.



INNOVATIVE SPRAY SYSTEM

For decades, Thomas Processing has stood at the forefront of innovation in pharmaceutical manufacturing, continuously advancing the efficiency and precision of tablet coating processes. Our latest breakthrough, the Thomas Spray Bar (TSB), epitomizes this legacy, setting new standards in coating technology.

● A LEAP IN COATING TECHNOLOGY

At the core of TSB's innovation is its patented design, which integrates all fluid and air handling mechanisms within the bar itself. This integration eliminates the need for external lines that often disrupt airflow and lead to tablet entrapment, a common issue in traditional systems. This advanced design not only enhances the smooth operation, but also significantly reduces the risk of clogging and inconsistency, ensuring a flawless coating application every time.

● DESIGNED FOR EFFICIENCY AND EASE OF USE

Understanding the high demands of pharmaceutical production environments, TSB is engineered for ease. It offers quick maintenance features allowing for rapid nozzle cleaning and replacement, reducing typical downtime from 45 minutes to a mere 5 minutes. Such operational efficiency is invaluable, significantly boosting production throughput without sacrificing quality.

● ENHANCED SAFETY AND SUPERIOR COATING QUALITY

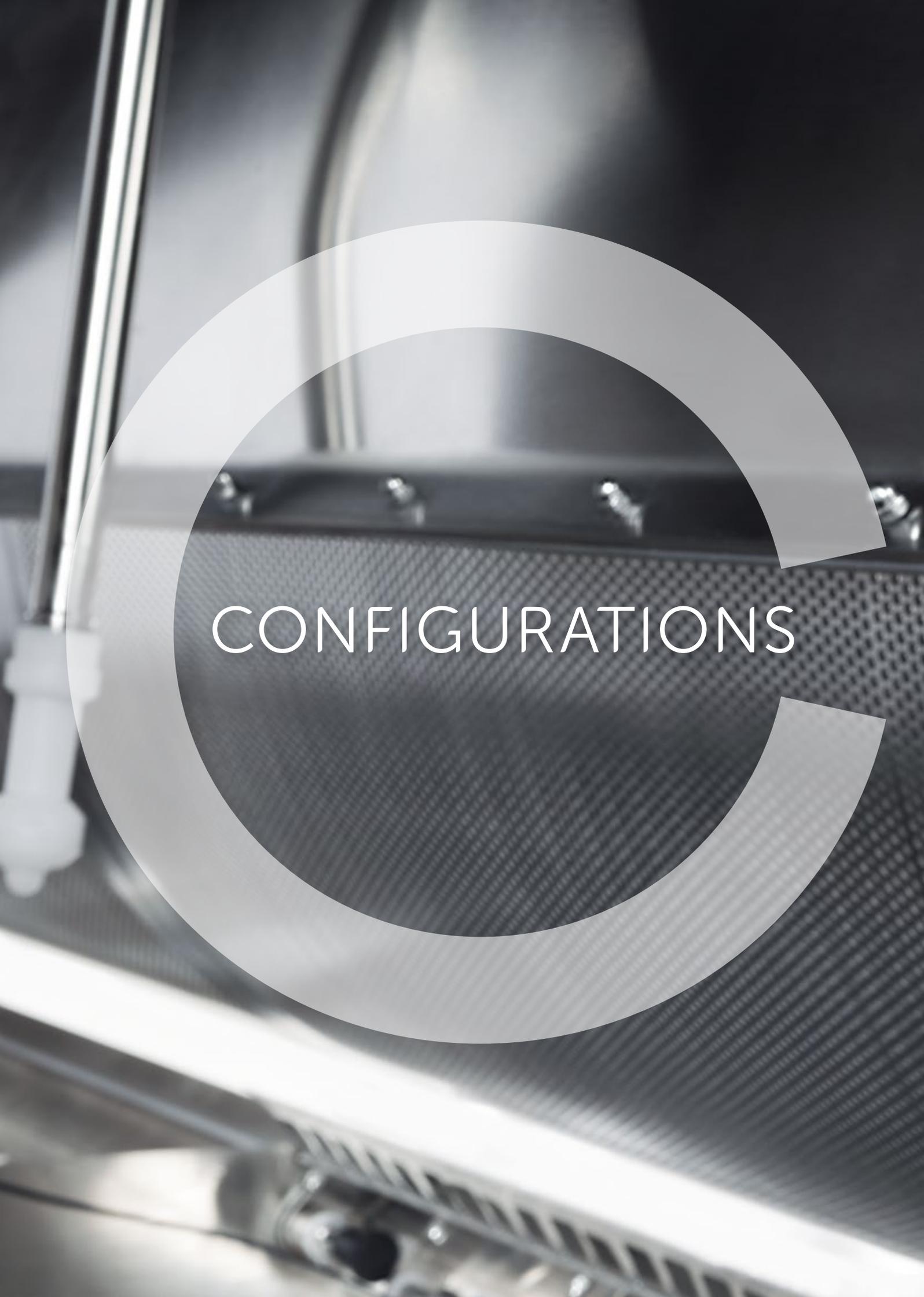
Safety and hygiene are paramount in pharmaceutical manufacturing. TSB's streamlined design minimizes crevices and exposed threads, drastically reducing contamination risks and simplifying cleaning processes. This hygienic design, coupled with the spray bar's efficient use of coating materials, not only improves safety but also enhances end product quality. Tablets are coated uniformly, with reduced incidences of spray drying or over-wetting, which are often detrimental to tablet integrity and efficacy.

● A TESTAMENT TO EXPERTISE AND INNOVATION

The Thomas Spray Bar is more than just a component of our coating systems; it is a testament to Thomas Processing's commitment to excellence and innovation in the pharmaceutical industry. With over 1,600 installations worldwide, our technologies, including the pioneering TSB, demonstrate our in-depth process knowledge and our drive to advance pharmaceutical manufacturing.

SPRAY BARS CAN BE EQUIPPED WITH UP TO 16 GUNS WITH THE FOLLOWING FEATURES:

- Made of lightweight FDA compliant material
- Atomizing and pattern air control
- No multiple air and fluid lines
- No trapped cores
- Easiest cleaning of any spray manifold
- Fewer parts than conventional manifold
- Less than 25% of O-rings versus other spray bars
- Solution continues in recirculation even when air cap and nozzle are removed



CONFIGURATIONS



WASH-IN-PLACE

Thomas coaters are designed to meet stringent GMP standards, ensuring consistently high product quality.

A critical element in achieving this objective is our cleaning technology, designed to be both efficient and effective, minimizing the risk of cross-contamination.

Our wash strategies are built upon our “total access” coater design, which features intelligent engineering and precise surface finishing.

This ensures that our coaters are thoroughly cleanable, eliminating potential shadowing and blind spots. Leveraging extensive experience and a deep understanding of cleaning dynamics, Thomas continues to advance our cleaning technology to meet evolving industry demands. Notably, our innovative tankless WIP system exemplifies our commitment to efficiency, providing rapid and effective cleaning while also reducing water usage and utility burden.

**STRATEGICALLY PLACED CLEANING DEVICES ENSURE COMPLETE
COVERAGE OF PRODUCT CONTACT SURFACES WITHIN THE COATER.
AUTOMATION SUPPORTS RECIPE VALIDATION, ENSURING THE
COATER OPERATES EFFICIENTLY AND RELIABLY.**





CONTAINMENT

IMA Thomas offers advanced containment tablet coaters, prioritizing operator safety and compliance with stringent environmental regulations. Our commitment to high-containment technology ensures maximum safety when handling Highly Active Pharmaceutical Ingredients (HAPI), capable of achieving Occupational Exposure Band

(OEB) levels up to OEB6. Our innovative approach features robust automation and safety functions allowing coating processes to be conducted and monitored without direct operator intervention. With Thomas, you can expect a safe and efficient operation that significantly minimizes the risk of exposure to potentially harmful substances.

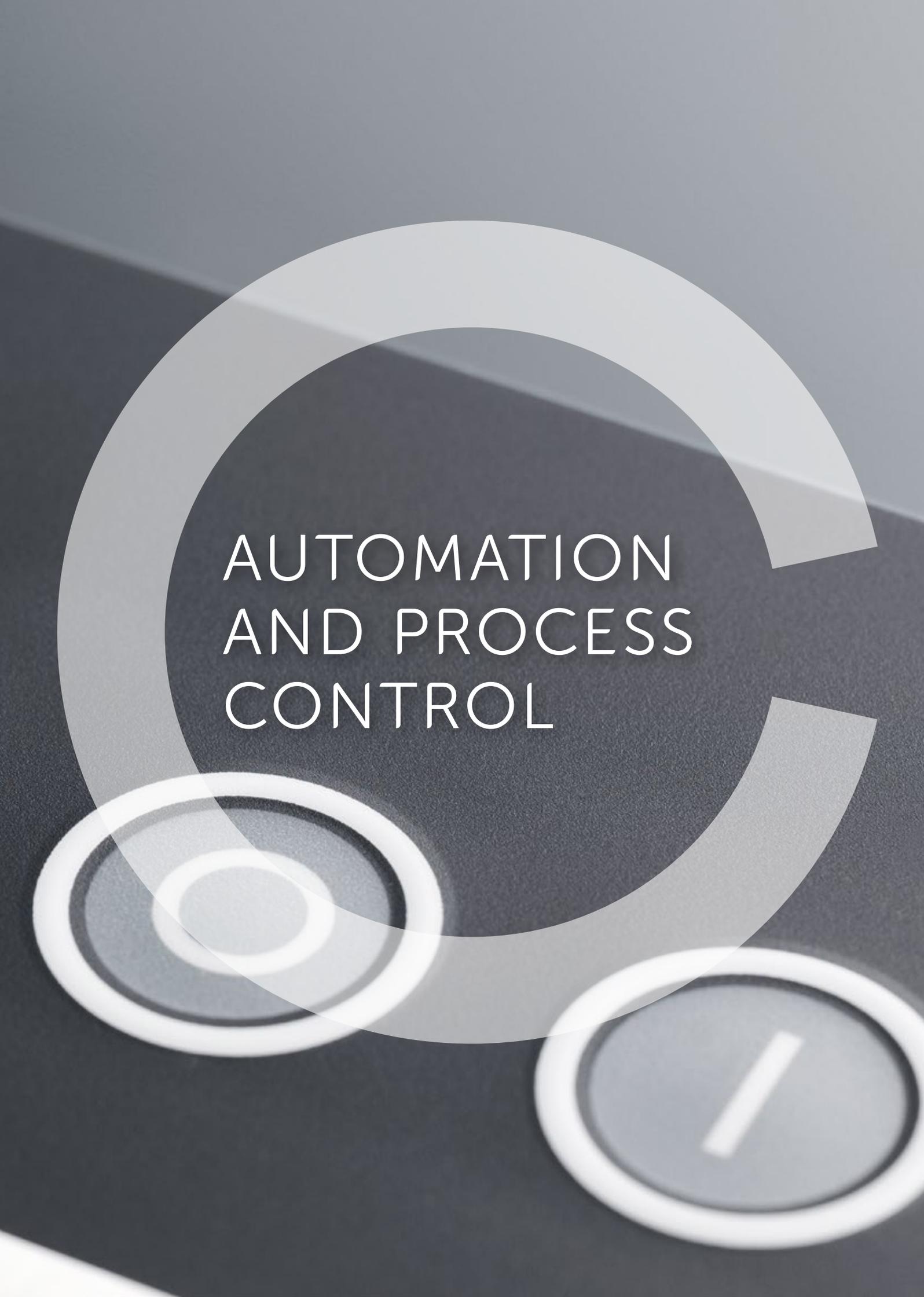
TECHNOLOGIES TO ENSURE MAXIMUM SAFETY WITHIN THE PROCESSING ENVIRONMENT

- ISOLATION of processing areas.
- CLOSED TRANSFERS for tablet core loading and discharge.
- SAMPLING SOLUTIONS for retrieval and transfer.
- CONTROLS INTEGRATION with split butterfly valves and docking systems.
- EXTERNAL SPRAY GUN POSITIONING without breaking containment.
- COMPREHENSIVE WASH-IN-PLACE execution.







The image features a dark, textured background with a large, semi-transparent white circle in the center. Inside this circle, the text "AUTOMATION AND PROCESS CONTROL" is written in a white, sans-serif font. Below the central circle, there are two circular elements: one on the left with concentric white rings, and one on the right with a white vertical bar. The overall aesthetic is modern and technical.

AUTOMATION AND PROCESS CONTROL

MAX HUMAN MACHINE INTERFACE



COMMUNICATION AREA

Informs and connects
the people involved
in production

MULTI-USER VIEW

Different content
for each
user profile

USER GUIDE AREA

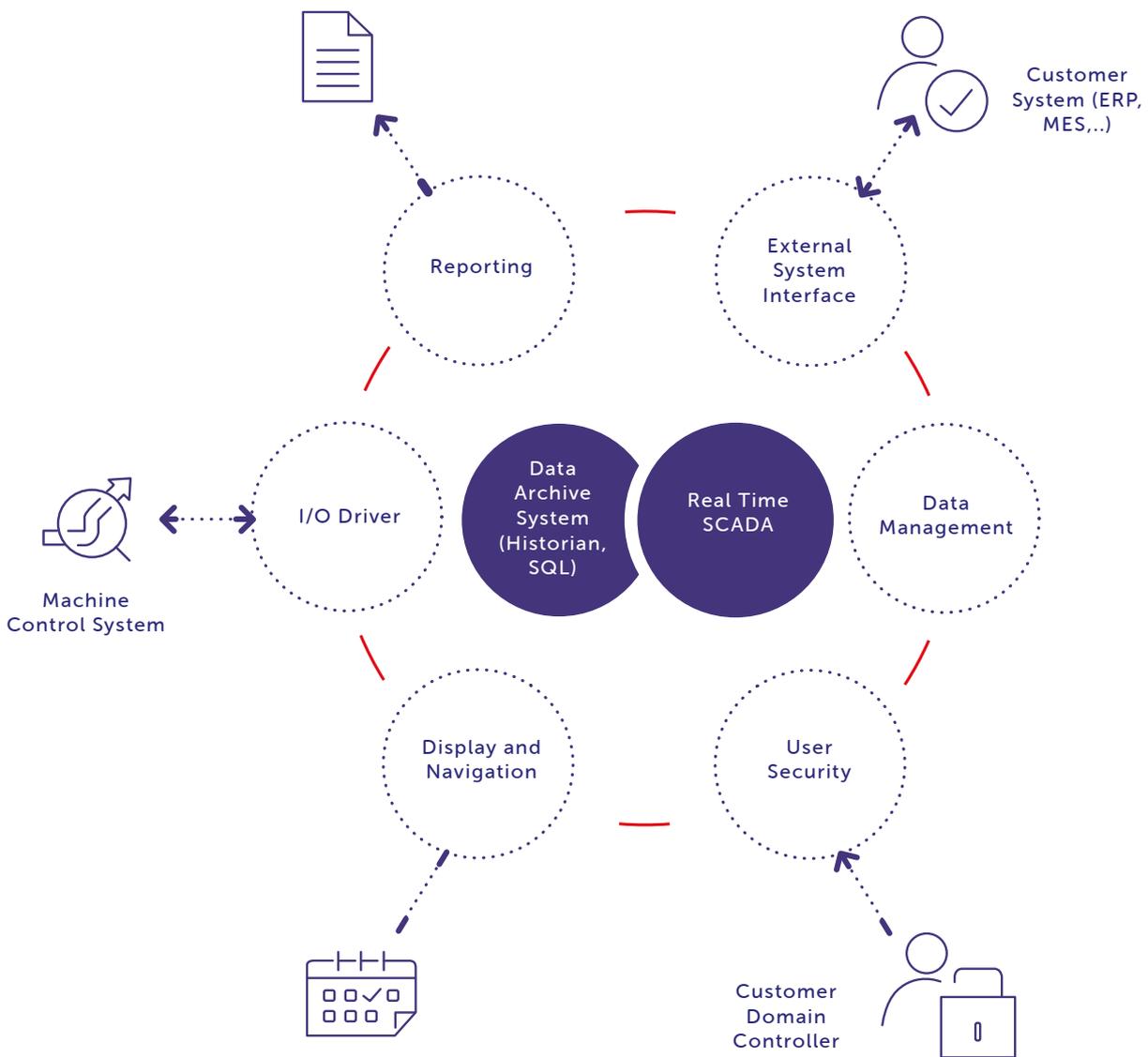
Wizards to
minimize errors
and timing

CONFIGURABLE AREA

Collection,
monitoring
and data display

MAX, the latest generation of IMA HMI, has been created paying maximum attention to User Experience and based on Visual Design to enhance User Interaction. MAX ensures prompt responsiveness, enhanced predictability and easy learning. MAX HMI is based on iFix SCADA, IoT ready, to facilitate connection with other equipment in solid-dose processing lines.

Communication can be extended to a plant-wide supervision system and also to IMA remote service assistance. Automatic recipes, reports and audit trails for processing or cleaning can be edited and managed to ensure maximum efficiency and consistent results in compliance with current directives and guidelines (ANSI/ISA-88, FDA CFR 21 part 11, GAMP®, MHRA GMP Data Integrity).



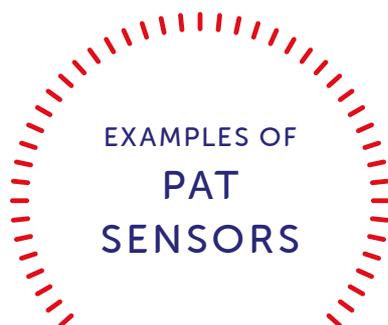
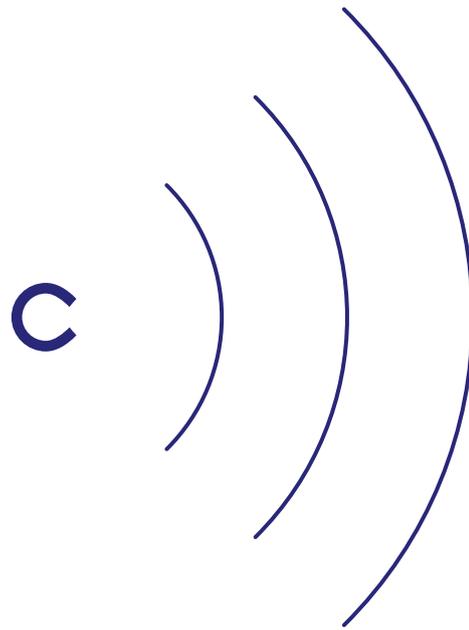
PROCESS CONTROL

Process control can be enhanced with full integration of PAT tools and use of mathematical models for measurement or prediction of Critical Process Parameters (CPP) that determine Critical Quality Attributes (CQA).

Process data collection from each unit and their proper management provide full understanding and favor continuous process improvement.

In this way, the critical process parameters can be managed until diversion criteria are defined, so that only out-of-specification dosage forms are discarded and the rest of the lot is preserved.

To facilitate this task, it is recommended to rely on state-of-the-art sensors able to measure quality attributes (e.g. moisture content, API content uniformity, blend uniformity, coating uniformity, etc.). These are the called PAT sensors.



● **IRIDE IMAGING DEVICE**

At coater exit chute to check color uniformity

● **NIR**

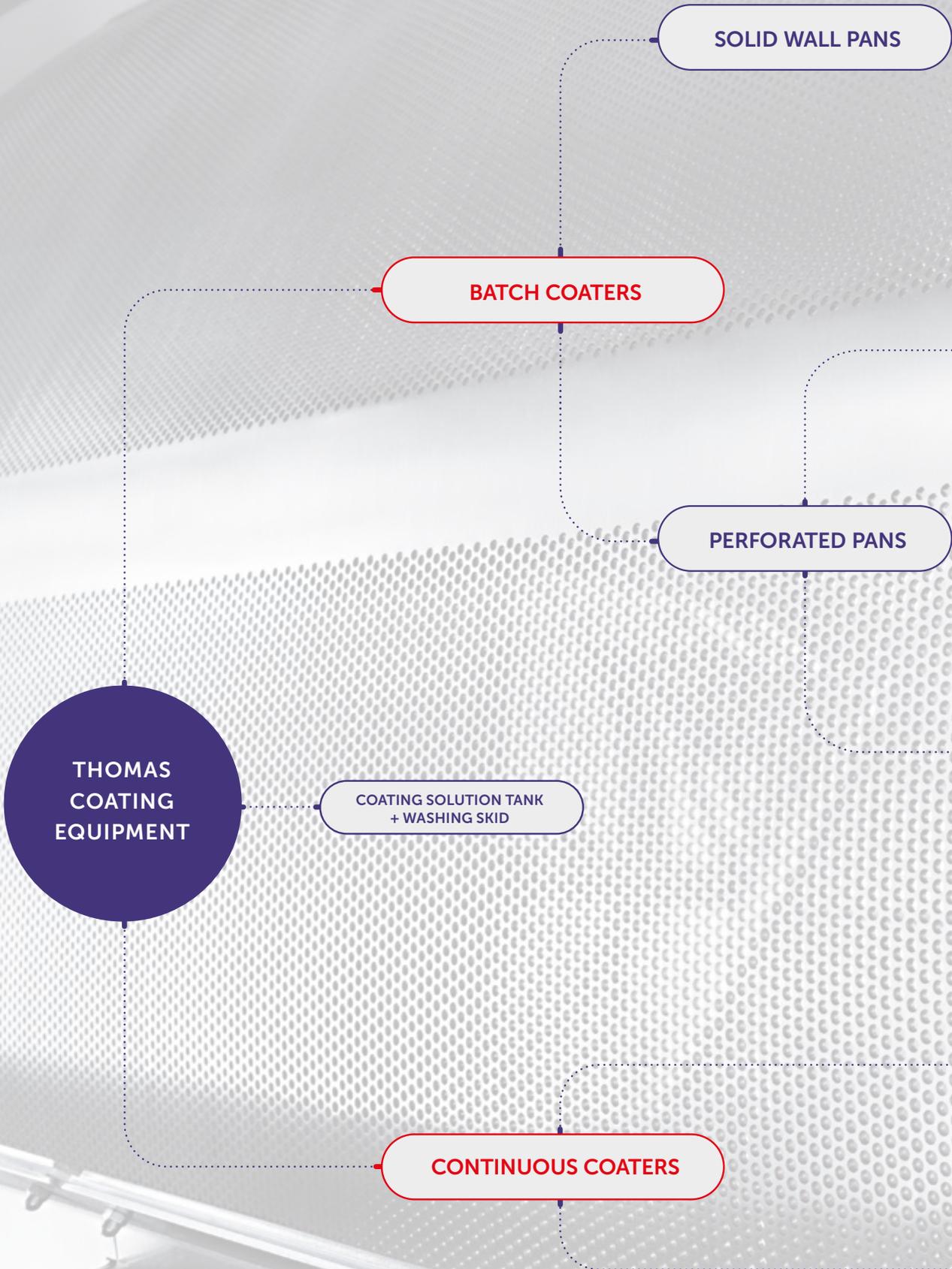
At coater exit chute to check coating quality







COATING
PORTFOLIO



SOLID WALL PANS

BATCH COATERS

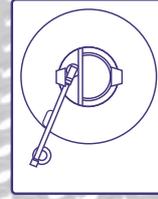
PERFORATED PANS

THOMAS
COATING
EQUIPMENT

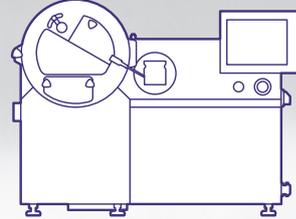
COATING SOLUTION TANK
+ WASHING SKID

CONTINUOUS COATERS

GS
IMA ACTIVE

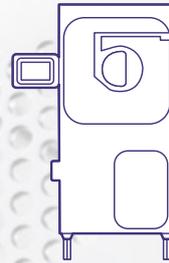


FLEX 05

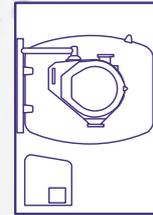


LAB / DEVELOPMENT

ACCELA COTA LAB

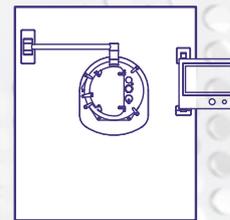


FLEX

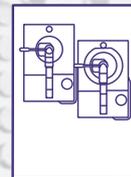


PILOT / PRODUCTION

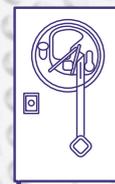
ACCELA COTA PRO



CROMA
IMA ACTIVE



ACCELA CTC



BATCH COATERS

FLEX

FLEX tablet coaters provide an ideal manufacturing solution that enhances productivity while maintaining high standards in quality, consistency, and reliability. These coaters feature exchangeable drums, interchangeable mixing baffles, and the patented Thomas Spray Bar (TSB), offering unmatched versatility and improving overall equipment effectiveness (OEE). Additionally, they include configuration enhancements specifically for processing potent compounds, ensuring safe product handling and operator protection.



ACCELA COTA PRO

The ACCELA COTA PRO marks a significant evolution in Thomas Processing's tablet coating technology. Building on the trusted performance of the traditional ACCELA COTA, the PRO model offers enhanced productivity and efficiency. It features a cylindrical drum design with increased capacity and airflow, leading to faster coating times and superior coating uniformity. Leveraging Thomas' legacy of technical advancements, including the first fully perforated coater and patented spray bar technologies, the ACCELA COTA PRO continues to set industry standards, ensuring optimal performance and versatility for pharmaceutical manufacturing.

ACCELA COTA LAB

ACCELA COTA LAB is the newest addition to the ACCELA COTA series of fully perforated drum coaters. A must-have coater for formulation and scale-up studies, ACCELA COTA LAB easily achieves production-scale quality in a compact and portable system. ACCELA COTA LAB emphasizes all the hallmarks of the ACCELA COTA system, being evidence of Thomas' passion for building on the tradition of innovation. Compliant with the most stringent GMP guidelines and highly ergonomic, ACCELA COTA LAB provides a unique combination of flexibility, functionality, and ease of handling.



GS

GS coating equipment is designed in different sizes and fitted with a patented core drying system. GS can be equipped with exhausting paddles for tablet film and sugar coating, as an alternative it can feature either exhausting or blowing paddles to perform tablet film and sugar coating as well as to process pellets and microgranules. The machine is equipped with an automatic Wash-In-Place (WIP) system.

- Solid wall drum
- Batch size range: from 7.5 l to 700 l

FLEX 05

FLEX 05 is perfect choice for rapid product development and laboratory batch testing. This benchtop powerhouse handles batches ranging from just a handful of tablets up to 5 liters. Process capabilities include aqueous and solvent film coatings, also with advanced functional and modified release types. Containment execution is also available for handling potent compounds with closed loading, discharge, and sampling. Our TAAC process modeling program is already on board and may be used off line or during actual process execution. Operator interface is by color touchscreen; system includes data acquisition and process reports.



CONTINUOUS COATERS

CROMA

CROMA continuous coater is IMA Active's novel technology for a fast and truly continuous process. Designed to be modular to manage a range of tablet throughput and a range of coating weight gain. A single CROMA module works in ranges of 20-100 kg/h and average 2-4% weight gain, depending on tablets and film types. By virtue of its versatility, CROMA allows product development, clinical trials, and manufacturing all to be managed with one equipment size and no need for scale-up. The working principle behind CROMA is based on a traditional coating system.

Uncoated tablets transit a perforated drum in a continuous flow, where they are mixed subjected to a flow of hot air and coated with liquid polymer using spray guns.

- Product volumes: 20-100 kg/h
- Weight gain:
 - Clear coating: 0.5-1%
 - Color coating: 2-3%
 - Enteric coating: 3.5-7%





ACCELA CTC

Featuring the continuous coating technology pioneered by Thomas Processing, ACCELA CTC is designed to manage high production throughputs between 100 and 1,200 kg/h, processing large tablet batches in continuous mode.

The equipment's advanced design eliminates material waste from the process and avoids reprocessing during startup and shutdown.

ACCELA CTC, unique in the market, integrates a standard curing chamber and optional wax

addition system, streamlining the coating process while minimizing overall equipment footprint.

ACCELA CTC can be equipped with automatic Wash-In-Place (WIP) system.

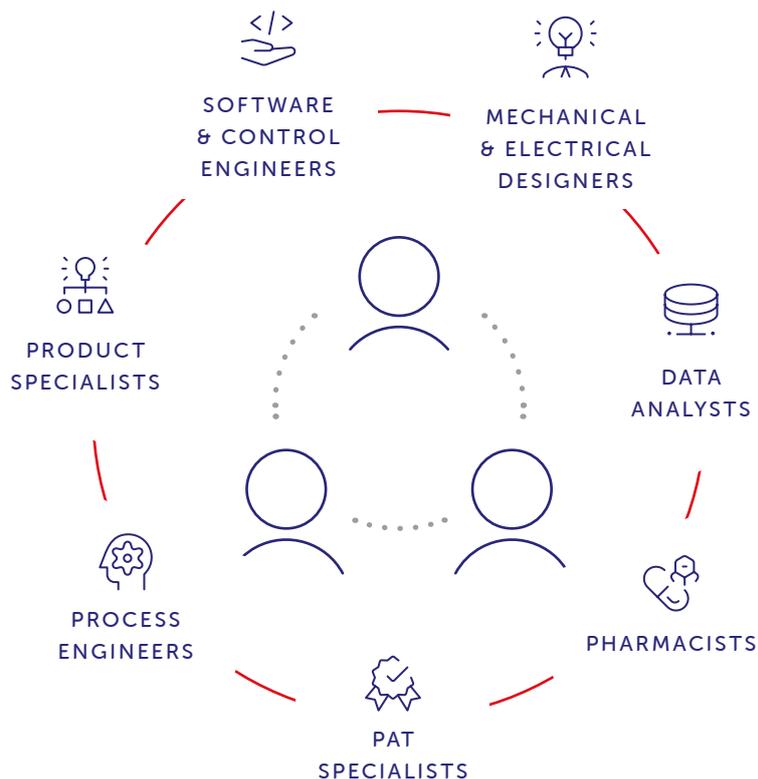
- Product volumes: 100-1,200 kg/h
- Weight gain:
 - Clear coating: 0.5-1%
 - Color coating: 2-3%
 - Enteric coating: 3.5-7%

IMA THOMAS COMPETENCE CENTER

IMA Thomas supports innovation in manufacturing by bringing together all the necessary competences: Process Engineering, Equipment Design, Process Control and Process Analytical Technology. Evolving market needs have been evaluated resulting in a multidisciplinary approach that

supports any kind of pharmaceutical company. IMA Thomas Competence Center includes dedicated coating test rooms with a controlled environment. Additional test rooms are available in Italy at IMA Active facility.

TO BETTER UNDERSTAND END-USERS AND MATCH THEIR NEEDS,
IMA THOMAS HAS BROUGHT IN ITS R&D TEAM PEOPLE WITH
DIFFERENT SKILLS AND A HIGH LEVEL OF COMPETENCE.
ONLY A MULTIDISCIPLINARY APPROACH CAN GENERATE EFFECTIVE
TECHNOLOGIES FOR THE FUTURE OF PHARMACEUTICAL MANUFACTURING.





IMA THOMAS

IMA THOMAS HAS BEEN SHARING THE SAME VISION WITH SOME STRATEGIC PARTNERS TO DEVELOP HIGH QUALITY EQUIPMENT FOR AN OPTIMAL PRODUCTION PROCESS. THE RESULT IS A NETWORK OF PARTNERS DELIVERING SERVICES TO THE PHARMACEUTICAL SEGMENT. THIS LEADS ULTIMATELY TO A PRODUCTIVE COLLABORATION IN WHICH ALL THE STAKEHOLDERS ENGAGE WITH THEIR RESPECTIVE ENERGIES AND COMPETENCES.



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