Continuous Processing
Solutions for Oral Solid Dosage Forms
14 Years of Inspiration

No other company has as much experience and done more to pioneer continuous manufacturing for the pharmaceutical industry.

Pharmaceutical manufacturers face many challenges when developing products and getting them to market in a timely, safe and cost-effective way.

From formulating new molecular entities to improving the production methods for generic drugs or extending the lifecycle of existing oral solid dosage (OSD) forms, issues such as reducing the cost-per-tablet, increasing patient safety and optimizing the price/performance balance are common daily concerns.

Many pharmaceutical companies still rely on traditional batch manufacturing processes to produce drugs. Now, however, with changing perspectives from the regulatory bodies, such as FDA and EMA, the pharmaceutical industry, slightly less risk averse and willing to improve both supply chain efficiency and product throughput, has recognized that continuous manufacturing (CM) solutions can accelerate product development, reduce costs, improve production economics and increase manufacturing flexibility.

CM is more efficient, agile and flexible technology, offering more consistent and reliable tablet production with the reduced use and loss of resources such as precious APIs and raw materials, less stoppage time and minimal manual intervention. Plus, by producing tablets continuously, batch sizes are simply determined by how long you run the machine. It is also helping the pharmaceutical industry to produce higher quality products, enhance drug safety, reduce its industrial footprint and decrease waste (particularly during start-up and shutdown), which provides significant advantages to governments, companies and patients alike.

Continuous processing is clearly the future of pharmaceutical manufacturing. In fact, a majority of the top ten pharmaceutical companies have now confirmed that their strategy is to develop both new chemical entities (NCEs) and, when economically and technically viable, also manufacture legacy ethical and generic products using continuous technologies.
14 Years of Continuous Learning

With a continuous line running at a customer’s site since 2007, GEA has, from the very beginning, led the field with flexible development options that facilitate the commercial manufacturing process and enable greater process understanding to be achieved with smaller quantities of material.

Also, its experience in pharmaceutical OSD production technologies and continuous processing experience in other industries, such as chemicals and food, gives GEA an edge in supporting the pharmaceutical industry in this game-changing switch from batch to continuous.

At the heart of GEA’s fully integrated, powder-to-tablet CM solution is ConsiGma®, a complete portfolio of technologies designed to transfer powder into finished dosage forms in development, pilot, clinical and production volumes. ConsiGma® includes systems for dosing and mixing raw materials, wet or dry granulation, drying, tableting, coating and quality control, which can be integrated in one compact production line.

With a range of solutions developed according to Lean and Six Sigma process guidelines, GEA is an established expert and a single-source solution provider of equipment, technology and know-how for this evolutionary powder-to-tablet manufacturing concept. Thanks to our collaboration with complementary partners (universities, research institutes and industrial partners, such as RCPE, Siemens, UGent, etc.) we can offer a 360° approach to continuous manufacturing, taking you from early development to commercial manufacturing and including equipment, process, control strategy, formulation and regulatory support.

GEA has taken the lead in providing the pharmaceutical industry with new technologies based on the most innovative way of granulating, drying and making tablets using potent APIs. The company has pioneered continuous manufacturing in drug production and was the first supplier to provide and install a complete powder-to-tablet line for customer use.

Using a QbD approach, drug manufacturing cycle times — from API to product release — can now be measured in hours rather than weeks. The clear benefits demonstrated by the use of ConsiGma® technology are facilitating the switch to continuous manufacturing and helping pharmaceutical companies to minimize risk as they transition from batch systems. By reducing development timelines and API use, and eliminating scale-up and product transfer, ConsiGma® is not only compact and cost-effective, it also offers greater operational efficiencies and more environmentally friendly manufacturing.
By focusing on quality during the whole product lifecycle — not just “tested in” quality — and by understanding the capability of your processes, sources of variability can be managed and any associated risk can be eliminated.

ConsiGma® is a Six Sigma-inspired manufacturing platform, incorporating different technologies to produce oral solid dosage forms in a continuous, cost-efficient way:
- by collecting more information during R&D with less product
- by excluding risky, time- and product-consuming scale-up exercises
- by introducing online measurement and closed loop control targeting real-time release (Six Sigma production), reducing waste to zero
- by incorporating flexible batch size (JIT production), reducing inventory
- by decreasing the energy cost per tablet, reducing environmental impact.

ConsiGma® was developed in compliance with the FDA’s QbD initiative. It satisfies the industry’s need for reduced risk and higher quality while avoiding lengthy and costly validation and scale-up to bring products to market much faster. This flexibility enables the production of products to meet demand, keeps expensive cleanroom space to a minimum and reduces inventory costs. Integrated advanced process control and PAT tools allow monitoring during production, so quality can be designed into products from the start.

ConsiGma® continuous oral solid dosage tableting lines (granulation, drying, tablet compression) are designed for plug-flow, first-in first-out (FIFO) production, avoiding back-mixing, providing a consistent quality and allowing for the inline control of critical quality attributes. ConsiGma® ticks all the pharmaceutical industry’s boxes:
- broad opportunity, ethical and generic, worldwide
- R&D: flexible batch size, no scale-up, fast DOE
- reduced investment and running costs: easy to install, reduced use of utilities, parametric release, reduced quality cost
- time-to-market: fast deployment, full flexibility with modular construction, POD-based installations possible.

The ConsiGma® Principle
The ConsiGma® platform allows users to make exactly the number of tablets required to meet immediate demand — with the quantity limited only by the running time of the machine or by how much inbound material is supplied; and, because of ConsiGma®’s innovative design, the amount of waste produced during start-up and shut down is significantly reduced compared with conventional methods.

Using continuous production and a “risk-based approach” to GMP, the ConsiGma® system delivers much higher and consistent quality. Parametric release is achieved through inline testing.

Quality is measured throughout the process and, as such, drastically reduces the cost per tablet. Critical quality attributes are measured second-by-second and any deviation from the specification is immediately reported to the operator. Optionally integrated advanced process control and PAT tools enable monitoring during production, so quality can be designed into products from the start.

Going Continuous
The shift from batch to continuous production could represent one of the largest paradigm shifts in pharma processing since validation and qualification systems were introduced.
Process Chain

Powder Dosing
The accurate dosing of powdered excipients is a key and critical technology for the continuous production of oral solid dosage forms. As an enabler of its CM philosophy, and to meet market requirements, GEA, in an alliance with a supplier of extremely accurate load cells, offers a range of compact feeders that operate on the gravimetric, loss-in-weight principle.

They will be included in all GEA continuous manufacturing lines and are technically superior to commercially available feeders.

Dry Blending
Blending is one of the most demanding unit operation in today’s processing industries and a critical step in the production of high quality end products. Affecting both cycle times and total cost of ownership, selecting the most appropriate mixing technology is crucial.

Based on extensive process knowledge and continuous research, GEA offers a wide range of technical solutions and process options to ensure the efficient mixing and blending of pharmaceutical powders and granules.

Depending on the process, product and system set-up, even when height is a limiting factor, we can select and provide the most appropriate blender for your project.

Granulation
As most fine pharmaceutical compounds need their flowability and processing properties to be improved for downstream processes, granulation, which allows primary powder particles to adhere and form granules, is the most important unit operation in drug manufacturing, with wet granulation accounting for up to 80% of the tablet formulations.

GEA’s continuous wet granulation module is based on high-shear twin-screw granulation. The technology produces granules with a more consistent uniformity, using less liquid than traditional methods.
**Drying**
For drying the wet granules, the dryer module – based on fluid-bed drying principles – splits the continuous flow of granules into packages, drying each of them in a separate segment of the dryer and thereby guaranteeing plug flow. When each segment is dry, it is emptied and transferred to the evaluation module – where critical quality attributes such as particle size distribution, humidity and content uniformity can be measured using specially designed PAT tools – and refilled with a new package of wet granules.

**Tablet Compression**
Tablet presses have always operated continuously. Until now, however, because of regulatory restrictions and the fact that granules were delivered to the press in batches, they have mainly been used in batch mode. Both of these hurdles to continuous tableting have been removed in recent years.

GEA MODUL tablet presses are an essential component of the company’s ConsiGma® continuous processing line for solid dosage forms. Special features such as the air compensator and enhanced dual process control make them ideal components of a continuous line allowing the tablet press to react to any variation in production rate, without affecting the tablet quality.

**Tablet Coating**
Designed specifically to be an integral part of the ConsiGma® continuous tableting lines, the ConsiGma® coater is able to process small quantities of tablets at very high rates, offering improved heat and mass transfer.

Presenting a paradigm shift in tablet coating, this new type of coater entrains tablets in a cascading movement that enables greater fluid application rates (higher coating build-rates) than traditional coating pans. It intensifies the conventional process by applying the coating more quickly, more gently and more precisely.

These advantages lead to better end product quality and safer products for patients.
MAKING CONTI REAL

In collaboration with Pfizer and G-Con, GEA developed the PCMM (Portable, Continuous, Miniature and Modular manufacturing) platform, now operational at Pfizer’s facility in Groton, Connecticut, USA.

Conceived, designed and built through a future-facing initiative between the three partners, the PCMM technology has at its center GEA’s state-of-the-art miniaturized and mobile ConsiGma® continuous oral solid dosage (OSD) pharmaceutical processing technology. Configurable for either direct blending and the compression of powder streams into tablets, or for wet granulation, drying, milling and tableting, the ConsiGma® system features a new vertical inline powder blender.

Five process analytical technologies (PATs) have been integrated into the system to continuously monitor and control all process and quality parameters, and ensure minimal losses in the event that production needs to be stopped or process parameters need to be changed. G-CON has designed and constructed a modular, prefabricated, and highly maneuverable POD® system that can rapidly be set up around the equipment to provide a GMP-compliant cleanroom environment.

The PCMM technology represents a completely self-contained and mobile continuous manufacturing system that can be transported to geographical areas of need, and installed within days to produce as much or as little drug as required, whether for product development, clinical trials manufacture or commercial production. When production is no longer required the unit can just as easily be disassembled and transported to another site.

This agile concept for continuous manufacturing could feasibly make huge, purpose-built production plants a thing of the past, significantly reducing capital expenditure and operational redundancy. And with industry driving to reduce costs, increase quality and focus on patient-centric manufacturing, GEA believes that PCMM manufacturing will become the industry standard platform for processing OSD therapeutics.
Continuous Production Solutions

Without the issues of start-up and/or shutdown waste, the ConsiGma® manufacturing platform is capable of continuously producing pharmaceutical products. This concept enables the use of the same system for both development and production work without the need for scale-up; the determining factor for the amount of material handled is not the size of the process vessel, but the running time.

Scale-up has always been a very risky, time-consuming and costly exercise in tablet development and manufacturing. From now on, we can optimize the process parameters and increase overall throughput rates without altering the production conditions.

Combining processes into a single machine means reduced space requirements, smaller buildings, smaller cleanrooms, less waste and less consumption of power and raw materials.

ConsiGma® provides maximum output in an energy efficient way, has been tested using a wide variety of formulations and is already being used by several large pharmaceutical companies, and both ethical and generic research and manufacturing centers worldwide.

To enhance its flexibility even further, the ConsiGma® can also be configured for dry and melt granulation, and connected to a MODUL tablet press with an Exchangeable Compression Module (ECM) and a single or twin drum ConsiGma® coater to form a truly continuous tableting line.
ACCELERATING DRUG DEVELOPMENT

To investigate continuous manufacturing (CM) and streamline, Vertex Pharmaceuticals, Inc. partnered with GEA to enhance their existing technology and implement primary and backup CM processes. The company invested in a multi-product development and launch rig (DLR) to manufacture multiple drug products in a fully continuous mode – starting with the blending of individual excipients, ending with film-coated tablets and incorporating PAT (process analytical technology) to allow real-time release.

Focusing on the integration of separate processing steps into a fully continuous process, as well as ensuring product processing adaptability for multi-product use, the DLR installation had to incorporate continuous wet granulation, fluidized bed drying and tablet compression, as well as initial blending and final film coating of tablets, and include the option of dry granulation and direct compression as an alternative to wet granulation. The rig is also equipped for real-time release, incorporating multiple PAT points to monitor and characterize process intermediates and final product.

The process starts by blending the API with the excipients, dispensed using loss-in-weight feeders into a continuous inline blender. After initial blending, the machine can be configured so that the blend flows into a twin-screw wet granulator (wet granulation), a roller compactor (dry granulation) or directly into the second inline blender (direct compression). For wet granulation, the granules are dried in a segmented fluid bed dryer before being conveyed to the mill. For dry granulation, the milling occurs directly after granulation.

The final blend is then processed in the second inline blender and compressed with a GEA MODUL P press that is equipped with a punch-face lubrication system. This facilitates the production of high drug load tablets with “sticky” APIs while mitigating problems such as tablet picking and sticking. Tablet cores are coated in one of two ConsiGma® coaters.

The DLR employs ten PAT systems to monitor each unit operation, utilizing NIR, Raman and light scattering for particle sizing. Quality is assured after each unit operation and, ultimately, the process is enabled for real-time release testing (RTRt).

The first product that was developed on the DLR system has been approved by the FDA for commercial production.
ConsiGma® Continuous Granulation Line

Production-scale continuous high-shear granulation, drying and tableting

The ConsiGma® 25/50/100 is an innovative solid dosage production platform designed to achieve operational excellence in the pharmaceutical manufacturing Industry. Raw materials are converted into final dosage forms in development, pilot, clinical and production volumes using wet granulation in one continuous production line.

It replaces the time- and space-consuming batch-based unit operations and incorporates quality control in the production process, resulting in substantial cost savings and increased quality assurance.

Fast process development and improved technology transfer (no scale-up) significantly reduce time to market. Further advances include reduced resource consumption and process intensification.

Standard Scope of Supply

- One loss-in-weight (LIW) feeder for preblended materials
- Twin-screw granulator
- Post-granulation sampling system
- Liquid addition via peristaltic pump and mass-flow meter
- Six-segment fluid bed dryer
- Granule conditioning unit with mill
- External phase feeding (two LIW feeders) and blending
- MODUL tablet press with tablet checker, metal detector and deduster
Options

- Horizontal or vertical layout
- Post hoist for IBC feeding to LIW feeder
- Preblending station with up to six feeders and two linear blenders
- One additional LIW feeder to add individual raw materials into the granulator
- Diverter system to remove OOS material before and after granule conditioning unit
- Upgrades for solvent processing available (PSR and EX)
- Secondary liquid addition via peristaltic pump and mass-flow meter
- PAT integration
  - Loss-on-Drying (LOD) monitoring in the granule conditioning unit
  - Blend uniformity (BU) in the tablet press
  - Post-compression content uniformity (CU)
- Installation without tablet press possible (powder to granule)
- Optional roller compaction, direct compression and/or ConsiGma® coater
- Wash-off-Line/WIP (wetting in place)/CIP (assisted clean-in-place) options
- High containment solutions

Main Benefits

- No scale-up or tech transfer risk
- Reduced operational risk compared with batch
- Minimal operators required
- Lower risk of OOS product
- Less operational cost (less space, no work in progress, higher efficiency, etc.)
- Less personal protective equipment (PPE) required
- Higher overall equipment effectiveness (OEE)
- Higher yield (more consistent granulation process), less waste
- Up to 70% less GMP investment compared with traditional batch systems

Test Opportunities

The ConsiGma® technology can be tested at the GEA Pharma Solids Center (GPSC) in Wommelgem, Belgium, or at our partner labs at the university of Ghent, Belgium, and at RCPE in Graz, Austria.

As well as production-scale equipment, R&D-scale plant for early development and feasibility studies is also available at the GPSC.

<table>
<thead>
<tr>
<th>Dimensions</th>
<th>CTL 25</th>
<th>CTL 50</th>
<th>CTL 100</th>
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</thead>
<tbody>
<tr>
<td>Maximum height</td>
<td>6 m</td>
<td>6 m</td>
<td>10 m (three floors)</td>
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<tr>
<td>Maximum width</td>
<td>10.4 m</td>
<td>10.4 m</td>
<td>13 m</td>
</tr>
<tr>
<td>Maximum depth</td>
<td>8 m</td>
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<table>
<thead>
<tr>
<th>Technical and Process Data</th>
<th>CTL 25</th>
<th>CTL 50</th>
<th>CTL 100</th>
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</thead>
<tbody>
<tr>
<td>Nominal throughput</td>
<td>25 kg/h</td>
<td>50 kg/h</td>
<td>100 kg/h</td>
</tr>
<tr>
<td>Throughput limits*</td>
<td>5–40 kg/h</td>
<td>10–80 kg/h</td>
<td>20–160 kg/h</td>
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<tr>
<td>Amount of product in process (granulator)*</td>
<td>Less than 10 g</td>
<td>Less than 20 g</td>
<td>Less than 40 g</td>
</tr>
<tr>
<td>Nominal size drying package</td>
<td>0.5–1.5 kg</td>
<td>1–3 kg</td>
<td>2–6 kg</td>
</tr>
<tr>
<td>Maximum airflow dryer</td>
<td>500 m³/h</td>
<td>1000 m³/h</td>
<td>2000 m³/h</td>
</tr>
</tbody>
</table>

* Depending on product characteristics
The ConsiGma® Continuous Direct Compression (CDC) is a compact, all-in-one, tablet production line for direct compression formulations, meaning that the dispensing area, blending area and intermediate storage requirements are a thing of the past. Up to six ingredients can be fed separately via specially developed loss-in-weight (LIW) feeders and, thanks to the integration of the feeding, blending and compression operations, segregation issues are eliminated.

Proven blending technology results in minimized start-up and shutdown losses and the unique GEA Air Compensator compression technology offers extended and controlled dwell times, accurate weight management and minimal variability in critical tablet quality attributes (an automatic tablet sampling and analysis system is also available).

The modular design allows for containment, Wash-off-Line (WOL) cleaning and fast product changeover. The system complies with the latest QbD guidelines (ICH Q8, Q9, Q10) and is fully compatible with the latest developments in co-processed materials and DC-specific excipients with enhanced compression characteristics.

**Standard Scope of Supply**

- Six LIW feeders (GEA Compact Feeders)
- Two linear blenders
- MODUL S tablet press
- Fully integrated system in one enclosed unit
- Embedded quality management system
- Wash-off-Line (WOL)

**Options**

- PAT integration
  - Blend uniformity
  - Tablet properties and content uniformity
- Containment upgrade available
- Wetting-in-Place (WIP)
- Various material handling options, such as pneumatic transport, gravity feeding, split butterfly valves, etc.
- Access to all GEA Compact Feeders options

**Main Benefits**

- Up to 70% faster from R&D to manufacturing
- Less operational risk compared with batch processing
- Faster product release with fewer resources
- Reduced risk of OOS product
- Up to 70% less GMP investment compared with traditional batch systems
- Lower personal protective equipment requirements for operators
- Lower risk of exposure
- Wide pharmaceutical product application range
- Excellent investment value, low investment risk
- Reduced cost per tablet

**Test Opportunities**

The ConsiGma® for direct compression technology can be tested at the GEA Pharma Solids Center (GPSC) in Wommelgem, Belgium.

As well as the direct compression line, a production-scale ConsiGma® granulation and drying system, including tableting and coating, is available for continuous wet granulation and drying trials at the GPSC.
CONSIGNMA® CDC 50 COMPLETES 120 HOUR TRIAL RUN

In conjunction with MSD, a tradename of Merck & Co., Inc., we’ve recently completed an extended trial run to assess the robustness of our ConsiGma® CDC 50 Continuous Direct Compression system at the GPSC. By the end of the 120-hour trial, more than 15 million tablets had been made using approximately 6200 kg of raw material in a single production area. Importantly, final analysis indicated that the campaign length could be increased even further and run for longer.

<table>
<thead>
<tr>
<th>Dimensions</th>
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<tr>
<td>Height</td>
<td>3350 mm</td>
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<tr>
<td>Width</td>
<td>4875 mm</td>
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<td>Depth</td>
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<tr>
<td>Volume: GMP area</td>
<td>120 m³</td>
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<tr>
<td>Volume: technical area</td>
<td>3 m³</td>
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<table>
<thead>
<tr>
<th>Technical and Process Data</th>
<th>CDC 50</th>
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</thead>
<tbody>
<tr>
<td>Nominal throughput</td>
<td>50 kg/h</td>
</tr>
<tr>
<td>Throughput limits*</td>
<td>2–130 kg/h</td>
</tr>
<tr>
<td>Amount of product in process*</td>
<td>±2.5 kg at 50 kg/h</td>
</tr>
</tbody>
</table>

* Depending on product characteristics
The ConsiGma® coater from GEA is a revolutionary, high performance tablet coating technology that gently and accurately deposits controlled amounts of coating materials onto tablet cores — even if they are hygroscopic or extremely friable (zero friability demonstrated).

The ConsiGma® coater is able to process both small and large quantities of tablets at very high suspension application rates. Improved heat and mass transfer offers fast drying times and improved process efficiencies.

PAT-compatible, the ConsiGma® coater is easy to clean and offers significant cost savings compared with conventional systems in terms of time, materials, downtime, process revalidation, stability testing, etc.

With a smaller technical space requirement than established technologies, less cleaning and a reduced plant area is needed. The ConsiGma® coater has a very low energy requirement and, being a continuous production technology, the concept of scale-up in film coating has now been eliminated; the maximum batch size is almost infinite.

### Features and Benefits

Incorporating a small, simple and modular design, tablet cores (from 3 kg upwards) are loaded into a perforated wheel and are formed into a ring by rapidly accelerating the wheel to high speed. Once the ring is formed, radially placed air knives induce the tablet cores into a stable, free-falling cascade, presenting the tablet cores to the coating suspension, which is sprayed in a vertical plane.

The drying efficiency is increased by spraying the coating suspension into the cascading cloud of cores. As such, the process is much faster, offering a target weight gain of 3% (15% solids content) in less than 10 minutes — compared with at least 90 minutes in a conventional process.

Plus, the predictable throughput and operating conditions — obtained through heat and mass balance modeling — ensure excellent color uniformity at lower weight gains. In addition, superior coating thickness uniformity can be achieved using less coating suspension, even for enteric and sustainable release coating formulations.

Offering both batch and continuous functionality, very short processing times and superior film-coat layer uniformity (see SEM image), the ConsiGma® coater is also able to accurately coat expensive modified release formulations using up to 60% less material.

### Technical and Process Data

<table>
<thead>
<tr>
<th></th>
<th>Single Coater</th>
<th>Twin Coater</th>
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<tbody>
<tr>
<td>Coater wheel width</td>
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<td>320.00 mm</td>
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<tr>
<td>Nominal throughput*</td>
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<tr>
<td>Typical size coating sub-batch</td>
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<td>6.00 kg</td>
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<tr>
<td>Typical coating time*</td>
<td>6 – 12 min</td>
<td>6 – 12 min</td>
</tr>
</tbody>
</table>

* Depends on process parameters, tablet and coating suspension characteristics
THE CONSIGMA® COATER — A REVOLUTIONARY, HIGH PERFORMANCE TABLET COATING TECHNOLOGY
Continuous R&D Solutions

A complete range of lab-scale equipment for solid dosage applications

During early research and formulation development, the availability of the active ingredient is often limited. As such, there is an absolute requirement for process equipment that is capable of producing just a few hundred grams of finished product to develop new drug formulations.

The ConsiGma® 1 and CDB 1 units offer the same patented continuous processing technology as the ConsiGma® production systems and are equipped with all the necessary equipment to optimize the process. As direct transfer of the process parameters to the production-scale ConsiGma® systems can be achieved, no scale-up is required. And, as the retention time of the product in the system is minimal, a change in parameters is almost immediately visible in the product. This enables the design space to be explored in a quick and easy manner.

The ConsiGma® platform combines Quality by Design (QbD) principles with Design of Experiments (DoE) to explore and optimize a wide range of process parameters with less product in a shorter time frame, resulting in a better understanding of continuous manufacturing.

A single CM line can be used to process any volume of product, from small quantities for formulation development and design of experiments (DoE), through to clinical trials and full-scale manufacture of new chemical entities and high-volume generics.

Product output is rapid, and volume can be adjusted according to need, such as in the event of major disease outbreaks, without the need for investment in costly new equipment or dedicated plant.
THE CONSIGMA® CONCEPT ENABLES SMALL AMOUNTS OF PRODUCT TO BE PROCESSED AND DEVELOPED QUICKLY AND EFFICIENTLY
**ConsiGma® 1**

Continuous High-Shear Granulation for More Efficient R&D

ConsiGma® 1 offers the same patented continuous high-shear granulator technology as the ConsiGma® 25 system and is equipped with all the necessary equipment to optimize the granulation process.

A small dryer — equivalent to one drying segment of the ConsiGma® production-scale dryer and capable of handling 0.5–1.5 kg of granules — can be added to the lab machine to create a unique combination with integrated controls to enhance your continuous processes. This allows you to develop your products on the same scale with quantities starting from a few hundred grams up to a few kilograms. The results are directly transferrable to the ConsiGma® 25.

**Standard Scope of Supply**

- Mobile standalone plug & play unit
- Twin-screw granulator (identical in design to the production-scale unit)
  - Horizontally split barrel allows inspection of the process
- One loss-in-weight (LIW) powder feeder
- Liquid addition with peristaltic pump and mass-flow meter
- User friendly operator interface

**Options**

- Fluid bed dryer segment to determine dryer parameters (batch sizes from 0.5 to 1.5 kg)
- Integrated Lighthouse Probe for online moisture monitoring in the dryer segment
- Upgrade for contained and solvent-based processing
- Hot melt granulation configuration
- Choice of Brabender or Ktron LIW feeders
- Choice of transparent or stainless steel dryer (ATEX reasons)

**Main Benefits**

- Cost-effective processing
  - Less API used in R&D
  - Minimized losses
  - No scale-up required
  - Decreased operational costs
  (less space, no work in progress, higher efficiency)
- Less risk
- No scale-up or tech transfer to production-scale unit
- Flexible batch size
- Fast changeover
- User-friendly controls
- Plug and play, ready to use
- Fast and easy exploration of design space
- Process parameters directly transferrable to production unit
FDA EMBRACES THE BENEFITS OF GEA’S CONTINUOUS TECHNOLOGY

Staying true to its mission of ensuring that safe, effective and high quality drugs are available for the American public, the US Food and Drug Administration (FDA) has recently purchased a GEA ConsiGma® 1 oral solid dosage development unit to conduct further research into continuous manufacturing.

Housed in the agency’s CDER/OPQ (Office of Pharmaceutical Quality), the “important asset” will be used by the Testing and Research and Emerging Technologies Team to support the development and adoption of novel technologies and modernize pharmaceutical processing and manufacturing.

The ConsiGma® 1 combines QbD principles with DoE to explore and optimize a wide range of process parameters with less product in a shorter timeframe, resulting in a better understanding of continuous manufacturing.

As such, research scientists and engineers can introduce cost-effective strategies that meet the pharmaceutical industry’s demands for faster product development, improved production economics and increased manufacturing flexibility.

Test Opportunities
The ConsiGma® 1 can be tested at the GEA Pharma Solids Center (GPSC) in Wommelgem, Belgium, at our test center in Maryland, USA, and at our Japanese agent’s lab (Euro-Techno) in Tokyo, Japan.

As well as lab-scale equipment, production-scale ConsiGma® granulation and drying systems, including tableting and coating, are also available at the GPSC.

<table>
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<table>
<thead>
<tr>
<th>Technical and Process Data</th>
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<tbody>
<tr>
<td>Nominal throughput</td>
</tr>
<tr>
<td>Amount of product in process (granulator)</td>
</tr>
<tr>
<td>Nominal size drying package</td>
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</tbody>
</table>
The ConsiGma® for Continuous Dosing and Blending (CDB 1) has been designed to explore and develop formulations consisting of 2–6 ingredients to facilitate process understanding during R&D with the minimal use of high value APIs.

The lessons learnt on the CBD1 can then be used to develop a direct compression formulation or a system for preblending the materials for a continuous wet granulation line.

**Standard Scope of Supply**
- Two to six loss-in-weight (LIW) feeders (Compact Feeders)
- One (exchangeable) continuous blender: 120 mm linear blender or a 70 mm linear blender on load cells
- Standalone unit
- User-friendly control system

**Options**
- Additional 120 mm linear blender
- Various material handling systems
- PAT measurement for blend uniformity
- GEA Compact Feeders for a wide range of products (even with poor flow properties)
  - Three gearbox ratios
  - Three sizes of outlet mesh
  - Asymmetric bridge breaker impeller
  - Static baffle in hopper
  - Three types of feeding screws
- Wetting-in-Place (WIP)
- Containment upgrade

**Main benefits**
- Up to 70% faster from R&D to manufacturing compared with batch
- Less operational risk compared with batch
- Faster product release with fewer resources
- Reduced risk of OOS product
- Up to 70% less GMP investment compared with traditional batch systems
- Lower personal protective equipment (PPE) requirements for operators
- Lower risk of exposure
- Wide range of pharmaceutical product applications
- Excellent investment value, low risk
- Low API consumption during R&D
- No scale-up
- High yield

**Test Opportunities**
ConsiGma® direct compression technology can be trialed at GEA Pharma Solids Center (GPSC) in Wommelgem, Belgium, and at our test center in Columbia, Maryland, USA.

**Dimensions**

<table>
<thead>
<tr>
<th>Dimensions</th>
<th>CDB 1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Height</td>
<td>2125 mm</td>
</tr>
<tr>
<td>Width</td>
<td>1700 mm</td>
</tr>
<tr>
<td>Depth</td>
<td>1625 mm</td>
</tr>
<tr>
<td>Volume: GMP area</td>
<td>20 m³</td>
</tr>
<tr>
<td>Volume: Technical area</td>
<td>0 m³</td>
</tr>
</tbody>
</table>

**Technical and Process Data**

<table>
<thead>
<tr>
<th>Technical and Process Data</th>
<th>70 mm</th>
<th>120 mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nominal throughput</td>
<td>10 kg/h</td>
<td>50 kg/h</td>
</tr>
<tr>
<td>Capacity limits*</td>
<td>0.5–25 kg/h</td>
<td>2–130 kg/h</td>
</tr>
<tr>
<td>Amount of product in process*</td>
<td>0.3 kg at 10 kg/h</td>
<td>1.5 kg at 50 kg/h</td>
</tr>
</tbody>
</table>

* Depending on product characteristics
SUPPORTED BY THE US FDA, PRODUCERS OF ORAL SOLID DOSAGE FORMS HAVE BEEN ENCOURAGED TO ADOPT CONTINUOUS MANUFACTURING TECHNOLOGIES TO MODERNIZE THEIR PRODUCTION INFRASTRUCTURE
Process Optimization with Digitalization

**PAT Possibilities**

Many people understand PAT to be the application of complex measurement tools on a production line. In our philosophy, however, PAT is not limited to this, and goes beyond this to the use of all data measured inline that may influence the product quality.

The system allows you to define certain process parameters as so-called Diverting Process Parameters (DPP) when they can influence the quality. The DPP can also be classified as PAT. Examples of such parameters are:

- powder feed factor(s)
- liquid addition (mass and density)
- torque measurement
- product temperature/drying curves
- air inlet/outlet temperature
- differential Pressure over filter
- rH dryer outlet
- mill temperature
- compression force.

Of course, we can integrate many online measurement tools to enhance the basic control system and actually measure certain critical quality attributes online, including moisture content, particle size distribution, blend homogeneity, content uniformity, coating quality and identity.

Examples of this include, but are not limited to a

- Lighthouse Probe equipped with an NDC spectrometer for moisture analysis after drying in the CTL 25
- Lighthouse Probe equipped with a DA-NIR spectrometer for measuring blend homogeneity before the tablet press, both in the CTL 25 and CDC 50
- PhAT Raman probe (Kaiser) for measuring coating quality in the ConsiGma® Coater.

**Control Philosophy**

For any continuous process, the control system is a critical component. Our continuous lines are monitored and regulated by an integrated system comprising a SCADA user interface, an automation layer and PAT tools that communicate with each other to ensure that the process is kept under control.

Process parameters and quality attributes are continuously measured or predicted to define the current state and quality of the product (normal operating range, proven acceptable range or out of specification).

To maintain the process parameters and quality attributes within set parameters and reduce process variability, the system is equipped with a low level feedback control loop and the option to implement advanced process controls (APCs). The user can implement multivariate controls or loops that cover multiple unit operations, including feed forward control, by overriding the recipe set-points of the designated critical control parameters (CCP) through the Dynamic Process Control interface (when the process parameters or quality attributes are between the warning and alarm limits).

To comply with regulatory guidelines, the system defines a batch according to the amount of product made. Each batch can be composed of different lots of finished product. To improve traceability and manage any recall if required, each batch/lot of raw material (input) is linked to specific finished product lots (output).
Customized Solutions for Specific Applications and Processes

We understand that designing a process line goes beyond basic manufacturing and must also include a wide range of other factors, such as containment, cleaning, sustainability and more. For every critical aspect, our engineers have developed solutions that match the requirements of a variety of specific products or applications.

During the sales process, we will help you to determine the most appropriate containment configuration, for example, based on a thorough risk analysis. Keeping the real operating conditions of the final installation in mind, GEA can determine what level of containment is required at each stage of the operation — assessing OEL levels, ADI, exposure risk, etc. — as well as optimizing the manufacturing process and making it efficient, safe and cost-effective.

We also offer a number of different cleaning concepts, such as WIP, CIP and WOL, which will be evaluated to ensure that the most suitable solution for your facility is selected and installed. In addition, our engineers will also consider environmental issues in the design of your equipment. If you’re working with organic solvents, for example, they will design the plant to eliminate solvent exhaust in a cost-efficient manner.

Working with GEA means partnering with a dedicated team of service experts. Our single goal is to help each customer to optimize their performance and productivity, improve their yields and output, and maintain a competitive edge.

From initial project analysis, design, engineering and equipment selection to plant commissioning, and from on-site operator/technician training to online support, maintenance and performance management, our service team and process performance experts will be with you every step of the way, for the entire lifecycle of every single piece of equipment in your plant.

**Customer-Specific Solutions for Every Application**

**Driving your future:** GEA's centers of excellence give you access to a full range of test facilities and teams of experts, all of whom work closely with our customers to optimize procedures and evaluate their products, enabling them to achieve their process and production goals.

A trusted supplier of plant and equipment, GEA offers manufacturers all over the world the opportunity to enter into a profitable partnership to develop products, processes and technologies.
The company combines advanced in-house technology with a thorough understanding of the processing industries to help customers maximize their development results, gain more know-how and discover additional opportunities for their applications.

**Driving solutions:** From cost assurance and process optimization to real-life simulations and test and loan machines, we provide a unique range of services that are designed to enhance production and expedite time-to-market. Your needs are critical and individual; our worldwide test centers have been created to meet those needs.

And, from new product and feasibility trials to scale-up studies, training programs and process support, we believe that our services greatly benefit anyone involved in industrial R&D, equipment selection, process optimization and product development.

**Driving technologies:** At our technology centers, you, the customer, can test any unit operation, from lab to pilot scale, or perform comparative process studies with our skilled operators by testing complete process trains. In addition, you can rely on a permanent staff of experienced engineers, technicians and industrial pharmacists who can assist you with any production problems, new developments and the modification of GEA technology to meet your needs. Our personnel remain constantly up to date with the most recent developments in the industry to be able to provide you with the best assistance possible.

By overcoming technical barriers throughout the entire process chain, there’s no limit to where GEA’s global network of test centers can take your research.
Collaboration Facilitates Continuous Manufacturing

Working together to make a difference

By collaborating with industry peers, GEA is leading the way towards smaller, more flexible continuous processing technologies that have the potential to transform the future of pharmaceutical development and manufacturing — and deliver customized quantities of drugs to patients in need in a quick and efficient way.

There are many hurdles to negotiate when a company in the pharmaceutical industry decides to adopt continuous manufacturing. And whereas GEA can supply a wide range of process technology solutions, we don’t have the skills or capabilities in every service area to solve all the problems that might arise.

To overcome these issues, GEA has initiated a number of industry collaborations with key suppliers to the pharmaceutical sector to facilitate the uptake of CM technology in the drug production sector. We believe that businesses should work together to overcome the various challenges involved in adopting continuous manufacturing. If, for example, a GEA customer requires some initial material characterization test work — such as flowability analysis to assess whether a powder can be processed — that’s not something we offer; but, it’s a service that an academic institution such as RCPE can provide.
To cite another example, continuous manufacturing generates a huge volume of data, which can be quite daunting at first. In such a situation, GEA would recommend a PAT management system, such as Simatic Sipat from Siemens. A considerable amount of work has been done in computer modeling to predict how a powder or product will behave within a process. One of the main benefits is that it reduces the amount of actual physical testing you need to do during development, which massively reduces the overall cost because the quantity of API required is much less.

The move from batch-based processing to continuous manufacturing is complex, but a fundamental aim of these collaborations is to highlight that there are people available to help our mutual customers — both old and new — to negotiate the various obstacles and provide assistance — from justifying the business case to process development and testing, right the way through to supplying the equipment, control systems and modelling software — where and when they need it.
Collaboration Facilitates Continuous Manufacturing

The key message is about companies, such as those listed below, working together to help the pharmaceutical industry overcome the different challenges involved in adopting continuous manufacturing.

- **Accenture**: a leading global professional services company providing a range of strategy, consulting, and technology solutions
- **G-CON Manufacturing**: designs, produces and installs prefabricated, autonomous cleanroom PODs for the pharmaceutical and biopharmaceutical industries
- **Leistritz**: a developer, manufacturer and marketer of engineered products for the process and pharmaceutical industries
- **MG2**: technology leaders in capsule filling
- **Perceptive Engineering**: delivers intelligent monitoring and control systems to clients across the world
- **RCPE**: performs cutting-edge research in the field of process and product optimization
- **Siemens**: one of the world’s largest producers of energy efficient, resource-saving technologies.

Accenture, for example, are already active in the pharma CM sector and fully understand that making the change from batch-based production is not just about the process; it’s also about logistics, footprint, utility costs, etc., which they can assess and review, and compile a business case to advise how much money a company might save by investing in continuous technology.

From a technology perspective, Leistritz has worked in twin-screw processing in many different industries for decades. Similarly, there are customers out there who are keen to use continuous processes for capsule-based products. Whereas GEA has its own tablet compression technology, we are happy to work with capsule filling experts such as MG2 to meet the needs of companies wishing to exploit the benefits of CM for other dosage forms.

By collaborating with industry peers, GEA is leading the way towards smaller, more flexible continuous processing technologies that have the potential to transform the future of pharmaceutical development and manufacturing — and deliver customized quantities of drugs to patients in need in a quick and efficient way.

With ConsiGma®, GEA offers a state-of-the-art CM solution and is committed to making science work. But, we can’t do it all. These collaborations are all about a group of companies who are willing and able to co-operate in a particular area of business for the greater good of the pharmaceutical industry and, above all, the patient.”
All the companies we work with have been actively building collaborative partnerships with providers of complementary technologies and solutions. This is allowing us to deliver the services and infrastructure that our customers need to be able to implement continuous manufacturing.

**Investing in the Future of Pharma**

GEA recognizes the important role that training plays in the proper use of its equipment. Whether the need is theory, general operational training or tuition on a specific process, GEA can help you to learn to use our technology to the fullest.

To support the needs of our customer base, regular training courses are scheduled at the GEA Pharma Solids Center (GPSC). Opened in May 2017, the GPSC in Wommelgem, Belgium, represents our continued commitment to and our ongoing support for the current and future pharmaceutical industry.

From cost assurance and process enhancement to real-life simulations and test and loan machines, we provide a unique range of services that are designed to improve production and expedite time to market. Custom classes can also be arranged, either at the customer’s own facility or at the GPSC. Currently available courses include:

- Understanding Continuous Processing
- Successful Tableting: How to Achieve Operational Excellence
- Tableting Technology Seminars (operator, technical and process level)
- Customized training, etc.

With facilities all over the world, GEA’s centers of excellence provide access to a full range of test facilities and teams of experts, all of whom work closely with their customers to optimize procedures and evaluate their products, enabling them to achieve their process and production goals.

...COMPANIES WORKING TOGETHER TO HELP THE PHARMACEUTICAL INDUSTRY OVERCOME THE DIFFERENT CHALLENGES INVOLVED IN ADOPTING CONTINUOUS MANUFACTURING
Taking the pharmaceutical industry further, faster, the GEA Pharma Solids Center (GPSC) represents our continued commitment to and our ongoing support for the current and future drug production sector.

Providing a full range of batch and continuous manufacturing technologies, the GPSC also offers process optimization, real-life simulations and test and loan machines, all of which are designed to improve production and expedite time-to-market.

The GPSC Offers
- customer demonstrations and trials on our batch and continuous equipment
- training sessions and classes
- hands-on laboratory experience
- pharmaceutical product development assistance
- CQA evaluation support
- testing of new concepts (equipment and advanced controls)
- scale-up from laboratory to production (1:10)
- process development/refinement to increase the understanding and capability of GEA equipment.

The company combines advanced in-house technology with a thorough understanding of the processing industries to help customers maximize their development results, gain more know-how and discover additional opportunities for their applications.

GEA’s centers of excellence provide access to a full range of test facilities and teams of experts, all of whom work closely with their customers to optimize procedures and evaluate their products, enabling them to achieve their process and production goals.

Continuous Processing Technologies
The GPSC enables you to investigate the possibilities that continuous manufacturing can offer for your production. In the GPSC, the following technologies are available for testing.
- Continuous Tableting Line CTL 25
- Continuous Direct Compression line CDC 50
- Off-line Compact Feeder CF
- ConsiGma® 1
- ConsiGma® Coater

To discover more or organize a test, demonstration or training session, contact our dedicated, passionate and experienced team. With a long history of solid dosage form expertise, including more than 125 formulations on CM equipment, everyone at the GPSC is committed to going the extra mile to meet customer expectations. Wherever you are in the world, whatever your application, we’ll take you further, faster.
WE HAVE THE EXPERIENCE AND EXPERTISE TO TRANSFORM A WIDE RANGE OF TECHNOLOGIES AND PROCESSES INTO VIABLE SOLUTIONS
The Final Piece of the Puzzle

Conti-specific solutions for contained materials handling

It might not be the first thing on your list of critical issues to consider when implementing a continuous manufacturing solution — and some might argue that it’s often something that gets forgotten — but contained materials handling is a vitally important aspect of ensuring the efficiency, productivity and, above all, the safety of your entire line.

Although some comparisons can be drawn with batch processing, continuous manufacturing (CM) poses a number of unique materials handling challenges. In particular, material logistics is a key consideration on long runs, especially if the formulation is supplied as a pre-blend. Often, the materials handling equipment (MHE) will need to interface with the CM line when the associated intermediate bulk container (IBC) systems are docked/undocked or being actively weighed. Furthermore, the MHE may also need to interact with other non-CM equipment on site and, for highly potent applications, it will need to cleaned safely. Having upfront conversations with your supplier to address these issues is key to any successful CM installation.

For example, process steps such as weighing, dispensing, feeding the granulator and washing the IBCs should not be overlooked. When planning a CM line, whether that incorporates blending, wet granulation and/or dust-producing exercises such as compression, for instance, MHE should be a prominent feature of your implementation strategy from the very beginning.
Another significant element of CM, however, is the elimination of scale-up; this means that the MHE element will need to accommodate a wide range of volumes, from smaller pilot-scale production runs to larger clinical production requirements and full-scale manufacturing. Understanding the entire process is fundamental to installing the right MHE solution for your application.

**How much containment?**

Of paramount importance is identifying and choosing the required level of equipment; containment performance is not simply a matter of measuring the Occupational Exposure Limit (OEL) of the product. This is a common misconception and, as a result, there is a tendency within the industry to over specify. Selecting an overly complicated solution means that the system is more difficult to operate, difficult to clean and maintain and, of course, more expensive to buy. It can be problematic to show that a particular solution is “good enough,” but it can be done. By understanding containment and looking at the product, the operator and the equipment, GEA can create well-engineered and better-value solutions that are bespoke, reliable and robust.

For CM in particular, contained materials handling should not be an afterthought or treated as a commodity element of the plant or process. No matter whether you’re working at R&D or production scale, from the ConsiGma® 1 to the CDC 50, contained materials handling is a fundamental aspect of the entire line and facility.
Batch Processing

If continuous manufacturing isn’t a current requirement or you’re looking to implement highly efficient batch production at any scale, we can help with that too.

From powder to coated tablet and from R&D to full-scale manufacturing, no other supplier offers such a comprehensive range of batch technologies for oral solid dosage form production.

Whatever your application, no matter how challenging, GEAs contained powder handling, granulating, drying, compression and coating solutions will meet and exceed your individual requirements.

Designed with integration in mind, you can select from a variety of standard process modules to suit your project needs.

Granulation

In the pharmaceutical industry, tablets remain the most commonly produced oral dosage form; most fine pharmaceutical compounds require granulation to improve their flowability and processing properties before tableting. As such, granulation, which allows primary powder particles to adhere and form granules, is one of the most important unit operations in drug manufacturing.

A number of different granulation and compression technologies are available to pharmaceutical manufacturers, all of which have individual strengths and weaknesses depending on the specific application. However, the theory of granulation is often poorly understood, and the selection of a particular machine and granulation method is frequently made on the basis of tradition and the operator’s experience, rather than by using strict scientific or cost-benefit criteria.

Whatever your application or requirement, every granulation and drying plant from GEA is a unique union of proven technology and individual solutions. Based on standard components, we supply plants for cGMP production that are configured to meet the customer’s specific requirements.

Successful Tableting

As a single-source supplier of state-of-the-art tableting technologies, our innovations include a unique dual control, PAT-compatible technology that monitors and controls tablet weight, hardness and density with an accuracy that cannot be achieved any other way.

Weight is controlled at pre-compression and hardness is controlled at main compression. As a result, weight and hardness can be controlled simultaneously and continuously on a standard tablet press.

GEA also offers adjustable dwell times at pre-compression (by up to 300%) without slowing the press: this functionality allows an increase in dwell time at pre-compression that’s independent of machine speed, resulting in higher outputs and more consistent tablet quality.

In addition, constant dwell times with adjustable compression speeds can be used to match the production capacity of the line without influencing tablet quality. Other unique features ensure a constant flow and equal distribution of powder that are without equal, as well as integrated data collection and analysis, and advanced process control.
Materials Handling

GEA is a trusted supplier of material handling equipment with significant expertise in containment and the provision of integrated solutions to the global pharmaceutical and healthcare industries. Taking an individual approach to each customer’s needs, and applying our extensive experience and know-how, we combine performance excellence with technological innovation to deliver long-term competitive advantages.

With thousands of installations worldwide, GEA has developed an outstanding reputation for quality and service to become the clear leader in contained materials handling technology, including powder handling, intermediate bulk container (IBC) systems, containment valves, container systems, in-container blending, tablet handling and IBC washing.

Our distinctive specialization lies in the integration of BUCK® containment technology into complete solutions for pharmaceutical solid dosage form facilities.
GEA Service – For your continued success

GEA Service partners with our pharma customers, supporting them throughout the entire lifecycle of their plant and equipment to ensure business success. To guarantee optimum performance and operational excellence, we provide a wide range of services to maintain and improve your plant and equipment.

Getting you started: seamless support for instant productivity and performance
From installation onwards, our GEA Service teams will work with you to get the best out of your plant and equipment. As a supportive and committed partner for life, we start as we mean to go on.

We plan and build according to individual needs, sharing process knowledge, training staff and supporting operators to get you up and running and deliver a smooth, seamless and ongoing service for optimum performance and safety.

Keeping it running: the cost-efficient way to ensure safety and reliability
Regular maintenance is not a cost, it’s an investment. By implementing corrective and preventive maintenance techniques, we ensure high performance, availability and quality — as well as maximizing the lifecycle of your equipment or plant.

To ensure you benefit from continuous production and minimal downtime, we provide fast support and top quality spare parts, whenever and wherever they’re needed.

Constantly improving: sharing our knowledge to safeguard your investment
To meet your production requirements — today and tomorrow — GEA works with you to keep your equipment up to date and optimized.

We safeguard your investments by constantly looking ahead, by upgrading or modernizing equipment and enhancing processes to meet changing needs and new market demands. We are always working to increase production efficiency and ensure peak performance.

Together with you: enduring commitment to you and your business
By integrating the latest automation and control solutions, we boost your output and efficiency, reduce waste and minimize both resource use and the need for manual intervention.

Our commitment to you and your business means investing in your objectives, your risks and your future success. We collaborate with you to provide ongoing systems audits and on-site support, and to generate improved performance through innovative new service models.
PROCESS OPTIMIZATION

By integrating the latest automation and control solutions, we boost your output and efficiency, reduce waste and minimize both resource use and the need for manual intervention.
GEA is a global technology company with multi-billion euro sales operations in more than 50 countries. Founded in 1881 the company is one of the largest providers of innovative equipment and process technology. GEA is listed in the STOXX® Europe 600 Index. In addition, the company is included in selected MSCI Global Sustainability Indexes.

We live our values.
Excellence • Passion • Integrity • Responsibility • GEA-versity

GEA Group
Keerbaan 70, B-2160
Wommelgem, Belgium
Tel +32 3 350 1211
Fax +32 3 353 2055
gea.com/contact