GEA Pharma Systems

Containment Technology

engineering for a better world
GEA Pharma Systems – Know-How on a Global Scale

GEA Pharma Systems is part of the Process Engineering Segment of the GEA Group. It specialises in the supply of advanced technologies for the preparation and processing of Active Pharmaceutical Ingredients (APIs) for the production of oral and parenteral dosage forms.

Trusted brands
GEA Pharma Systems combines trusted technology with a continual programme of innovation aimed at maintaining price/performance leadership for its pharmaceutical manufacturing customers. The GPS scope of supply is recognised worldwide through its well established and globally known brands: Aeromatic-Fielder™ and Collette™ – batch and continuous granulation, drying, pelletizing and coating; Buck® – contained materials handling; Courtoy™ – tablet compression; Lyophil™ – pharmaceutical freeze drying and automated vial handling systems; and Diessel™ – fermentation and liquid formulation.

Local supply and technical know-how
The organisation includes manufacturing and technology centres in Belgium, Denmark, Germany, Switzerland, the UK, Singapore and the USA, and additional manufacturing facilities worldwide including India and China. Based at these centres, the organisation provides a wide range of services for the pharmaceutical industry including local manufacturing and supply, test facilities for product development and process evaluation, project management and ongoing support – all backed by GEA’s unique experience and technical know-how.

Partners for productivity
GEA Pharma Systems works closely with its customers to develop new products, reduce time to market and enhance clinical effectiveness. This can include the supply of R&D-scale and standalone production equipment, through to the installation of complete integrated production lines and continuous processing technology that will maximise operational reliability and productivity while providing unrivalled flexibility and unbeatable total cost of ownership.
Containment is an issue in 9 out of 10 cases of solid dosage form production.

**Why?**

Containment issues are becoming an increasingly important aspect of solid dosage form production. Active pharmaceutical ingredients (APIs) are becoming evermore effective, with more than 50% of all new chemical entities (NCEs) being classified as potent (OEL <10 µg/m³); at the same time, the health and protection of operators, all over the world, is being put under an increasingly intense spotlight. In addition, navigating the maze of available hardware components and the huge variety of containment solutions has made it progressively more difficult to select the most appropriate equipment for the specified task: suppliers of various hardware components have developed a huge variety of containment solutions, making it difficult to decide on the optimal solution, even for experienced people.

**Containment Experts**

GEA Pharma Systems has a long history of expertise and an unparalleled depth of experience in the field of containment. The company not only offers a comprehensive range of robust and compliant containment products, it also boasts unrivalled experience in identifying the most appropriate solution and a thorough understanding of containment risk analysis. We don’t just know about containment, we live and breathe it.

**Buck® Technology and SMEPAC**

GEA was fundamentally involved and worked with an international working group to create a guide to containment testing. Now published by the International Society for Pharmaceutical Engineering (ISPE) and known as SMEPAC (Standardised Measurement of Equipment Particulate Airborne Concentration), this guide defines the test processes and parameters needed to assess the different levels of containment required throughout a plant. Keeping the real operating conditions of the final installation in mind, GEA Pharma Systems can determine what level of containment is required where, optimizing the manufacturing process and making it efficient, safe and cost-effective.
The production of oncology drugs, hormonal products and/or other highly potent compounds requires particular attention: it is essential to avoid exposure of the operators to the drug as well as prevent the cross-contamination of other products manufactured in the same facility.

Contained Materials Handling Expertise
GEA Pharma Systems specialises in contained materials handling solutions for primary and secondary pharmaceuticals and healthcare companies. With Buck Systems™ and BUCK® high containment split butterfly valves, we offer a wide range of technologies and equipment that improve and enhance the efficiency and performance of solid dosage form plants for the safe transfer of powders. We know what level of containment is needed where.

With a long-established pedigree of expertise and implementation, GEA equipment and technologies meet the very stringent demands of production performance, plant and market flexibility (single and multi-product) and, of course, value. With worldwide experience and market-leading credentials, we have developed an outstanding reputation for quality and service to become the leader in contained materials handling.

Dispensary Handling Expertise and Management
The Buck Systems™ range of modular dispensing solutions ensures simple, ergonomic operation and consistent flow whilst effectively controlling the dispensing process. The control system integrates the process with the recipe management system to provide batch data security and traceability for validation purposes.

Additional features such as removable hoppers and supplementary extraction provide increased safety for operators and facilitate cleaning. Solutions range from single-level, simple application solutions to multiple-level, integrated dispensary management systems. Bulk ingredient dispensing includes fully automated excipient dosing or interfacing with bulk ingredients for high containment. Active Pharmaceutical Ingredients (APIs) can be dispensed into a contained charge vessel, which can then be safely transported to the point of use within the plant.
IBC Blending

Flexible blending solutions

Container blending as part of an intermediate bulk container (IBC) system has long been established as the most efficient method of blending granules and powders in pharmaceutical manufacturing. R&D, small-scale and full-scale pharmaceutical production blenders enable contained process technology transfer during scale-up, minimising process validation activity.

This is fully supported by Buck®’s detailed research programme and testing facilities. Hoist- and pedestal-mounted versions are available, as well as through-the-wall designs that offer significant room layout benefits.

Vibroflow™

Prevents product segregation

Vibroflow™ technology allows IBCs to discharge poor-flowing product in a reliable and repeatable manner. With product containment and operator safety being of paramount importance, it is no longer acceptable for operators to intervene and open the IBC to remove blockages. Vibroflow™ is a proven discharge technology that has been thoroughly tested by leading pharmaceutical manufacturers and installed successfully in a number of primary and secondary API plants.

Containment Project Case Study

Direct Compression of Hormonal Tablets

Wishing to maximise the solid dosage production of a highly potent hormonal product, a leading drug manufacturer tasked GEA Pharma Systems with significantly increasing their output, providing a safer and more efficient factory environment and introducing new systems that would replace the existing isolator-based process.

The challenge for GEA Pharma Systems was to use their product flow and containment expertise to remove as much isolator-based processing as possible, making the production flow more efficient, whilst maintaining the high levels of containment and operator safety required. Another key factor was maintaining blend homogeneity.

GEA first demonstrated a patented high containment system, the Courtoy™ MODUL™ S rotary tablet press with a wash-off-line (WOL) Exchangeable Compression Module (ECM). GEA also demonstrated the use of multi-tip tooling: using two tips per punch (station) doubled the tablet press output. A specially designed feeder and dedicated software ensure optimal output. GEA then demonstrated their ability to successfully blend the low levels of API with poor-flowing excipients. This was achieved using the Buck Systems™ blending Prism™ technology, a very effective aid to the bin-blending process.

The new system was fast tracked; the preliminary details were agreed within 4 months and the equipment was delivered less than one year after contract signing. Removing much of the isolator-based processing and expanding into the new factory space will enable a significant increase in both batch size and yield and improve the overall working environment.

What level of containment do I need?
Feeding the Granulation Process

Process flow interfaces for the granulation area

The effective and safe transfer of both excipients and active ingredients is essential. A number of options are available:

Gravity feeding: Gravity loading through a discharge station from above or via a post hoist are ideal solutions, ensuring containment and simplicity of cleaning. API discharge vessels can be used to deliver more potent formulations directly into the granulator.

Vacuum feeding: When room height is a limiting factor, a contained vacuum station can be used: incorporating containment valves that improve airborne dust levels, they can help to reduce area classification categories. Safety levels can also be improved by combining interlocking containment valves with a nitrogen purge system.

Unloading granulation equipment: In-line sieving or milling before the granules are loaded into a container can facilitate the process. A lubricant or other materials can then be added (often done using charge containers or Hicoflex® bags) and blended with the granules.

Granulation

Designed for integrated containment

GEA Pharma Systems specialises in the design and manufacture of fluid bed and high-shear granulation technology and is uniquely qualified to provide integrated, state-of-the-art high shear mixer-granulator and fluid bed drying solutions. A modular approach means that customers can select standard process modules to suit their project needs. Fluid bed dryers and coaters can be combined with high shear mixer-granulators, wet and dry milling facilities, product handling systems, binder and coating preparation units, and filtration units, all of which have been designed for use in fully contained integrated systems. Safety, product flow and building requirements are built in for full integration and optimal process efficiency.

Single-pot processing: By definition, a single-pot process is contained, making it the first choice for the granulation of highly potent compounds. No transfers are required between process steps, except to load the raw materials and unload the dry granules. This not only protects the operators from exposure to potent products, it also protects the products from external factors such as heat, light and moisture. Specific solutions are available for product loading and discharging to achieve the desired level of containment for the whole process.
Can I improve tablet press changeover times, even when compressing potent actives?

MODUL™ tablet press
When dealing with highly potent substances, owing to the complex geometry of tablet presses, compression is the most challenging stage of the tablet manufacturing process. All MODUL™ tablet presses are based on the Courtoy™ Exchangeable Compression Module (ECM) concept. The ECM is a small and completely isolated section in the machine; it contains all product contact parts and can be quickly and easily removed from the press in a contained way. This means that the press itself remains powder-free and requires no cleaning. The Wash-off-Line feature allows the ECM to be washed and cleaned away from the machine without any risk to the operator or environment.

This is the only concept that combines containment with productivity. Whereas, in the past, tablet presses were out of operation for 8–12 hours for cleaning (manual or wash-in-place), Courtoy™’s ECM technology means that a full product changeover can be achieved in less than 2 hours. All product contact parts are contained in an isolated dust-tight module, which can be disconnected and removed in minutes. Another clean and prepared Wash-off-Line ECM can then be installed and the tablet press is ready for a new product. Off-line washing and cleaning is done away from the tablet press area, allowing the machine to do what it has to do – make tablets.

Oral Solid Dosage Case Study: Zydus Cadila

When GEA Pharma Systems supplied a complete oncology manufacturing line to a customer in India, they didn’t just ensure the health and safety of the operators – complying with internationally recognised standards – the company also increased yields, reduced production cycle times and implemented an ultimate containment solution.

Zydus Cadila intended to improve its solid oral dosage form production processes for highly potent drugs. Planning to use high containment equipment, the company approached GEA Pharma Systems.

GEA Pharma Systems recommended the use of two single-pot processors in a set-up that met all the key requirements: for the development laboratory, an UltimaPro™ 10 equipped with Hicoflex® technology for containment; and for production, an UltimaPro™ 75 equipped with Hicoflex® and MC valves. Both single pot processors were equipped with all the available drying techniques, including microwaves, to ensure flexible processing, higher yields and shorter cycle times.

GEA Pharma Systems was able to supply the company with a complete oncology manufacturing line. The entire project was managed in-house, beginning with a risk analysis regarding the amount of containment required, progressing through the overall design of the building and solution to installation and start-up. By choosing the UltimaPro™ 10 and 75, equipped with all the available options, and with Hicoflex® technology and MC valves, Zydus Cadila has ensured that it will be able to produce their OEB 3 and 4 drugs in a safe, cGMP-compliant environment and guarantee maximum yields with reduced cycle times.
System Integration with Containment Interfaces (loading/unloading)
Our distinctive specialisation lies in the integration of the BUCK® containment technology into complete solutions for pharmaceutical solid dosage form facilities. With an emphasis on quality and good manufacturing practice (GMP) standards, we are committed to working together with our customers to deliver first-class tailored solutions for projects of all sizes and complexity. With worldwide experience, GEA has developed an outstanding reputation for quality and service.

BUCK® Valves
*High containment valves for the pharmaceutical industry*

BUCK® is the market leading supplier of split butterfly valves and contained docking systems for the transfer of powders. The BUCK® range of containment products includes the split butterfly valve for solid containers use and the unique Hicoflex® disposable containment system.

As pioneers of the split butterfly valve, BUCK® has been actively involved in many powder containment Communities of Practice, particularly in the development of ISPE’s SMEPAC guidelines for evaluating containment equipment and in the risk-based approach to the selection of containment equipment. The BUCK® MC Valve (Modular Containment) split butterfly valve builds on the proven design principles of the first generation of split butterfly valves and offers a number of key additional features and benefits.
Case Study: Penn Pharma

Fully integrated, high-containment, contract drug development and manufacturing.

After conducting extensive market research, Penn Pharma identified an increased need in the solid dose oncology market for the outsourced development and production of highly toxic drugs. Its production site had been manufacturing potent solid dosage products for more than 20 years but needed additional capacity.

Penn Pharma elected to work with GEA Pharma Systems because of its proven track record in containment technology and expertise in creating fully integrated production lines. GEA’s approach was to eliminate the use of isolation suits in favour of containment interfaces (BUCK® MC high-containment valves and Hicoflex®).

The new plant now includes the first commercial PharmaConnect® “through the wall” system in Europe. The contained R&D line for wet granulation also includes the dispensing of excipients and potent powders, GEA’s PMA 150 and FlexStream™ 1000 for granulation and drying, dry milling, granule collection and blending, tablet compression using a MODUL™ P tablet press with a Wash-off-Line ECM (exchangeable compression module) and pellet coating.

The plant also has a contained R&D line for direct compression and a separate production line that offers containment interfaces for powders, API and excipient dispensing, dry milling and powder collection and blending. Penn Pharma is now a single source for the development and production of highly toxic drugs at one of the world’s most advanced and efficient plants. The project has significantly increased their capacity and the company can now manufacture approximately 500 additional batches during a standard two-shift operation.

Features of the BUCK® MC Split Butterfly Valve

- Unique passive-to-passive valve design with a centralised actuation collar; the passive valves freely orientate, reducing operator docking error
- Modular containment: with 1–10 µg/m³ containment level as standard, the system can easily be upgraded with an advanced air cleaning actuator to further improve containment levels to <1 µg/m³, allowing for reduced investment today with the flexibility for more potent products tomorrow
- Simple operation: the need for vacuum clamping between the valve halves has been eliminated
- Simple maintenance: fewer component parts and more identical parts owing to the passive-to-passive design, reducing spare part inventory
- Clean-in-place (CIP) or clean-out-of-place (COP) as standard
- Contained quick changeover of the contaminated valve core with working parts remaining on the station, allowing for extremely fast product changeover – fully complementing the Courtoy™ MODUL™ tablet press ECM containment concept!
- Robust docking: the new central actuator design overcomes potential misalignment from fabrication tolerances of the container and docking station.
Hicoflex® Disposable Containment

The Hicoflex® disposable containment system has been designed to provide a highly contained docking solution between the product handling bag and the process. The system is simple, effective and provides a safe working environment for a minimal investment.

Hicoflex® charge bag docked and open with sample bag:
Flexible disposable bags provide a number of benefits compared with solid containers for handling small quantities of material in a production or R&D facility. Benefits include the following:

• Lightweight and easy for a single operator to handle
• Flexibility to allow poor flowing materials to be manipulated out of the bag
• Disposable, so no cleaning or validation
• Low cost compared with solid transfer systems
• Full yield discharge
• No cross-contamination
• Instant high protection for operator and product
• Very fast installation
• Simple/fast materials handling
• Visual product transfer.

The Hicoflex® disposable containment technology consists of two identical couplings that are joined together to seal the external faces, thus enabling closed transfer. The Hicoflex® disposable containment system is opened by applying a compression force to both ends to create an opening through which product transfers. The Hicoflex® is attached to both a disposable containment bag (from 1–50 L) to transport material and to a disposable containment adapter that fits the inlet or outlet chute of the process to allow product transfer.

With containment performance from 1–10 µg/m³ (ST TWA), the system is more than suitable for both API and biotech manufacture, as well as secondary solid dosage production.
Contamination Free Sampling

BUCK® Sampler
Based on split valve technology, the BUCK® Sampler was specifically developed for gravity based process sampling applications in combination with commonly used product sampling equipment in processes such as like granulation and drying. The Sampler offers a fully contained sampling process, even maintaining a process-related pressure resistance during all stages of docking, sampling and undocking.

Disposable Hicoflex® Sampling Technology
The Hicoflex®-Sample Bag is a fully contained sampling device that enables a process sample or the bulk material in a Hicoflex® charge bag to be taken through an adaptor. Sampling volumes range from 1–10 mL.

Compression sampling
*Complete tablet production lines for potent/toxic drugs*
As powder in-feeding, tablet handling, sampling and tablet collection all have to be done under “high containment” conditions, it became imperative to design complete lines that also integrate the peripheral equipment, such as the powder discharge station, tablet deduster, metal detector, dust extractor and tablet analyser. Initially, the most commonly used technique was to build isolators around the equipment and provide wash-in-place capability. However, the latest design trend is toward at-source containment and off-line washing, as these concepts allow equipment to be smaller, easier to install and operate, and lower priced.

Sample Case Study
Servier, Ireland

*High-containment tablet compression*
Servier, Ireland, invested in three high-containment MODUL™ S tablet presses with WOL-ECM. The raw material is delivered in IBCs, which are lifted above the press with a post hoist. The material is fed into the press through a split butterfly valve.

A custom-designed high-containment Pharma Flex deduster (Pharma Technology Inc.) was installed for dedusting and to check for metal particles, including a buffer system that releases the tablets into an IBC after every combi tester tablet check.

Accepted tablets are collected in an IBC, which is connected via an SBV, whereas rejected tablets are taken to a closed bin.

A separate Kraemer-Elektronik washable high-containment Combi-Test tablet weight, hardness and thickness tester performs automatic tablet sampling and measuring for batch reporting and process control.
Integrated Cleaning

Process optimisation depends on efficient, effective cleaning. Automation of the cleaning process ensures repeatability, allows validation and minimises downtime. In recognition of the fundamental role played in today’s contained powder processing by automated clean-in-place (CIP) procedures, GEA Pharma Systems has developed a unique approach to CIP.

Concealed Services
The integrated design ensures that all lines and hoses for the utilities of the plant (water, electricity, hydraulics, etc.) are concealed. This creates a safe and uncluttered working space.

CIP and WIP Systems
More efficient cleaning is one of the key advantages of system integration. We provide validated cleaning with minimal downtime. GEA Pharma Systems offers CIP-by-design (patented) features in all of its processes. Every aspect of the integrated plant, from inlet to discharge, has been value-engineered for optimum cleanability. Spray system, tanks cleaners, nozzles and seals are an integral part of our equipment design.

In addition to providing complete containment plant services, the company also offers multi-functional wash skids that can be moved from one location to another and used to clean different parts of the process. Every plant delivered by GEA Pharma Systems has a tailor made WIP or CIP system that suits your process.

Easy and Safe Single-Pot Processor Cleaning
To verify the CIP approach, a cleaning validation study was done on a single-pot processor in the Process Development Centre, using both a water-soluble (theophylline) and a water-insoluble (mebendazole) material. The results showed that the CIP system is capable of removing both products to a level well below the generally accepted acceptance criteria.

Using the unique CIP approach, a product changeover can take place in 2–3 hours, reducing the downtime of the equipment (depending on the product characteristics and the cleaning programme used). As the whole CIP cycle can take place automatically, it is also possible to start the cleaning in the evening, allowing it to run overnight and prepare the equipment for a new production run in the morning.

IBC Washing
Although it is important to handle and transfer powders in a contained way to prevent operator exposure, it is equally important to be able to wash the IBC and the containment valves in place – without the need for operator intervention to strip and clean the valve. Any system that relies on the operator to remove a contaminated valve for cleaning will directly expose the operator to the product. All Buck® IBCs and their passive valves are designed to be fully cleaned-in-place within the Buck wash station.

Tablet Press Cleaning
The patented Wash-off-Line (WOL) concept improves on WIP/CIP solutions for tablet presses
With the MODUL™ tablet press Wash-off-Line (WOL) concept, Courtoy™ compression introduces a high-containment solution that has a low operational cost, is practical in use and offers the highest productivity. Thanks to its inherently closed design, the ECM model significantly reduces the concentration of airborne particles in the tablet compression room and contributes to the protection of equipment operators and supervisors.

After the WOL-ECM has been removed from the machine, it can be connected to a washing station in the cleaning area. The WOL-ECM features an ECM made out of corrosion-free materials and offers automatic, low water consumption washing using specially designed water jets. “Off-line” automatic washing offers considerable advantages compared with “in-place” washing, such as
- higher productivity
- low-cost, flexible implementation
- no risk of seal damage, protecting the electromechanical section of the press.
Do you have an automated cleaning system?
Off-line analysis is too slow. How can I optimise end-point detection?

Process Intelligence

The US Food and Drug Administration’s PAT (Process Analytical Technology) initiative has enabled GEA Pharma Systems to combine its equipment design skills and process engineering know-how to integrate online (PAT) analysers into its process systems in a way that provides real process operation insight and can help customers to achieve key product quality targets.

The goal of the PAT initiative is to ensure that pharmaceutical products are manufactured using processes that are understood and monitored – so that the key product quality characteristics can be actively controlled.

Combining online analysis/monitoring with solid process engineering principles and advanced modelling techniques will enable processes to be actively controlled to compensate for minor input variations (such as raw materials), so that final product specifications will be close to ideal.

Using process models that identify optimal conditions during specific production steps means that the whole production process can be optimized to improve the performance of the final dose, rather than just focusing on each unit operation individually. GEA Pharma Systems’ wide scope gives it a unique perspective on the complete process.

Lighthouse Probe™

After multiple tests with various customers and suppliers of optical measurement techniques in its labs, GEA Pharma Systems has developed the Lighthouse Probe™ in co-operation with J&M Analytik AG. The combination of GEA’s expertise in containment, automation and pharmaceutical processing and J&M’s expertise in optics has resulted in a robust and reliable probe with in-line calibration and cleaning capabilities.

The Lighthouse Probe™ is the only probe on the market that can clean its own observation window and recalibrate online. And, combining the online measurement capability of the Lighthouse Probe™ with the correct process models even enables real-time release and eliminates the need for sampling, further enhancing containment.

The Lighthouse platform ranges from manual to fully automated and is suitable for (and upgradeable from) R&D up to (continuous) production. It stretches from a standalone online LOD sensor to a completely integrated solution capable of using online multivariate models.
The last 20 years have seen a significant increase in the need for contained handling and processing in the pharmaceutical industry, driven by the development of more potent APIs and a stronger focus on health and safety by the regulatory authorities.

Established standards and practices in western countries are now being adopted in emerging geographies as mandatory procedures migrate from using PPE (personal protection equipment) to maintain operator safety to practicing containment at the source. The message has never been clearer: it is the first duty of the employer to protect the health of their staff. And PPE has been found to be inadequate during modern pharmaceutical drug production.

In addition, it is becoming increasingly apparent to manufacturers that the implementation of seamless containment solutions offers considerable housekeeping benefits, such as:

• faster changeover times owing to reduced (room) cleaning
• significantly decreased cross-contamination risks
• substantial savings (air filters, air suits, contaminated cleaning fluid, for example).

GEA Pharma Systems has pioneered contained material handling for many years and has been instrumental in developing state-of-the-art solutions. Examples involve:

• The GEA range of containment interfaces
  - the BUCK® TC (total containment) high performance split valve
  - the highly flexible BUCK® MC (modular containment) split valve
  - Hicoflex®, which has become a synonym for disposable containment in solid dosage manufacturing
• Vibroflow™ for reliable and repeatable powder/product discharging
• The Lighthouse Probe™, replacing offline IPCs with inline, operator-free PAT analysis.

Even for experienced manufacturers, however, the selection, placement and implementation of suitable containment equipment can be a daunting task; it requires an in depth understanding of the overall process, primarily to ensure that the chosen equipment performs at the necessary level, but also, from a financial point of view, to prevent any expensive and unnecessary investment into an over-performing solution.

GEA Pharma Systems not only offers the largest variety of robust and compliant hardware solutions for contained materials handling, it also boasts unrivalled expertise in identifying the most appropriate solution and a thorough understanding of containment risk analysis.

GEA Pharma Systems can assist and advise you to determine what level of containment is required where and when, optimizing the manufacturing process and making it efficient, safe and cost-effective. We provide tailor made containment for the pharmaceutical industry – for now and for the future. Contact us today to learn more about our extensive containment experience and discuss your specific project. We have the right solution for you.
We live our values.
Excellence • Passion • Integrity • Responsibility • GEA-versity

GEA Group is a global engineering company with multi-billion euro sales and operations in more than 50 countries. Founded in 1881, the company is one of the largest providers of innovative equipment and process technology. GEA Group is listed in the STOXX® Europe 600 index.

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