

A photograph of a pharmaceutical manufacturing plant. The scene is filled with complex machinery, including stainless steel tanks, pipes, and valves. A person in a blue uniform is visible on the left, walking through the facility. The image is overlaid with a large, semi-transparent blue diagonal shape that covers the bottom half and part of the left side. The text 'PROCESS SYSTEMS' is centered in white, bold, sans-serif font over the blue area.

PROCESS SYSTEMS

WALDNER



WALDNER QUALITY SETS THE STANDARD

Welcome to Process Systems and Hermann WALDNER GmbH & Co. KG. We are part of the global WALDNER Holding GmbH & Co. KG with about 1,400 employees, which has its headquarters in Wangen, Germany. The company was established in 1908 by Hermann Waldner.

Within this strong and continuously growing Group, WALDNER offers its customers process systems, vessels, isolators, cooking systems, packaging machines and systems for the food, chemical and pharmaceutical industries. WALDNER is also synonymous with laboratory furniture, which we design and fit across the world for scientific and technical educational institutions.

It's not just our employees who are familiar with all departments within WALDNER – WALDNER's various systems also dovetail with each other with ease. By way of example, WALDNER's cooking and packaging systems coordinate seamlessly with each other, in the same way that our process systems, isolators and laboratory furniture fit perfectly together.

You'll be in expert and experienced hands with Process Systems – from individual solutions to complete systems.

FROM A SINGLE UNIT TO A COMPLETE SYSTEM

From single vessels to complete custom-made manufacturing processes – you'll find everything according to your needs – from A to Z. Depending on your requirements, we can configure our products, including measuring, control and regulation technology, on a modular basis in all sizes and versions. In short: we are specialised in custom-made process solutions. Since we were established over 30 years ago, we have already supplied over 25,000 individual solutions worldwide.

Our cooperation with our customers begins with a professional consultation, followed by process development, design and execution of turnkey projects, to final qualification and our maintenance service. Your demands and requirements are crucial.

Our experience and expertise extends across the pharmaceutical, food, chemical and healthcare sectors, for which we offer the following:

- Skids & process lines
Skids and package-units for a fast and reliable commissioning and qualification on site. Thus you have fewer tests when setting up your unit on site. It's your choice: from individual CIP/ SIP units to complete preparation lines.
- Containment systems and isolators
Full containment systems to protect your employees with the contamination-free and safe handling of highly active and toxic substances (APIs) and isolators for sterile applications to protect your products.
- Vessels
Vessel technology, ranging from single preparation, pressure and reaction vessels – including measuring and control systems - as well as round and cubic reusable stainless steel containers.
- Drying technology
Mobile vacuum contact dryers for dust-free handling of powder, GMP-compliant vacuum tray dryers, air-circulating and intermittent drying cabinets for the efficient drying of your products.
- Cooking equipment
We offer a range of different batch cooking lines for the food industry, including systems for the production of aseptic fruit preparations, fruit jams, sauces and soups. Our vessels are ideal for efficient cooking, stirring and boiling.

Our quality and environmental management system is certified according to ISO 9001 and ISO 14001. We are engineering in compliance with all current regulations, including PED, AD2000, DIN EN 13445, ASME, China Licence and TR certificates, ensuring that you are perfectly equipped for all markets.



EXPERT ADVICE, RELIABLE SERVICE

Here at Waldner, we are a committed team of designers, technicians and engineers from the most diverse fields, which is why we have experts to provide you with in-depth knowledge and experience to meet every challenge, at every stage in the creation of your system – from design to commissioning. It also means that you always have a permanent contact who is available to answer all kinds of questions.

Your ideas are crucial! The start of any cooperation always begins with a comprehensive consultation. After all, we need to understand precisely what you envisage and what requirements you have to achieve on the market to design the system to meet your precise demands. If you already have operational processes and systems, we will slot your new system perfectly into your existing system and workflows.

Naturally our engineers will also assist you with the required qualifications (DQ, IQ, OQ) and with validation. You will then also receive all the necessary test results and certifications, including non-destructive testing with X-ray fluorescence, surface roughness testing or CIP cleaning certification using the riboflavin test. We can also undertake further tests, for instance X-raying welded seams, on individual skids in our factory, saving you time and effort on site.

Our systems are made throughout of stainless steel – that is to say that your Process Systems equipment will have a service life of several decades. And we will continue to be on hand throughout this entire time after the equipment has actually been set up: This starts with the training of your staff to ensure that they get the best out of your system and, after commissioning, continues with regular maintenance, reliable spare parts supply, software updates and adaptations as well as further advice or training, as required. Our ultimate goal is to have a successful and long-lasting partnership with you.



**CLEVERLY
COMBINED:
SKIDS &
PROCESS LINES**

Formulation line
with filter skid



Do you wish to add functions to your system or do you immediately need an entire functional system? Not a problem: we are your one-stop shop for vessels and package units right through to custom-made complete process lines. Our core expertise includes the batching of liquid products, such as buffer solutions, as well as the mixing and handling of viscose products under aseptic/sterile conditions. On request, we will combine your system with our isolators or a suitable solids handling system. CIP and SIP units are naturally factory-integrated into our systems.

Plan for the future with us

We will adapt to your required process design or alternatively develop it together with you – keeping an eye on all the necessary regulations and statutory requirements at all times, including drainage of residual liquids, ease of cleaning and sterilisation. At the design stage we are also able to advise you in detail what services you require for your system – including the volume of compressed air, WFI or nitrogen – and thereby facilitate their integration into existing systems or spaces, or even the design of a new building.

We also ensure fast qualification

Our impressive team of designers, technicians and engineers in the fields of mechanical engineering, process engineering and qualification will be on hand to offer advice and assistance from the design stage, along the qualification chain to final handover, taking as much work away from you as possible. One way we do this is by combining your system into skids or package units in our factory in Wangen: valves, pumps, filters, pipes are pre-assembled on a stainless steel frame and combined to form sensible units. We undertake the necessary qualification measures (IQ and OQ) on these units – saving you a lot of time and effort in your own production facilities.

You get integrated safety and hygiene

Quality and safety is a priority at WALDNER, hence our pipework is generally orbitally welded, tested using endoscopic processes and supplied with the appropriate documentation. Pipework and connections comply with DIN11866 or DIN 11864 hygiene standards. CIP and SIP systems are integrated and, if required, we can also provide the necessary provision for services. The relevant control for the entire system offers you maximum production and employee safety – as well as protection against improper operation.

You will also receive the required level of automation to meet your needs. In doing so, our focus is on the technical process – after all, an optimum software solution can only be achieved by understanding the technical and physical process. We make use of all popular control and field bus systems to meet our customers' individual requirements.

When it comes to the development of control-based projects for the pharmaceutical industry, we systematically apply the provisions of the current GAMP Guidelines – and implement them taking into consideration the requirements of CFR 21 Part 11 and Annex 11.

We offer made-to-measure solutions

Do you need isolators, drying cabinets or other vessels to fit your system? These are all WALDNER products that we are happy to combine with our systems. Naturally, we are also able to integrate other manufacturers' process equipment. You receive everything perfectly coordinated from a single supplier. Simply get in touch with us – we'll find the right solution for you.



Mobile preparation
vessels in front of
the filling panel

CLEAN AND SAFE: ISOLATORS

Our isolators offer you the maximum possible protection you need for your personnel as well as for your products from receipt of goods, through production to the laboratory – either as full containment or as sterile isolators. At the same time, we are able to manufacture made-to-measure isolators. We therefore simulate and test handling processes with your personnel using 1:1 scale ergonomic timber models (mock-ups) and adapt the outer dimensions and equipment in your isolator precisely to your needs and requirements.



IPC laboratory isolator



EX-protected isolator with removable 1 litre preparation vessel



Formulation isolator with mobile vessel



Isolators with directly integrated compounding vessels for parenteral production



Isolator with integrated vacuum tray dryer and sieve mill

We comply with GMP and FDA requirements

All modules and components are specifically designed to comply with GMP and FDA requirements and meet the most stringent requirements in the production of toxic and biologically active substances. Our isolators are certified to comply with an Occupational Exposure Limit (OEL) of well below 0.1µg/ m³.

You receive a wide range of coordinated components

Select from our broad-based range of coordinated and proven components – including the corresponding automation systems. Among other things, we also offer the following as functional standard units, which we provide for the contamination-free handling, supply and discharge of material:


- WALDNER docking system for vessel docking
- WALDNER endless liner system
- WALDNER Push-Push filter for contamination-free filter change
- WALDNER gloveport for contamination-free glove exchange
- WALDNER glove tester
- Monitored inflatable seals for front pane and airlock doors

- CIP/ WIP cleaning systems
- A laminar flow ventilation system for clean room class A adapted to your needs – optionally with integral H₂O₂ generator for sterilisation – we 100% certify the sterilisation of the isolator
- Halar coating of the internal surface
- WALDNER inertisation system

We also offer the following individually produced WALDNER products to combine with our isolators: preparation vessels, drying cabinets, preparation lines or laboratory furniture. Naturally, we are also pleased to integrate other process equipment, including mills, mixers and freeze-dryers.

Speak to our experts – we'd be glad to advise you and design the optimum system to meet your precise wishes and standards. On request, we would also be happy to plan and implement the complete IQ and OQ qualification of your system including SMEPAC testing as evidence of the OEL.

Besides as we have a metalworking background, our isolators have a 4 mm wall thickness, rendering them robust and stable. Simple balances have no need for a balance stone in our isolators.



FULL OF IDEAS: INDIVIDUAL VESSELS

The details of one process vessel or bio-reactor scarcely ever match another. The optimum design is always an individual solution adapted to your process workflows. Whether you require a simple storage container or a preparation vessel with integral control, whether your vessel needs to be stationary or mobile, single- or double-walled, standing, lying or suspended, whether it requires special stirrers or a heating or cooling system – we are happy to build one to your specific requirements. Naturally our vessels comply with all the requisite regulations and are capable of withstanding an operating pressure of -1 to 10 bar and operating temperatures of up to 200° Celsius.

Finish and material to meet your needs

Apart from popular grades of stainless steel, including 316L, we also use the most diverse special alloys, such as HC22: with a milled finish and with a surface roughness of up to $Ra < 0.2 \mu m$ by mechanical or electrolytic polishing, during the manufacture of our vessels and skids. PTFE or Halar coatings are also available.

We also offer state-of-the-art welding and grinding technology, inert gas welding, TIG/ argon arc or plasma welding, and our own acid cleaning and passivation system. We can also fit the size of the vessels to your needs. Our production plant is perfectly set up for all sizes – whether you require a laboratory-scale bio-reactor or a tank-sized batching vessel! And if your tank needs a control system, then we are also capable of developing one to meet your specific requirements.

Safely separating solids and liquids

Choose from a wide range when it comes to our pressure filters as well: the volumes range from 50 to 300 litres with filter surfaces of between 0.12 and 0.50 m². Naturally, a perfect connection is essential with our pressure filters to ensure that

your products can be transferred safely and leak-free.

We therefore employ our proven form-fitting WALDNER central lock, with which filter bases and casing enclosures can be sealed to each other in seconds – totally securely, pressure-resistant and leak-free. And, of course, we also supply our filters and standard closures. We are also able to design both parts, filter base and upper base, so that they can be lowered, raised and swivelled out to the side. We'll select the right solution to meet your specific needs together with you – whether it features a manual lifting spindle, pneumatic/ hydraulic or even hinged with an opening aid.

Our engineers will supervise your project from engineering through to factory handover with inspections, including non-destructive testing with X-ray fluorescence, surface roughness testing or CIP cleaning certification using the riboflavin test. We track our material with quality measurements from delivery to installation and functional testing. And naturally we also install our vessels in compliance with all current regulations, including ATEX, PED, AD2000, DIN EN 13445, ASME, China Licence and TR certificates, ensuring you are perfectly equipped for all markets.

10,000 litres
mixing vessel



Mobile preparation vessel
with WALDNER
docking system



WARMLY RECOMMENDED: DRYING TECHNOLOGY

You define the product to be dried – we supply the system customised to your needs: from simple tray dryers to complete drying systems for use in areas at risk of explosion in accordance with the Explosion Protection Directive 94/9/EC (ATEX) a – including the necessary system components. You can select from different grades of stainless steel and special alloys like Hastelloy and our tray dryers naturally also comply with the latest cGMP and FDA standards.



Vacuum tray dryer with retractable rack trolley for the drying of pharmaceutical products

Mobile: our MVK vacuum contact dryer

Our vacuum contact dryer is perfect when you need to dry contamination-free active or even highly active pharmaceutical ingredients (APIs and HAPIs). In short: MVK – a mobile, conical substance vessels with an integral agitator. It is enhanced by a stationary dryer station and a lifting column. Together they provide for the following process stages: filling, drying, emptying and cleaning performed at stations independent of each other in terms of location.

The MVK provides gentle and effective drying of your products at the same time as offering homogenization and continuous contamination-free product transfer. The mobile vacuum contact dryer is available from us with an operating volume of 10 – 250 litres – with stationary versions of up to 1,000 litres.

High-end pharmaceutical design: our VTP vacuum tray dryer

Designed for usable drying surfaces of 0.2 to 7.0 m², the VTP is ideally designed for the vacuum drying of API and HAPI products. The design principle is characterized by its gap-free welded construction with fully polished interior, rounded corners on all sides and large-radius edges. The VTP therefore offers excellent accessibility and is also extremely easy to clean. The shelves welded into the rear wall can be heated in the same way as the drying cabinet housing, which ensures even temperature distribution throughout the tray dryer. By the way, we can perfectly combine your VTP with our isolator to dry APIs and highly active products. The vacuum tray dryer can therefore be loaded and unloaded providing the highest level of operator protection. For Scale-up-tests our vacuum tray dryer with a usable surface of 1.4 m² is also available.

When it simply needs to be bigger: our VTW vacuum tray dryer

Our VTW range is designed for the high demands encountered in the chemical and pharmaceutical industry. It offers a usable drying surface of up to 27 m² and is designed especially for use in production facilities. These tray dryers are also designed as completely welded constructions, with no dead space, and also have a heated cabinet housing. The heated shelves in the VTW are welded into the side walls of the housing. The same applies here: the shelves and interior walls have the same temperature level and ensure even temperature distribution across the shelves, preventing the formation of condensation.

Optional equipment with our vacuum tray dryer

The following options are available as additional equipment for our vacuum drying cabinets:

- Heated doors
- An inclined base with integral drain channel
- Removable shelves
- A carrier gas lance for the optimum distribution of the carrier gas across all the shelves
- A wall mounting collar when installing the tray dryer into a partition wall
- A WIP cleaning system
- A mobile tray trolley provides easy loading and unloading of the trays

Designed for batches wetted with water and solvent: our HW & HC circulating air tray dryers

The convective drying of products wetted with solvent and water in HC and HW rack tray dryers represents a universal drying process, which has proved itself in the chemical and pharmaceutical industry. Types HW and HC with drying surfaces up to 24 m², differ in the manner of their construction and airflow. The HW tray dryer is designed as a cGMP-compliant design, while the HC tray dryer can be optionally equipped with built-in HEPA filters to retain dust from the product. The operating principle is similar for both modular assembled structures consisting of an integral fan, a heater and a condenser. Both types are characterised by the even distribution of the horizontal drying airflow over the trays. The dryers can either be operated in air-circulating mode or in partially fresh air mode. However products containing solvents being dried in a safe gas loop process with an inert gas blanketing in compliance with the ATEX Directive 2014/34/EU. Both tray dryers can be heated by steam or electrically and are characterized by their pharma-compliant quality finish and last but not least by tightly-closing cabinet doors. Above all, our HW dryer is designed to be easy to clean: all components wetted by the product are very well accessible. Even the air baffle elements can be easily unhinged and swiveled away. Our mobile tray trolleys ensure convenient and efficient handling of the product trays inside and outside the tray dryer.



Package unit in cGMP-compliant design with 1.0 m² VTP vacuum tray dryer for a gentle drying of pharmaceutical substances.



**SAFETY
THROUGH
EXPERIENCE:
COOKING
SYSTEMS**



Detail of a cooking line with aroma vessel and binding agent station



Container filling station

Professionals know: scaling up a recipe to a large system doesn't necessarily succeed just by making things bigger. Decades of experience have shown us how even your grandmother's favourite recipe can be scaled up – in appearance, quantity, flavour and taste. At the same time, our many years of experience in the pharmaceutical industry ensure the long shelf life of your products.

Working with us couldn't be simpler; you provide us with the raw materials and the recipe – we provide the technical process expertise. And if you wish to test small or medium-sized batches of your recipe, we also have separate pilot systems with a usable volume of up to 200 litres, which we can even set up on your premises, if you prefer. The pilot systems are fully equipped with control and energy module, including complete pipework – and simply need to be started up. The results achieved with our pilot systems can be scaled up and thus provide a reliable and stable basis for creating new manufacturing processes or improving existing technologies. Whether you are looking for a single parts group or a more complex production line – we are the one-stop shop for all your needs.

Our systems are predominantly used for the aseptic processing of food. The products that can be produced with our batch systems range from toppings and preparations for the bakery

industry, high-quality fruit preparations, fruit jams, marmalades and compotes to baby food, soups and convenience food. You can also thaw, fry, boil, cool and naturally mix in our vessels. Our gentle working rotor-agitator ensures the homogeneous mixing of the most diverse products. Binding agents can be produced directly in the system using the built-in dispersing station.

Our single- or multi-stage systems, either vertical or horizontal, are modular in design. Our standard batch sizes of 100 to 5,000 litres offer additional flexibility. We will design the optimum custom-made process system for you, customised to your requirements profile. We make use of our many years of experience in stainless steel machining for the first-class and fast production of system components and parts groups. Moreover, apart from the actual cooking and cooling systems per se, we naturally also supply all peripherals for your system including pipework and controls. As the systems are pre-tested in our factory, with the result that we can significantly shorten assembly and commissioning times.

Whatever you produce – our aim is to provide you with a process that delivers consistent quality that remains transparent and controllable at all times.

3D-model of a vertical pilot plant





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