

# QUALITY IS THE KEY . . .



**HOF FREEZE DRYING SYSTEMS**  
THE SPECIALIST FOR INDIVIDUAL SOLUTIONS

- INNOVATIVE
- POWERFUL AND EFFECTIVE IN SERVICE
- FORWARD-LOOKING

SERVICE

EXPERIENCE  
FUTURE  
**COMPETENCE**



# A SIMPLE MAXIM: ALWAYS THINK ONE STEP AHEAD . . .

## KNOWLEDGE AND EXPERIENCE YOU CAN RELY ON . . .

With over 25 years' experience, HOF Sonderanlagenbau GmbH is the leading specialist in the manufacture of individual freeze drying systems, loading and unloading systems, as well as freeze-thaw units for the pharmaceutical and biotechnological industry.

At our company location in Lohra, near Marburg, Germany, highly motivated and specially qualified employees work on the company's own production floor of some 12,500m<sup>2</sup>. A flexible service team keeps close contact with our customers, both nationally and internationally, providing support for the users of HOF systems.



SERVICE  
EXPERIENCE  
SKILL

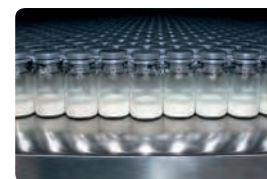


FUTURE

## . . . ENSURING FUTURE SUCCESS



In the pharmaceutical and biotechnological environment, quality and reliability are the decisive parameters in determining whether a company will be successful or not. This is guaranteed by using HOF's customized systems, but also because the company's systems technology is developed with an eye on the requirements of the future.



The company, a specialist in individual solutions since its founding, distinguishes itself by offering only the highest quality in all stages: from the idea to the fully developed plan, all the way to the scrupulous manufacture of the system, which is customized and convincingly reliable. HOF systems are always a good investment for the future.



## THE SPECIALIST . . .

### THE BEST SOLUTION OFTEN REQUIRES NEW APPROACHES . . .

The core of HOF's basic strategy is also the foundation to become the technological leader in the sector of freeze drying systems: the early identification of new requirements and the development of solutions in the form of trend-setting products. The innovative energy shown during construction and production, on the one hand, and the extensive support and assumption of responsibility for the entire project development, including a 24-hour support service, on the other hand, make HOF the specialist it is today.

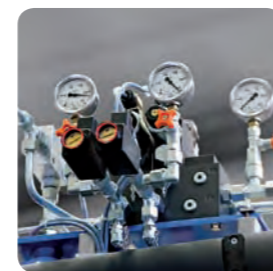
The use of production systems in the pharmaceutical and biotechnological environment requires the utmost standards of sterility and cleanliness. In addition, the high value of the batches and the specified production pattern require that everything runs smoothly and to 100%. The highest levels of quality, reliability and adherence to deadlines are indispensable. The employees and management of HOF consistently keep to these standards, providing suitable solutions for more than 25 years now.



SOLUTION CONCEPT  
INNOVATION

### CONSISTENTLY INNOVATIVE . . .

At a national and international level, HOF is a pioneer company for many new developments in the field of freeze-drying systems. One of our stated aims is to assert and expand this role as innovative pioneer as well as our customers benefit from it. HOF also develops new technologies not for technology's sake, but to meet our customer requirements. Innovative charging systems, flexible shelf adjustment, the use of liquid nitrogen and natural refrigerants, control integration of advanced measuring systems such as NIR and mass spectrometers, HOF SynchroFreeze and vacuum insulation: these are some examples for the company's innovative potential and willingness to take new approaches.



### EXPERIENCED IN LOOKING FOR THE BEST SOLUTION . . .

In a large number of projects, HOF has worked with international companies in the pharmaceutical industry on the development of special applications with the aim of finding the best system solution.

HOF systems represent state-of-the-art technology and comply with the regulatory certification standards of the European Union, the GMP rules and standards of the FDA as well as with the GAMP rules and standards of the ISPE.

### THE SPECIALIST, A DESIRED PARTNER FOR INDUSTRY AND RESEARCH . . .

HOF has an excellent reputation as a specialist for customized solutions and as a reliable partner to the pharmaceutical and biotechnological industry. The productive efficiency of HOF systems, the service and the adherence to deadlines are firmly established and known quantities in the company.

Alongside the company's own innovative potential and experience, HOF relies on close contact and cooperations with well-known technical colleges, universities, research facilities, technical universities, pharmaceutical companies and long-standing suppliers. As a result of this, HOF also focuses on the common research projects. This ensures that innovations can be transfer to daily practice in a professional way.

## HOF – 6 CONVINCING ARGUMENTS . . .

### ■ CONSULTING

A team of experienced employees will give you individual advice from the very beginning of a project and accompany you as a partner through all processes up to the point when the system is working successfully. You can rely on employees who were trained especially for this task by HOF and received solid training as engineers, scientists, technicians, service fitters and skilled workers.

### ■ INNOVATION

Future-proof, high-performance and practice-oriented – these are the decisive parameters by which HOF systems measure themselves. The company is well-known for creative products which are developed to satisfy customer requirements using the latest technologies. Individual solutions and ground-breaking designs help our customers to successfully achieve their goals.

### ■ TECHNOLOGY

At HOF, it isn't technology which determines the product; it's the product properties which determine the technology. We rely on the most modern technological advances in our facilities and systems so we can provide our customers with excellent results, as reliably and as efficiently as possible. These technological advances include, for example, recipe-controlled automatic shelf adjustment, the use of PAT sensor technology and comparative pressure measurement.

### ■ MANUFACTURE

Our dominant position compels us to be consistently excellent in our performance, high quality and farsightedness when developing trend-setting technologies. All HOF systems are manufactured and inspected fully by our employees at our production sites. This way we are able to guarantee the highest standards of quality.

### ■ QUALITY

With every HOF system, our goal is only achieved when the result fully meets your expectations, not to 99%, but to the full 100%. For HOF, quality is the highest measure of things, and that applies to all areas, from the concept all the way to service – you can count on that!

### ■ SKILL

The knowledge, ability and experience of our employees form the basis of our work. Decisive investments in our future are comprehensive training and a continual transfer of knowledge, which ensures that our highly qualified employees have wide-ranging expertise and can identify themselves with the products of HOF. This large skillset gives you the security of knowing you've made the right choice, which you can rely on during everyday production.

ADVICE  
INNOVATION  
TECHNOLOGY



## EXPERTISE . . .

### LETTING KNOWLEDGE GROW . . .

Knowledge can only be put to good use when it's alive in the minds of people. As a technological pioneer, HOF has a large pool of specialists, who know how to fulfil the future requirements of pharmacy and biotechnology in their specific areas of expertise. Their high levels of expertise are constantly advanced and deepened through both internal and external training and further education options. Top research facilities of colleges and universities act as partners in providing this further education.

As a result, the needed expertise in order to design, plan and implement complex, customer-oriented systems is continually deepened - always to the complete satisfaction of the customer.



**PRACTICE**  
CONSTRUCTION  
**PRODUCT**  
SPECIALIST

### ONGOING ADVICE IN PRACTICE . . .

The specialists at HOF are working together with pharmaceutical and biotechnological companies for many years now and can offer advice in all of the most important areas: Automation & software, qualification, process technology & process development, mechanics and design, as well as electrical engineering. Our experienced staff accompanies HOF's customers with their specific expert knowledge from the initial idea all the way to the running of the lab and production operation, regardless of whether it's a new facility, expansion to existing facilities or modification.



TECHNOLOGY PRACTICE  
PERFORMANCE

### TO THE POINT: THE ENGINEERING . . .

HOF develops suitable, project-related solutions. Numerous proprietary patents reflect the innovative energy of the company. HOF's highly-qualified employees carry out invaluable work, giving our customers a clear advantage. The intense dialogue with research institutes and partners from the industry can make even the most technically demanding visions reality.



### MECHANICAL ENGINEERING . . .

HOF takes care of the entire plant layout, from the first design and concept studies, to drafting a layout and pressure vessel construction, all the way to the manufacture drawing of individual parts and the creation of a P+ID. All work is done by HOF in-house – on time and to the highest quality.

KNOWLEDGE  
ADVICE

### AUTOMATION AND SOFTWARE . . .

Suitable software is one of the most important requirements of research and production in the pharmaceutical and biotechnological industries. HOF accompanies the development and generation of the software, from the design phase to the project work, initial operation and qualification, all the way to service support provided by our own software specialists. In the end, a solution is always found with the greatest possible standardisation, which also fully satisfies the individual software requirements.



## EXPERTISE ...

### ELECTRICAL HARDWARE ...

HOF's employees create the entire wiring documentation including circuit diagrams, cabling diagrams, parts lists, terminal diagrams and much more for your projects.

From planning to initial operation, HOF covers all areas: Switch cabinet construction, assembly planning, functional security, security technology and energy optimisation, as well as parts selection are all included.



### PROCESS DEVELOPMENT ...

The services provided by HOF include qualified process development and process optimisation, which means that our customers can be provided with greater security in these areas. With the help of extensive equipment and an available lab freeze dryer, we are able to support our customers when it comes to answering questions on process management. It may be possible to reduce process times and optimise the quality of the dried products. Among other things, we have devices for measuring resistance and temperature, as well as a cryomicroscope, which enable a comprehensive examination of the product.



## PLANNING DEVELOPMENT MANUFACTURE

### EVERYTHING FROM A SINGLE SOURCE: MANUFACTURE ...

Manufacturing at HOF comprises the areas of metal processing, refrigeration technology & service, electrical assembly & insulation in which the electrical and mechanical assembly work and individual production jobs are taken care of by the company's own workers.

The construction of the switch cabinet is just as much a part of this as the cabling of the system, the insulation and full function testing with the respective documentation.

## TECHNOLOGY

PRODUCT

# COMPETENCE QUALITY

EXPERIENCE

### QUALITY IN CAPITAL LETTERS: CERTIFICATION ...

The high demands we apply to our own work are one of the requirements for the success of HOF. The company processes are certified according to DIN EN ISO 9001:2008. This ensures the quality during both the development and manufacture of the facilities and systems.

In order to guarantee quality, all areas are subject to continuous quality testing – from incoming parts, to the various phases of manufacture, all the way to completion. Supplier audits and documented initial operation tests make sure that products always satisfy the highest standards of quality.

### QUALIFICATION – GOOD CONDITIONS FOR A RELIABLE PRODUCTION ...

The employees of HOF perform validation of the systems in a GxP-regulated environment. The company's own qualification department generates the qualification and validation requirements of our systems on a case-by-case basis.

This includes:

- Functional specification
- Project and quality plan
- System description
- Risk analysis for system-dependent risk scenarios
- Hardware-Design-Specification
- Software-Design-Specification
- Traceability Matrix
- Calibration and SAT (Site Acceptance Test)
- Qualification documentation for IQ and OQ





## PRODUCT-ORIENTED ...

HOF SYSTEMS – TAILOR-MADE,  
RELIABLE AND EASY TO USE ...

The systems of HOF are precisely tailored to the respective, individual task and the specific production requirements. The systems built for research or product & process development guarantee that the respective process parameters are transferrable to the production systems. This creates security for production.

Every system is optimally and perfectly adapted to the structural conditions.



**SAFETY**  
EXPERIENCE DEVELOPMENT  
SYSTEM

The specially developed software of HOF makes the process operation of HOF systems particularly user-friendly. An overview of every function can be seen at all times, meaning that irregularities can be reported immediately. The optional remote monitoring adds further security to the production process, as the cause of problems can be precisely analysed straight away.

Our own products include a visualisation system for creating product-specific temperature profiles, system visualisations and load-oriented documentation of process routines.



## PERFORMANCE CONCEPT PRODUCT

## ENERGY

THE LOADING AND UNLOADING SYSTEMS –  
VERSATILE AND SECURE ...

The core property of the loading and unloading systems of HOF is the safe, optimal and integrated transport of pharmaceutical products and primary packaging. The variety of models for loading freeze driers range in size from pilot plant to production size and enable the individual customization for any layout. A new design, adapted to customer-specific requirements, was developed. High performance in connection with reliability is a determining factor in this case. The performance range covers manual, semiautomatic or fully automatic systems. Special packages, dual-chamber ampoules or dual-chamber syringes are transported. Patents for technologies are held worldwide. The loading and unloading systems are installed and tested in our own production in combination with the freeze dryer or a specific equivalent dummy. All settings and functions can be tested extensively. This has the advantage that the installation and testing times are shorter at our customers site. It is possible to upgrade existing freeze driers with HOF loading and unloading systems and therefore to meet customer requirements. Depending on the requirement it is possible to couple a freeze-drying plant and loading and unloading system with isolator and RABS technology.



FREEZE-THAW UNITS –  
PRECISE PROCESSES SAVE ENERGY ...

Variable freezing speed and full process control are at the top of the list of specifications when it comes to the freeze-thaw units of HOF. All contents are fully and equally frozen irrespective of the bag size. Every product bag has the same process conditions at all times and the same shape in the end. Reliable documentation of temperature and time throughout the whole procedure is a matter of course.

The freeze-thaw units of HOF show low energy consumption due to indirect cooling and don't consume any power when idle. The large doors guarantee the ability for rapid loading and unloading. The inner section of the device is made from stainless steel and is easy to clean.





## PRODUCT-ORIENTED . . .

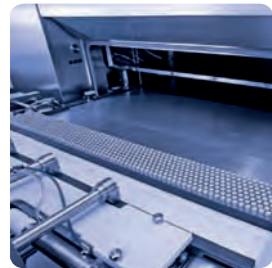
### AN OVERVIEW OF HOF SYSTEMS



- Vial Production Systems (GMP)



- Bulk Systems (GMP)



- Loading/Unloading Systems (various degrees of automation)



- Laboratory Systems (GLP)



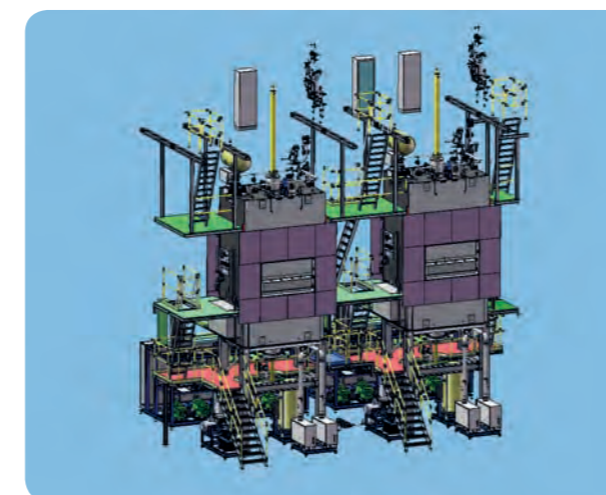
- Freeze-Thaw Units

## PRODUCT PERFORMANCE OVERVIEW

### PRODUCT PROTECTION AND EFFICIENCY – SAFETY THROUGH REDUNDANT SYSTEMS . . .

Particularly when it comes to sensitive contents, which require reliable product protection, HOF is the right partner. Absolutely reliable components and power units – integrated redundantly if desired – provide the utmost safety and protect against costly breakdowns.

The high cooling and heating power of the systems also enable optimum process management and reduce response times. An overview of every function can be seen at all times, which means that irregularities can be reported quickly and distinctly. Emergency support via remote monitoring and diagnosis make sure that downtimes are kept to a minimum.



### INDIVIDUAL DESIGN AND CONCEPT STUDIES . . .

A coherent concept is always the basis of any successful project. As a specialist in individual solutions, HOF provides the best possible integration of freeze drying facilities and systems, both for research purposes and for industry. These are based on customized concept studies as well as 2D and 3D designs which, alongside functionality, also take other important parameters into account:

- Reliability of the system
- Easy access for service and maintenance
- Safety
- Investments and availability of the systems
- System capacities

## HOF – A RELIABLE PARTNER WORLDWIDE . . .

### CUSTOMER SATISFACTION AS THE MEASURE OF ALL THINGS . . .

The success of HOF as a leading expert manufacturer of freeze drying systems, loading & unloading systems and freeze-thaw units is also down to the fact that HOF always thinks one step ahead. As such, the highly-qualified HOF employees receive advanced training, both internally and externally. Moreover: Our younger employees are mostly trained in the company itself.

The expert knowledge, practical ability and high level of motivation our employees have, guarantee that any malfunctions during production are kept to a minimum and rectified as quickly as possible. Our teams offer integral and personal support. This means that one team always assumes the full responsibility for an entire system, not just individual work areas.

### SPECIALISED TEAM WITH RESPONSIBILITY . . .

Every system is supported by the team which was originally responsible for the initial operation, test runs, calibration, qualification and validation, that is, by experts with precise project knowledge. This way, customers of HOF can enjoy the great advantage of always having the same contact person.

### 24 HOURS A DAY – EVERY DAY OF THE WEEK . . .

We attach great importance to offering comprehensive services. We look after your system from the beginning of the project to the successful conclusion: We transport your system, assemble it, put it into operation and qualify it, too. In this way, interfaces can be minimized and problems eliminated.

HOF systems are an important component in pharmaceutical production processes. As such, our employees can be reached 24 hours a day and are ready to go in the case of emergencies. Your HOF team from the Service and Production departments know all the ins and outs of your system and can provide immediate assistance.

### WHAT ABOUT SPARE PARTS? NO PROBLEM . . .

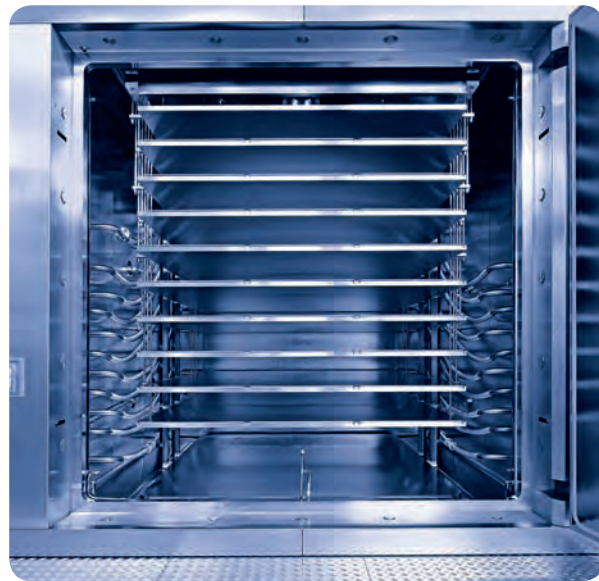
Our own warehouse with over 60,000 articles makes sure that the most essential spare parts for all systems are quickly available at all times, ensuring the product safety. Our emergency service can give you immediate advice if you call + 49 6462 9169-0.



## HOF AT A GLANCE ...

### HOF PRODUCTS

- GMP freeze drying systems
- Pilot freeze drying systems
- Laboratory freeze drying systems
- Automatic charging systems
- Freeze-thaw units
- Modification and system upgrades
- Automatic control and visualisation
- Retrofitting of refrigerants
- Nitrogen refrigeration technology
- Construction of stainless steel piping/  
Orbital welding
- Process development and optimisation



ADVICE  
PRODUCT  
CONFIDENCE

### HOF SERVICES

- Engineering
- Consulting and application support
- Complete assembly
- IQ installation qualification
- Calibration
- OQ operational qualification
- PQ assistance for process qualification
- RQ requalification measures
- Vacuum leak detection
- Repair and modification of existing systems  
with GMP-compliant documentation

RELIABILITY

CONSTRUCTION  
EXPERIENCE  
QUALITY  
TECHNOLOGY KNOWLEDGE  
PRODUCT RESEARCH



Imagefilm

COMMUNICATION

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