

PHARMA INDUSTRY

BLOW-FILL-SEAL TECHNOLOGY

Rieckermann GmbH

Mrs. Katrin Winter
Team Assistant, Pharmaceutical Industry

Moенckebergstr. 10
20095 Hamburg, Germany
Phone: +49 40 320 200
Email: k.winter@rieckermann.com

We look forward to hearing from you and meeting you in person.

Please find all addresses and contact information for local offices on our website: www.rieckermann.com



BLOW-FILL-SEAL TECHNOLOGY

“The design of each element of the manufacturing facility should contribute to minimizing the product contamination risk.”*

Reducing machine interfaces is a key factor to achieve this goal. The integrated Blow-Fill-Seal technology combines in one single machine:

- Forming
- Sterile/aseptic filling
- Closing

A Blow-Fill-Seal (BFS) machine therefore minimizes contamination risk and reduces production costs.

Knowing the integral parts of a pharmaceutical filling process and how to manage their interfaces, we are the reliable partner to set up your industrial solution for dedicated applications.

*ISPE Baseline © Guide: Sterile Product Manufacturing facilities, Second Edition / September 2011, page 26



BLOW-FILL-SEAL PROCESS

Thermoplastic resin is extruded into a tubular shape (parison) which is continuously flushed with sterile air.

The bottom of the parison is pinched and closed, while the top is held open with the help of the special mold design. At the proper length the mold is closed and the parison is cut. The parison in the mold is then conveyed to the point of fill.



ADVANTAGES

Process, qualification & GMP:

- Elimination of cross contamination risk within your filling process is the right GMP mind set
- Large batch production without direct human interference
- Significant reduction of qualification & validation efforts
- Fewer SOP's for easy control of your facility
- High degree of sterility assurance, backed up by scientific research*

*Sinclair, C.S./Tallentire, A., Predictive Sterility Assurance for Aseptic Processing, S.1 ff, Manchester 1993 Publication

Investment, operation and marketing:

- Smaller plant layout of facility
 - Less equipment
 - Less storage of raw materials & consumables
 - Less operational costs for clean rooms, machine maintenance, manpower, etc.
- Significantly lower costs per container compared to other liquid filling processes
- Automated CIP/SIP processes
- Flexible container design
- Improved functionality of finished product, e.g.:
 - No glass breakage
 - No refill of inhalers



BLOW



FILL



SEAL

USING ONE MACHINE FOR THREE PRODUCTION STEPS

In the sterile filling area the parison is formed to final shape by blowing sterile compressed air into the parison. This process is supported by applying vacuum from the mold.

The sterile product is filled in the container by the combined blowing/venting/filling nozzles.

In the final step the container is hermetically sealed by the sealing molds and discharged from the machine.

MODERN LIQUID PACKAGING PROCESSES

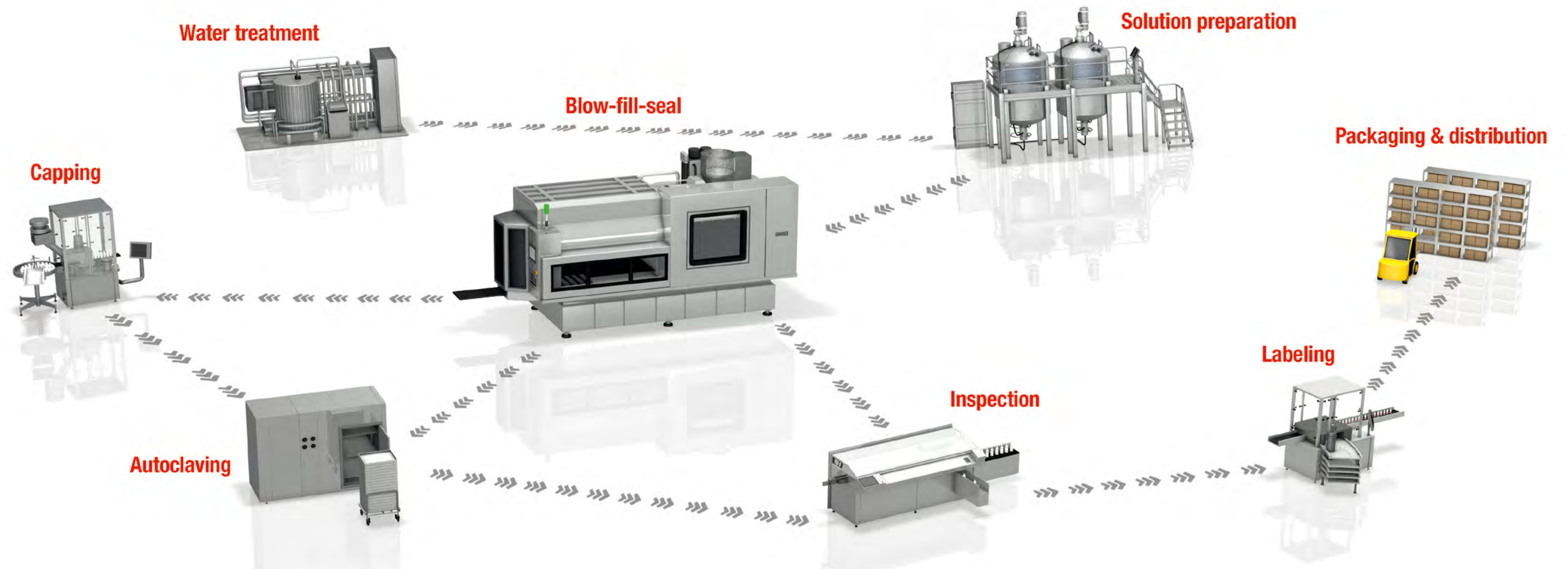
Increasingly comprehensive formulations and stricter regulatory frameworks result in extremely complex processes which need to be managed. Sizing of equipment and managing machine interfaces on the one hand, and simultaneously building up a suitable quality management system that complies with all possible regulatory frameworks on the other, is our daily business.

- You are planning to introduce a new product to the market and don't know which container shape and which resin type suits your production process best?
- You are interested in producing SVP's or LVP's, but are not familiar with today's state-of-the-art production methods and the configuration of an efficient OEE line?
- You feel uneasy about the overall complexity of a BFS facility?
- You are not sure how to properly maintain your BFS machine and how to execute the right preventive maintenance?

We understand the essential details of your liquid processing project and find perfectly fitting solutions for your individual requirements, helping you to become a unique and preferred pharmaceutical manufacturer in your markets.

Cooperating with us, you benefit from the extensive know-how of our international network of experts and partners. With their in-depth knowledge of sterile liquid processing and corresponding strict guidelines our pharma specialists will realize your liquid processing project, on budget and on time. We work closely together with you and will support you in each phase of the project.

WE UNDERSTAND THE ESSENTIAL DETAILS OF LIQUID PROCESSING



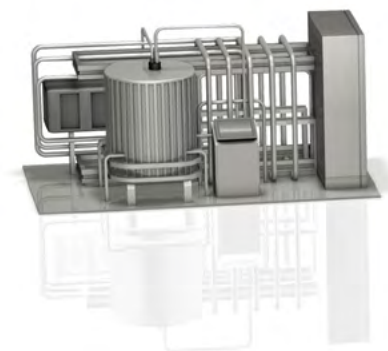
YOUR BFS PRODUCTION LINE

Interface challenges

With our experience we are able to design your BFS production line, meeting highest OEE and GMP requirements. Starting with an optimized solution preparation and right-sized water treatment system, we design the downstream equipment of your BFS system according to your expectations and the regulatory framework you are dealing with. We know which aspects need consideration and help you to bring in your project right on time and on budget.

Have you, for example, considered the following challenges for the design of your production line? We will be pleased to assist and consult you on these and any other challenges that may arise.

Water treatment



Water treatment is one of the most underestimated systems. In sterile processes, high quality water is the major raw material and must meet defined quality standards.

By oversizing your water treatment system you will unnecessarily increase your utility costs, by undersizing your system you will face bottlenecks in your production process. Local installation with non qualified subsuppliers might cause your PQ to fail.

Solution preparation



Solution preparation is more than just a tank. In order to improve your overall BFS process following points need consideration:

- System set-up designs of mixing and holding tanks
- Filling & mixing times
- CIP/SIP timing
- Batch sizes
- Sterile interfaces to the BFS machine

Autoclaving



Sterile filtration is no replacement for thermal sterilization. Autoclaving is the final “barrier of protection”. The functionality of your product depends on the resin you choose. There is no “one size fits all”. Soft resins, for example, might be good for functionality, however, they cannot be sterilized at high temperatures. To validate such processes, deep know-how and control of your process and your facility are required.

RIECKERMANN EASY BFS

While any pharmaceutical project can be seen as a challenge, some are more complex than others. The majority of products using BFS technology are very comparable in their formulation and functionality. We have converted this into your benefit. By designing standardized modules, we have created the RIECKERMANN EASY BFS solution. There has never been an easier way to develop, realize and operate a Blow-Fill-Seal facility in a shorter period of time.

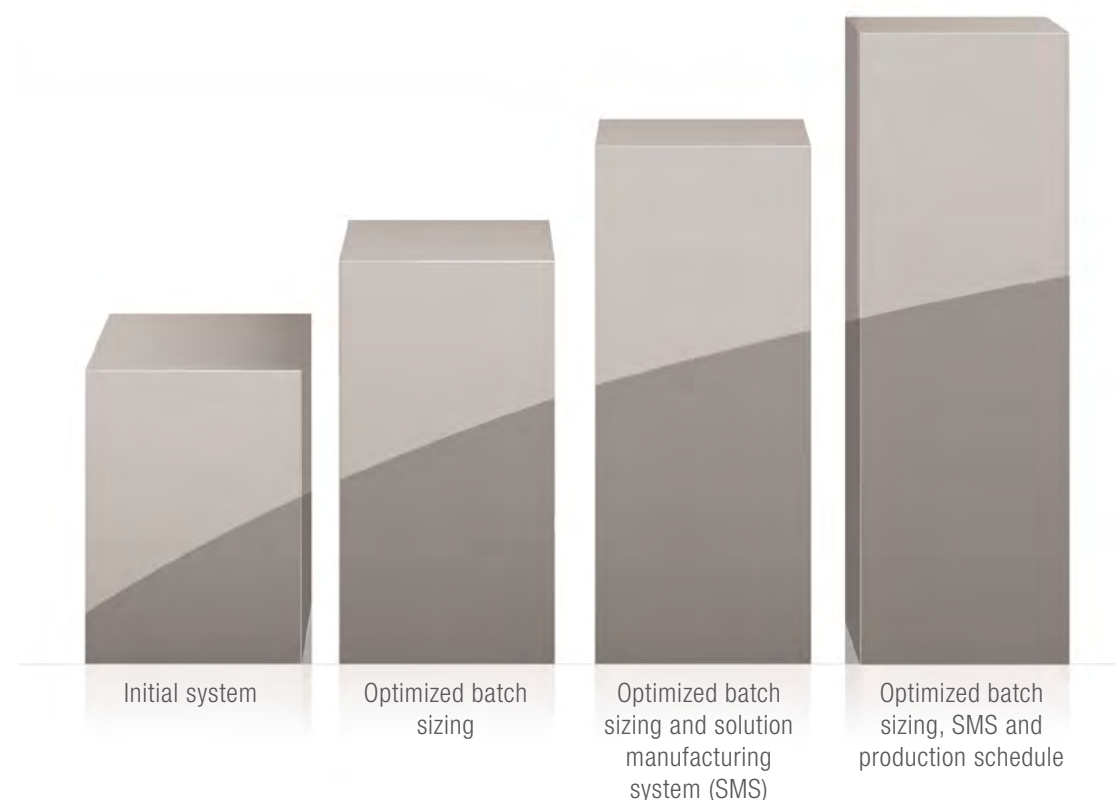
The planning and concept phase of your BFS production facility is the key to a flexible production in the future. By optimizing your production process you can increase your production capacity, while staying cost-efficient.

Our BFS team of pharma specialists covers the whole spectrum of functions required for successful BFS project implementation. We offer knowledge and experience in sterile manufacturing, filling and packaging, BFS product design and development as well as warehousing. In addition, we provide all necessary services to enable you to meet the required international and local regulatory standards.

INCREASE YOUR OUTPUT BY OPTIMIZING YOUR PRODUCTION PARAMETERS

Our engineering team will optimize your BFS process, recommending best batch size and solution manufacturing capability, defining the optimal autoclaving requirements, recommending shift patterns and scheduling – to get the very best from your investment in BFS technology.

OUTPUT SIMULATION FOR DIFFERENT OPTIMIZATION STAGES



INDUSTRIAL SOLUTIONS FOR LIQUID PROCESSING

Since 1892, Rieckermann has been your reliable partner for industrial production and processes. With a comprehensive range of high-quality services and technology, we provide solutions tailored to match your individual needs.

As a family-owned company, we personally accompany, guide, and support you on your path to drive your business to the next level. With over 130 years of experience and specific expertise in several industries and markets, we open new opportunities for you and your industrial production.

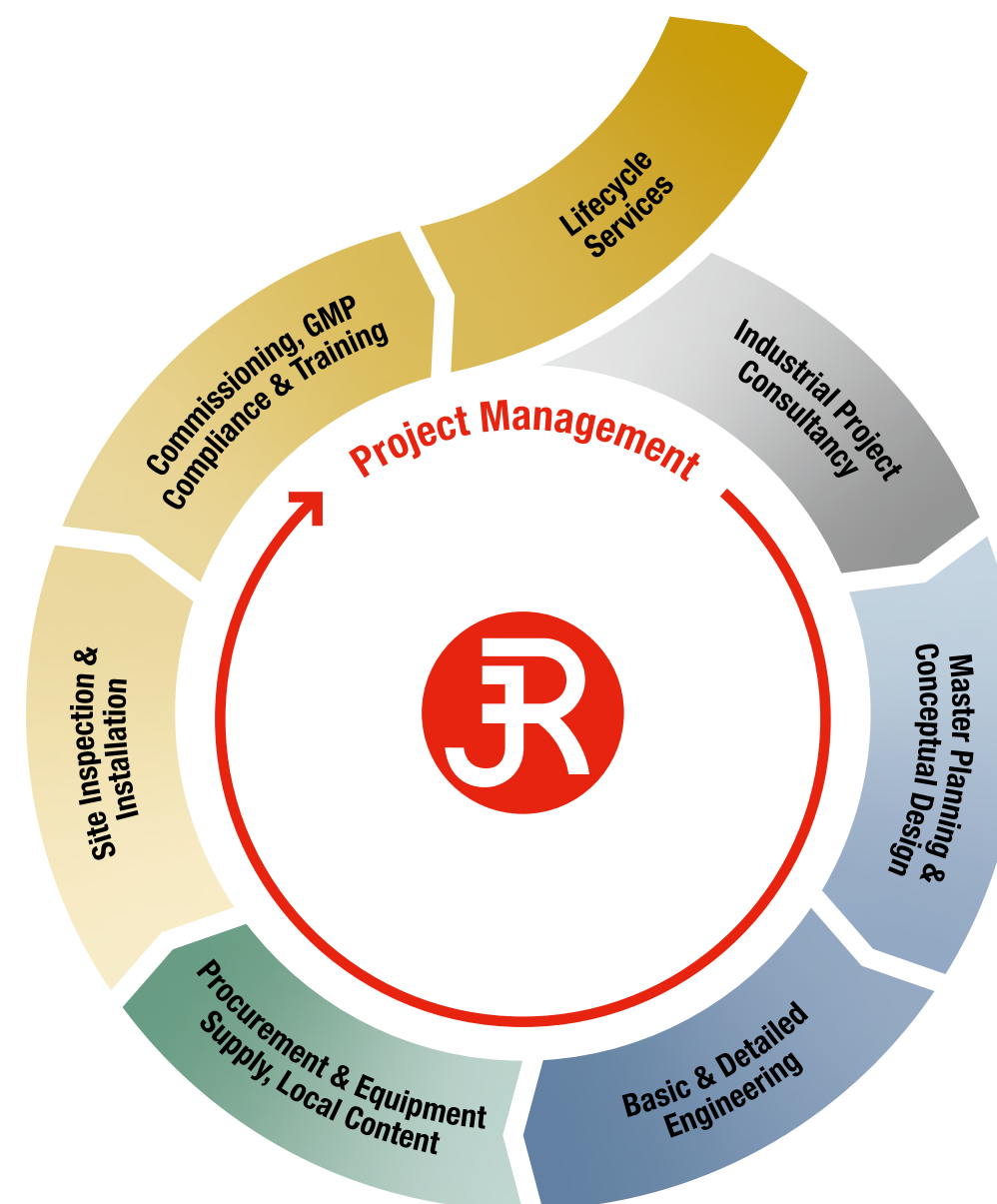
Our team of 750 employees is present in person in the Near and Middle East, Southeast Asia, and the Far East. To fulfil your expectations, we work close to the market and hand-in-hand with you on a local level.

We are Rieckermann, your first choice industrial solution provider.

Rieckermann has been providing support for the pharmaceutical industry for decades, with solutions and services for the processing, production, and packaging of all types of pharmaceuticals in liquid, solid, or semi-solid form. Furthermore, we serve clients who produce active pharmaceutical ingredients, medical devices, and cosmetics.

We continuously strive to expand our knowledge of pharmaceutical trends in different countries. This enables us to provide local solutions in line with international regulatory standards. When it comes to our engineering services, we offer expert advice on implementing good manufacturing practice (GMP) and ensuring PIC/S compliancy for virtually every pharmaceutical application.

Profit from the extensive know-how of our international network of experts and partners – and get access to the latest innovations.



RIECKERMANN PROJECT MANAGEMENT

We understand the complexity of your BFS project and will accompany you in each phase.

- Strategic consulting
- Engineering & design of your production line & factory
- Project management
- Assurance of GMP & technical compliance
- BFS container design & production process consulting
- Sourcing & supply of machinery & process equipment
- Consultancy & supply of auxiliaries (resin, caps, etc.)
- Installation
- Validation
- Commissioning
- After sales service

YOUR BENEFITS

Successful project management is the key to completing your projects on time and within budget. We make this happen by offering an ideal mix of international and regional specialists with up-to-date relevant experience and expertise. This combined team expertise ensures seamless interfaces between all project aspects and results in the future successful operation of your plant.



One strong partner

Benefit from professional consultation and project management from a one-stop, turn-key service. We act as an interface between client and manufacturer, selecting highly qualified suppliers and/or partners to provide you with the desired equipment and services. A designated contact person will assist you and focus on your interests throughout the whole project, customized to your needs.



Full-service approach

Take advantage of our wide service portfolio including consulting, engineering, machinery & equipment sourcing, financing, shipping, project management, installation, after sales services, and spare parts supply. Whether you need a single machine or a complete solution, we support you throughout the lifecycle of your industrial project.



Globally at home

Your personal Rieckermann contact speaks your language, understands local regulatory requirements, and is knowledgeable about cultural differences. With our long-standing local presence, you can trust our dedicated team to source relevant expertise from our vast network of specialists and partners within diversified industries.

GLOBALLY AT HOME



750 EMPLOYEES
24 OFFICES
17 COUNTRIES

Your local Rieckermann office is right around the corner from you. Our local team is ready to find the best solution for your business.

We look forward to hearing from you and meeting you in person. Please find all addresses and contact information for local offices on our website:

www.riekermann.com