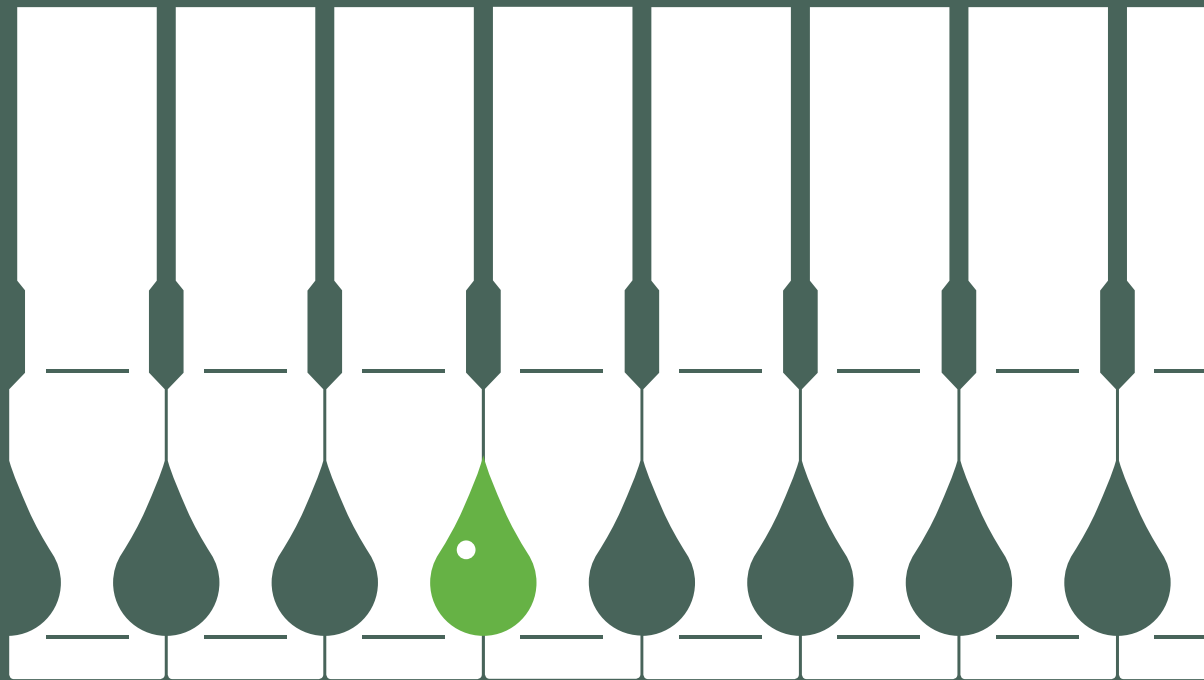


FILLING YOUR NEEDS



# WE BLOW-FILL-SEAL FOR YOU





# TELL US WHAT YOU'RE LOOKING FOR, AND WE'LL PROVIDE THE SOLUTION

INVESTING IN YOUR OWN, IN-HOUSE BOTTELPACK SYSTEM ISN'T FOR EVERYONE: SOME COMPANIES, FOR EXAMPLE, MAY ONLY HANDLE RELATIVELY LOW VOLUMES, WHILE OTHERS MAY SIMPLY NOT HAVE THE AVAILABLE FLOOR SPACE TO ACCOMMODATE ONE OF OUR SYSTEMS AT THEIR OWN SITE – DESPITE THEIR EXCEPTIONALLY COMPACT DIMENSIONS. BUT THAT'S NO REASON FOR YOU TO MISS OUT ON THE FLEXIBLE AND HIGHLY VERSATILE PACKAGING SOLUTIONS AFFORDED EXCLUSIVELY BY ROMMELAG'S BLOW-FILL-SEAL PROCESS.

Rommelag CMO provides you with quick and easy access to BFS technology without having to invest in either the mandatory GMP environment that goes with it or the specialists required to operate and maintain the machines. What we offer is the whole spectrum, including the entire infrastructure itself, over 50 years' experience in bottling using BFS aseptic systems, and the expertise you'd only get from the inventors of bottelpack technology.

Find out more about the diverse range of options available through Rommelag CMO and BFS technology.



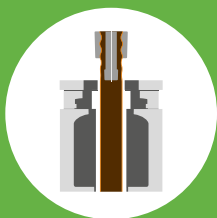
## BFS MAKES SHORT WORK OF INEFFICIENT PACKAGING SOLUTIONS

With over 50 systems in a whole host of different configurations, Rommelag CMO runs one of the world's largest, most state-of-the-art bottletpack system ranges. It goes without saying, we're ideally placed to meet your bottling needs in no time at all and at minimum cost. So whether you're looking for help with trial batches, the development phase (including feasibility studies, stability tests, and clinical samples) or getting batches ready for market, we've got it all covered. And if you're too limited on space to accommodate your own machines or extra personnel, we can simply operate your bottletpack system for you in our dedicated Pharma Suite. Whatever you have in mind, we've got the wealth of experience to bring your ideas to life.

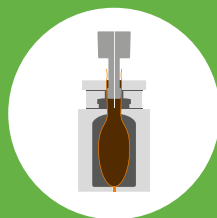


## BLOW-FILL-SEAL: WHAT'S IT ALL ABOUT?

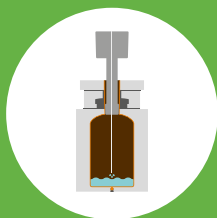
Every BFS process begins with the extrusion of a sterile polymer parison directly within the system. Once complete, the container can then be moulded, filled, sealed, and demoulded – all in a single process, in a self-contained system, and without the need for any external intervention. The bottlpack system – complete with its BFS process – falls under the umbrella of advanced aseptic processing technology, and ensures that the end product is always exactly what you wanted and just what your customers need.



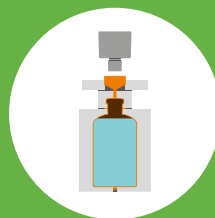
**EXTRUDING** – The polymer parison is extruded from granulate and positioned inside the open mould.



**BLOWING** – The mould closes and, in doing so, welds the base. The mandrel is positioned on the neck of the container and blows sterile air into the parison to create the desired shape. Small containers are created using a vacuum.



**FILLING** – The exact amount of filling as measured by the dosing system is fed into the container via the mandrel.



**SEALING** – Once the mandrel is removed, the head mould comes together to form the desired closure type.



**DEMOLDING** – Opening the mould releases the container from the system and the next cycle begins.

## CHOOSE BLOW-FILL-SEAL SOLUTIONS FROM ROMMELAG CMO: YOU WON'T REGRET IT

To allow you to benefit from the full scope of our services without having to invest unnecessary time or money, Rommelag CMO starts every cooperation with an in-depth consultation based on your needs so that we can go through the options we have available. This allows us to guarantee an exceptional level of process and production reliability, tailor packaging designs and materials perfectly to suit your products and applications, and even engineer every aspect of a filling test – all from the outset.

## COUNTLESS POSSIBILITIES

At Rommelag CMO, we've spent decades developing containers for the most varied range of products. In this time, we have designed thousands of containers with capacities ranging from 0.04 ml right through to 10 liters, setting new market standards for BFS filling operations in the process. Our use of plastic allows us to cater to virtually every shape and filling volume, but the possibilities don't end there: in addition to its primary packaging range, Rommelag CMO also offers a wide variety of secondary packaging solutions, blister packs, sachets, collapsible boxes, and much more.

### Everything from a single source

- ✦ Batch production
- ✦ Analytics
- ✦ Filling
- ✦ Packaging
- ✦ Process optimization
- ✦ Scale-ups
- ✦ Validation
- ✦ Help with registration/approvals
- ✦ Manufacturing in line with cGMP regulations
- ✦ Approval from FDA, ANVISA, and other official inspection bodies
- ✦ EU GMP manufacturing license and GMP certification
- ✦ ISO 9001 and ISO 13485 certification
- ✦ Insulated production rooms
- ✦ Clinical sample manufacturing
- ✦ Approval to work with narcotics
- ✦ And much more

## THE PERFECT FORM AND FUNCTION FOR YOUR PRODUCT

We work with you to come up with the best possible solution, making sure the BFS containers are the perfect fit for your product in terms of their shape, color, rigidity, appearance, barrier characteristics, and sterilizability. Our experts provide all the support you need when it comes to decisions such as having polyethylene or polypropylene packaging for your liquids, gels, or creams, or whether your containers should be manufactured with a monolayer or multilayer finish. This ensures that your product has the best possible protection while also allowing you to benefit from all the advantages of BFS technology.

### Benefits of BFS packaging

- ✦ Transparent
- ✦ Completely collapsible
- ✦ Self-contained system
- ✦ Lightweight
- ✦ Unbreakable
- ✦ Self-supporting
- ✦ Mounting brackets available (optional)
- ✦ Minimal manufacturing costs
- ✦ Suitable for use with various cap/closure types
- ✦ Made of PP, PE, and plastic mixtures
- ✦ Counterfeit-proof
- ✦ Tried-and-tested design
- ✦ Variable filling quantities
- ✦ Virtually particle-free manufacturing process
- ✦ And much more







## FOR PHARMACEUTICALS AND SO MUCH MORE

The pharmaceutical industry is one of the main sectors to rely on the blow-fill-seal process. After all, Rommelag CMO specializes not only in handling and filling extremely temperature-sensitive products, but also in manufacturing special products such as emulsions, suspensions, and highly potent APIs. And in addition to pharmaceuticals, the chemical industry is one of a number of other sectors in which liquid and semisolid materials are increasingly finding their way into BFS packaging.

### BFS packaging is the smart choice for

#### Medication and medical products in line with GMP

- ▼ Eye, ear, and nose drops
- ▼ Homeopathics
- ▼ Inhalation solutions
- ▼ Infusions and injections
- ▼ Rinsing solutions
- ▼ Drinkable solutions
- ▼ Creams, ointments, and gels
- ▼ Wound care products
- ▼ Vaginal applications
- ▼ Rectal applications
- ▼ Disinfectants

- ▼ Diagnostic agents
- ▼ Various biotechnical products

#### Non-GMP products

- ▼ Cosmetics
- ▼ Nutritional supplements

#### Technical products

- ▼ Pheromones
- ▼ Machine and motor oils
- ▼ Detergents
- ▼ And much more

## UNPARALLELED AROUND THE WORLD – BFS UP TO BIOSAFETY LEVEL 2

Rommelag CMO has a separate facility for filling all biological pharmaceuticals up to biosafety level 2 (BSL-2) – including active pharmaceutical ingredients (API) such as vaccines and antibodies. This is the only blow-fill-seal production facility in the world to meet this standard.

## THE RIGHT SEAL EVERY TIME

No matter whether your product is intended for single or multiple use, our systems are the ideal choice for manufacturing virtually every type of container complete with the appropriate seals to go with them.

## THE PERFECT SEAL: GUARANTEED

When it comes to deciding on the right tamper-evident seal for you, it essentially comes down to how the product will be used and whether it's for single or repeated use. But the one thing they all have in common is the fact that every container is hermetically sealed to create a fully functional closure for a clean, convenient, and practical result.



The **twist-off cap** is a closure design that has proven its worth millions of times and is used in a large number of production areas.



The **KME closure** is complemented by a screw cap with a mandrel. Screwing the mandrel in creates an opening through which the product can be dripped or squeezed out.



The **KMT closure** consists of two parts and allows the user to accurately dispense drops of the product.



With the **eurohead closure**, the hermetically sealed container is combined with the eurohead cap. It was specifically designed to meet the requirements of infusion bottles (IV bottles).

## TRUST IS GOOD – CONTROL IS INDISPENSABLE

Trust is a great thing when it comes to aseptically filling liquid and semisolid products, but seamless controls are obviously a matter of course. As such, all the containers are already inspected during the filling process, and the filled batches are then subjected to a further laboratory examination. We see it as our absolute duty – as opposed to a voluntary consideration – to perform and monitor quality control in accordance with GMP and FDA standards so that we can act in the best interests of your customers.

**To ensure that our bottlpack systems always produce exactly what you were looking for, we go the extra mile to offer you a range of services covering the filling process and beyond**

- ▶ Pilot batches for process development
- ▶ Scale-ups
- ▶ Microbiological examinations
- ▶ Comprehensive chemical tests
- ▶ Development and optimization of container designs
- ▶ Filling for stability and registration batches
- ▶ Pharma Suite concepts
- ▶ And much more

## WORKING TOGETHER TO CREATE UNIQUE SOLUTIONS

With Rommelag CMO as your partner, you can enjoy ongoing technical support directly from the machine manufacturer, as well as the expertise and close exchange of experience afforded by the entire Rommelag Group. We also work in partnership with you to develop innovative products and solutions, such as multilayer filling containers, or new applications with the specific properties needed to protect your product.

### This is what Rommelag CMO can do for you

- ✔ Tell us what you're looking for, and we'll create the product for you
- ✔ Individual, comprehensive advice courtesy of our experienced project team
- ✔ Filling processes for even tiny quantities (from as little as 1l right through to huge amounts in cubic volumes)
- ✔ Laboratory runs, scale-ups, test runs, and stability, registration, clinical, and market batches
- ✔ Over 100 individual, freely available moulds
- ✔ Filling volumes from 0.04 ml to 10 l
- ✔ GMP-compliant checks throughout the manufacturing process with full accompanying documentation
- ✔ Comprehensive product analytics both in-house and by external laboratory partners (licensed by us and FDA-approved) as required
- ✔ HPLC, UPLC, GC, NIR, FTIR, UV/VIS, TOC, AAS, and other physical-chemical methods
- ✔ Microbiological and sterility validations with external laboratory partners
- ✔ Exceptional process and product reliability
- ✔ Process validations and optimizations
- ✔ Stability storage and inspections in conjunction with external laboratory partners
- ✔ Customer-specific mould designs (over 5,000 moulds designed/drawn up to date)
- ✔ Help with registration (technical aspects of manufacturing)
- ✔ Back-up manufacturing for machine customers
- ✔ Pharma Suite concept
- ✔ And much more



*Our highly qualified teams ensure that all of our filling processes meet your requirements. And when it comes to pharmaceutical products, we never lose sight of GMP regulations and FDA specifications, meaning everything is always well under control.*

# THE END? OR JUST THE BEGINNING?

WE HOPE THIS HAS GIVEN YOU A TASTE OF WHAT ROMMELAG CMO CAN DO FOR YOU, BUT LET'S BE HONEST – NOTHING BEATS PERSONAL CONTACT. CONTACT US VIA [WWW.ROMMELAG.COM](http://WWW.ROMMELAG.COM) AND WE'LL BE GLAD TO TALK TO YOU ABOUT THE PACKAGING SOLUTIONS WE CAN OFFER USING THE BLOW-FILL-SEAL PROCESS. IT WILL BE OUR PLEASURE TO PAY YOU A VISIT.

## **We're always by your side**

With its four specialist divisions of ENGINEERING, CMO, FLEX, and SERVICE, the Rommelag brand represents a strong network of local, independent companies across Germany and Switzerland that each share the same end goal: reaffirming to you on each and every project that choosing Rommelag was the best decision you ever made.



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