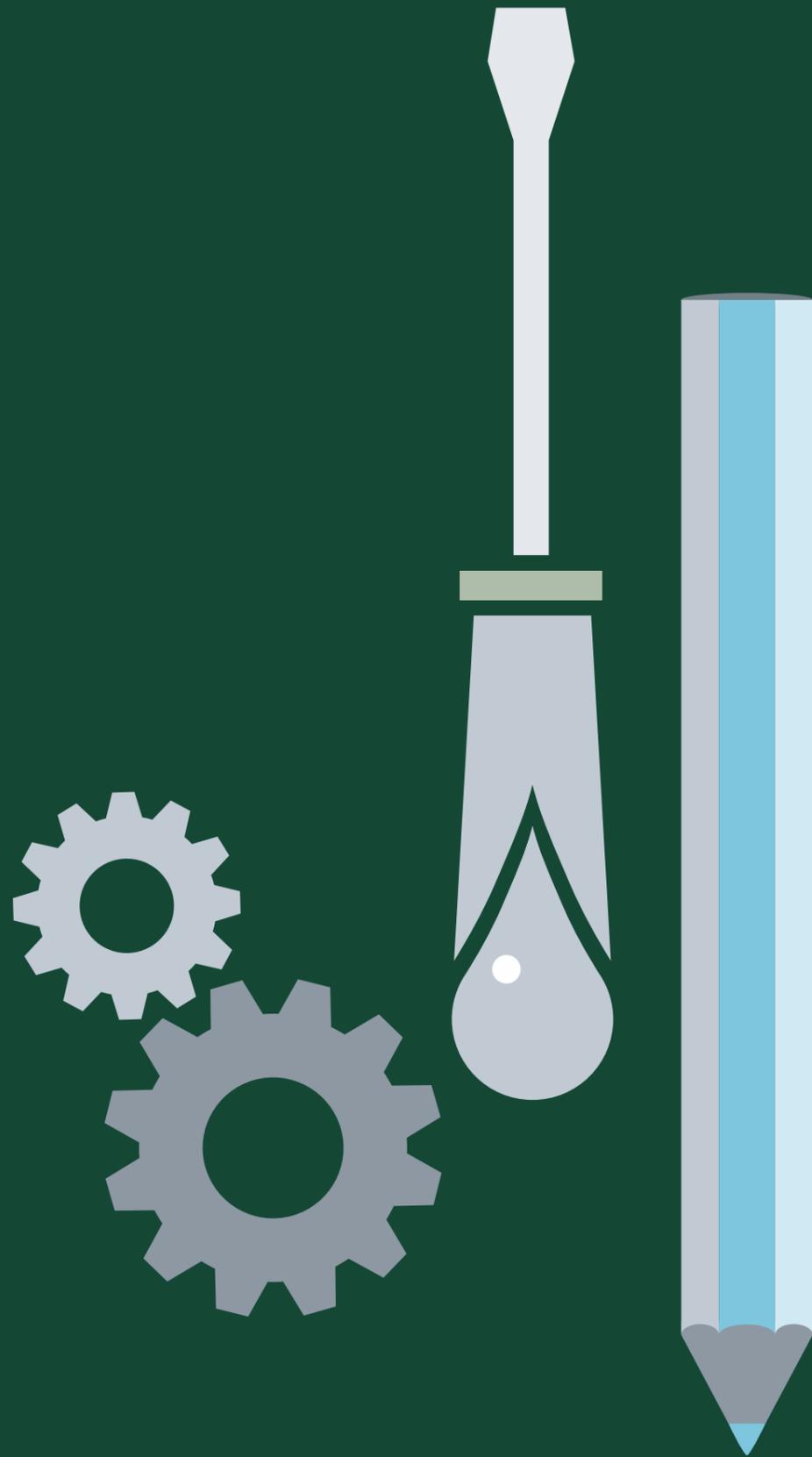


YOU PROVIDE THE  
CHALLENGE – WE’LL TAKE  
CARE OF THE REST.





## FROM A TO Z OR WHATEVER YOU LIKE

ROMMELAG SERVICE BEGINS WHEN YOU'RE STILL DEVELOPING A FORMULA OR FINE-TUNING YOUR PRODUCT DESIGN. WE'RE ALWAYS BY YOUR SIDE WHEN IT COMES TO COMMISSIONING, QUALIFYING, AND VALIDATING BFS SYSTEMS IN LINE WITH GMP GUIDELINES, WHEN IT'S TIME FOR MAINTENANCE, WHEN A PART NEEDS TO BE REPLACED, OR EVEN WHEN YOU JUST GET STUCK SOMEWHERE ALONG THE WAY. WE HELP DESIGN THE PACKAGING, OPTIMIZE PRODUCTION PROCESSES, ADAPT THE SYSTEM CONFIGURATION TO CHANGED CIRCUMSTANCES, AND HELP REDUCE COSTS. WE SUPPLY EVERYTHING FROM SPARE PARTS TO UPGRADES FROM A SINGLE SOURCE AND ARE ONLY EVER ONE PHONE CALL AWAY. THAT'S WHAT WE AT ROMMELAG SERVICE CONSIDER TO BE A REAL PARTNERSHIP.

### ALL INCLUSIVE AT ROMMELAG SERVICE

With our bottelpack customers in mind, we put together a Rommelag SERVICE package that includes a number of services to help you save real time and money. Speak with our service experts about your custom offer.

All services can naturally be requested individually, too.

## THE BEST ADVICE FOR QUALIFICATION AND VALIDATION

With the Rommelag Pharma Service, we offer customers who purchase our bottlpack systems a quick, economical, and officially accredited holistic scheme for qualification and validation. Thanks to our years of international experience, we know exactly what's important and can ensure that the entire process is more cost-effective, more successful, and more certain. Of course, you decide whether you want us to simply advise you, take on the project management, manage the complete validation service for you, or just provide you with the blank documents for your own processing.

You can also use the Rommelag Pharma Service for existing installed systems and systems already in use. Experience gleaned from our production facilities means that we are able to provide comprehensive advice and support for efficient system use and optimization of the entire production process.

Our experts can guide your entire project, from greenfield development sites to complete production processes. It's a good idea to contact Rommelag Pharma Service early on in your project – you won't regret it.

IMPORTANTLY, WE KNOW THE STRINGENT REQUIREMENTS PLACED ON PHARMACEUTICAL PRODUCTS IN THEIR DEVELOPMENT, PRODUCTION, AND PACKAGING, AND OBSERVE STRICT ADHERENCE TO ALL GMP AND FDA GUIDELINES.



## STEP BY STEP TO SUCCESSFUL VALIDATION

01

### User Requirement Specifications (URS)

We are happy to help you draw up the requirements and expectations for your new systems. Using your specific requirements for your future product, we work together with you to develop the necessary basic specification.

02

### Risk Analysis

We discuss with you all risks that need to be considered regarding the production of your product and the design of your system and process. We then draw up the risk analysis document.

03

### Design Qualification (DQ)

Our specialists help you carry out the design qualification and test the planned design according to the requirements of GMP/FDA guidelines. All requirements are placed against the corresponding verification in a clear traceability matrix.

04

### Installation Qualification (IQ)

Our service team ensures that your system has been set up and installed correctly. We also check that the machine documentation contains all relevant information. Our documentation extends into practical sub-areas and includes data that goes far beyond what the guidelines require.

05

### Operational Qualification (OQ)

Once your system is completely set up, we work with you to test all important functions. Our on-site testing verifies that the system meets the required specification in a reproducible and robust way.

06

### Performance Qualification (PQ)

Optionally we can also help you with your performance qualification. In this case, we conduct multiple test runs under real-world conditions, up to the maximum load. We test all system functions and components to ensure absolute functionality. If the test runs are successful, the process validation is finally complete and you are ready to start enjoying revenue from your new system.

## WANT A LITTLE BIT MORE?

If additional tests or qualifications are required in the course of validating your system, we are happy to implement these for you. Data obtained from the factory acceptance test (FAT) can also be used for qualification and validation documentation as part of our fast track concept. The specialists from Rommelag Pharma Service will be glad to advise you.



## WHAT ELSE CAN WE DO TO ENSURE YOUR SUCCESS?

### **We test**

At Rommelag we have taken part in thousands of projects, gaining experience in individual plastic packaging solutions. Test the bottelpack technology at our premises on systems assembled individually for you. For sample manufacturing, we fit our bottelpack systems with a wide range of test moulds and extrusion and dispensing systems. Do you need completely filled containers for marketing or packaging studies? Our system is ready and waiting for you.

### **... install your system**

The Rommelag Service team installs your entire bottelpack system, including all components, and conducts all relevant test runs to ensure that your system gives you full performance from day one with optimal cost-efficiency. We hand over the system to you only when everything is in perfect working order and the system is fully integrated into your machinery or into the entire infrastructure of your company.

### **... provide a warranty**

Regular preventative maintenance helps to significantly increase the product service life and also the cost-effectiveness of your bottelpack system. When you sign up for a Rommelag SERVICE package, you have the option, for example, of extending the warranty for new machines for a year.

### **... offer training**

We take it as a given that we will offer comprehensive training for your employees – at Rommelag or at your premises, step by step and in all processes that are essential for a smooth production workflow. But we don't stop there. We are also happy to impart our knowledge to you and your employees when it comes to safety training, maintenance and servicing, process optimization, or machine setup. On our premises, we use two fully functional training machines with a transparent setup. Comprehensive documentation both in printed and digital form complete our training offer.

### **... provide maintenance**

Regular and professional inspection of machinery minimizes the risk of system downtime and therefore increases your productivity and system availability. Our system inspectors will carry out all maintenance work for you. Simply make an appointment and Rommelag SERVICE will come and check that everything is running the way it should. In most cases the system is doing exactly that, but prevention is cheaper than repairs. With cycle machines, for example, we also take on the maintenance of the fire detection system.

Users with Rommelag SERVICE packages benefit from special terms and conditions for parts and services with this and the many other services.

### **... offer remote maintenance**

If a problem occurs, we always try to solve it via remote maintenance first. This can sometimes save you valuable time and money. All we need for this is an internet connection to the machine, which you can activate for us as required.

### **... recondition your machines**

Not everything that stops working fully needs to be replaced automatically. We work with premium components to recondition lots of machine parts cost-effectively.

### **... define wear parts packages**

Using Rommelag original parts ensures that system downtimes are reduced to a minimum. We supply the entire range of parts from a single source, in the quality and availability that only the system's original manufacturer can guarantee. Our service experts help you identify the parts you need and sends them to you on time before maintenance is scheduled to start.

### **... stock spare parts**

If desired, we can optimize your spare parts inventory by adding selected critical spare parts, so you can always have the most important parts ready to go on site if needed. We are happy to advise you on which parts you should have on site.

### **... support you**

If you get stuck somewhere along the way, another advantage of your partnership with Rommelag pays off. We design and manufacture all of our systems and virtually all of the required parts and components ourselves, so we know each machine like the back of our hand and can provide spare parts and manpower in minimum time around the world.

### **... rethink your solution**

If your bottelpack system is getting on in age, our specialists can give you extensive information about retrofitting option and steps for modernization.

### **... simplify your processes**

We offer the option of pre-booking a fixed number of service hours with us so that you can plan your annual budget more easily. Whether you want 50, 100, or any desired number of hours, as part of a package or on a time and material basis, we'll sit down with you to agree on exactly what you need.

### **and interact with you**

However you decide to contact us, our trained Rommelag SERVICE employees are ready to offer you competent, reliable, and quick support – on the telephone, by e-mail, and, of course, in person at your premises.

# BENEFIT FROM OUR GLOBAL SERVICE NETWORK



## NOW IT'S PERSONAL

VIRTUALLY EVERYTHING WE DEVELOP AND IMPLEMENT FOR OUR CUSTOMERS IS SO INDIVIDUAL THAT IT'S IMPOSSIBLE NOT TO FORGE A PERSONAL PARTNERSHIP WITH THEM. IT'S FOR THE BEST, BECAUSE FIRST-CLASS RESULTS CAN ONLY BE ACHIEVED WHEN WE ARE TOTALLY FAMILIAR WITH YOUR REQUIREMENTS AND DESIRES. LET'S FIND OUT TOGETHER HOW WE CAN MAKE YOUR WORK A LITTLE BIT BETTER AND MORE COST-EFFECTIVE – WITH VALUABLE SERVICES FROM ROMMELAG SERVICE AND YOUR INDIVIDUAL ROMMELAG SERVICE PACKAGE. DIRECT CONTACT INFORMATION FOR OUR SERVICE EXPERTS CAN BE FOUND AT [WWW.ROMMELAG.COM](http://WWW.ROMMELAG.COM)

### **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.

[www.rommelag.com](http://www.rommelag.com)



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