

**SERVICE OFFERING:**  
SINGLE SOURCE  
SOLUTION COMPETENCE



# SINGLE SOURCE SOLUTION FOR PARENTERAL DRUG PACKAGING

Datwyler's co-development capabilities and deep industry expertise deliver various benefits to its customers within the entire production process – from development to delivery.



**As a thought leader in the industry, Datwyler continuously strives for and accelerates innovation. In doing so, the company enables its customers to bring the most advanced and in-demand products to the worldwide market. Datwyler offers a suite of services designed to promote product safety and efficacy, secure a safe and fast regulatory approval, and ensure a path towards future growth. Datwyler's four service fields provide a comprehensive solution for primary and secondary packaging needs.**

Datwyler's service offering intends to provide its customers with the state-of-the-art solutions and testing strategies they require. In addition to supplying its customers with primary and secondary packaging, Datwyler's team of experts is prepared to assist with:

- Lab testing
- Custom product design
- Simulations: Finite Element Analysis (FEA)
- Business continuity plans

**By offering four service fields, Datwyler strives for product safety and efficacy.**

## LAB TESTING TO ASSURE CONFORMANCE WITH REGULATORY AND INDUSTRY REQUIREMENTS

With more than four decades of experience as a market leader in parenteral packaging, Datwyler understands the ever-changing requirements posed by the pharmaceutical industry and its regulatory bodies. To assure that the company's products meet those requirements prior to being distributed, Datwyler has assembled a series of tests to provide its customers with a comprehensive product analysis.

Datwyler's lab service begins with assisting in compound selection through questionnaires to specify the requirements for the customer's ideal product. Thanks to extensive product knowledge and experience, Datwyler's R & D team is able to recommend the ideal compound solution aligned with the indicated requirements.

## LAB TESTING SERVICES

|  |   |   |   |  |
|--|---|---|---|--|
| <b>Pharmacopoeia and normative testing</b> | Customized E.P.3.2.9 / USP<381> chemical testing            | Customized E.P.3.2.9 / USP<381> functional testing for injection stoppers | Normal and customized functional testing for infusion stoppers as per ISO8536-2   | ICP – Elemental impurities as per ICH Q3D                          |
| <b>Functionality testing</b>               | Fitting test, part 1: insertion force on vial               | Fitting test, part 2: popping up / off test                               | RSF – Residual Seal Force   | Gliding profile testing for prefilled syringes and cartridges      |
| <b>Container Closure Integrity testing</b> | PBSI – Plunger Barrel Seal Integrity test as per ISO 7886-1 | PBSI – Plunger Barrel Seal Integrity test using He-leak testing           | CCSI – Container Closure Seal Integrity test using laser-based headspace analyzer | CCSI – Container Closure Seal Integrity test using He-leak testing |
| <b>Other standard industry testing</b>     | Silicone oil determination using DCM / FTIR                 | Extractables and leachables services                                      | Moisture percentage of products   | And others   |

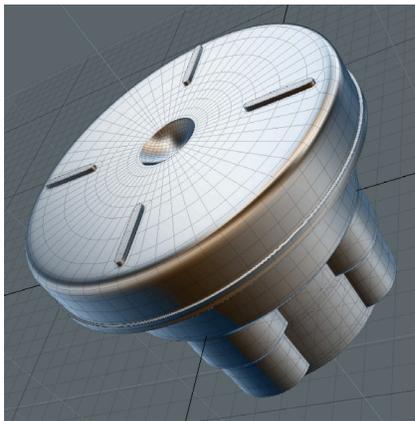
## CUSTOM PRODUCT DESIGN TO MAKE INDIVIDUAL IDEAS BECOME REALITY

Datwyler is constantly working on innovations and developments in order to offer a wide range of products to meet the different sealing solution needs. But the company also understands that the drug delivery market is ever-changing, and market leaders need to adapt to changing container closure requirements. Therefore, Datwyler provides its customers with the opportunity to develop custom sealing solutions for their drug product platform.

Datwyler calls this Co-Engineering. It means working with and alongside its customers to incorporate the company's unique process know-how into the design of their products from the very beginning of the development process.

As a leading industrial supplier and a key player in the global healthcare industry, Datwyler possesses a deep knowledge of different healthcare products, which allows them to understand the functions and applications of the customers' individual products. During the co-engineering process, Datwyler shares its know-how with the customers to assist them in determining their test criteria and functionality as accurately as possible. Every single small adjustment can help reduce the material and testing costs, and even cut the total investment outlay. Moreover, customers benefit from an optimized production process, which means that their products can be run on faster and more efficient production cycles in Datwyler's manufacturing sites – leading to a higher production quality and capacity.

## THE CO-ENGINEERING PROCESS INCORPORATES THREE MAIN PHASES



### 1 Product Design

The product and tool design team is responsible for the development of products and tooling. For each new custom design, Datwyler performs standard product design and development activities, including:

- Design and development of the product drawing
- Calculation of the total product surface and production of a product rendering
- Determination of product volume and realistic product rendering of the final design

### 2 Product Analysis

Once the desired product has been rendered, Datwyler provides a comprehensive analysis of the product design. By using 3D software, the company ensures that each product is rendered per the customer's requirements and is viable to real-world production. During the product analysis phase, the following aspects are reviewed:

- Ability to produce
- Product risk
- Dimensional analysis
- Dimensional setting and tolerances

### 3 Customized Engineering Activities

In every co-engineering process, Datwyler performs several standard services. Each customer can also choose specific upgrades in addition to the standard services to lower product risks and optimize the production process. At the end of the process, Datwyler's customers receive a reproducible, safe, and effective product to be integrated into their packaging solutions.

### STANDARD ENGINEERING DESIGN IS A MULTI-STEP PROCESS

| Standard process services                           | Optional process upgrades   |
|---|---|
| Preliminary product analysis                        | Calculation of drug contact surface                                 |
| Product feasibility assessment in selected compound | Calculation of vent / product opening during lyophilization process |
| Determination of design requirements                | Visualization of rubber product in application                      |
| Concept definition                                  | Creation of customer specific drawings                              |
| Preliminary tool concept / design                   | Metrology proposal of critical dimensions                           |
| Detailed tool design                                | Simulations   |
| Production planning tool construction               |   |
| Tool qualification activities                       |   |



Many years of expertise enable Datwyler to better understand the needs of its customers. In a co-engineering process, Datwyler works with its customers on tailor-made solutions for their individual product portfolio.

## FINITE ELEMENT ANALYSIS TO ELIMINATE POSSIBLE ISSUES AT AN EARLY STAGE

Datwyler is increasingly employing numerical simulation techniques to ensure the optimum development of the products and processes at the heart of customer applications. Datwyler uses Finite Element Analysis (FEA) to fully understand the functionality of new elastomer components at an early phase. FEA allows the assessment of a wide variety of engineering problems:

- Deformation
- Reaction forces
- Contact pressure
- Material stress
- Filling behavior
- Temperature

Among others, Datwyler’s customers benefit from an accelerated development cycle as well as superior product quality. By using Datwyler’s FEA services, customers are able to:

- Analyze a variety of engineering problems from structure concerns to reactions to certain environmental situations
- Understand increasingly complex products and production processes
- Identify potential functional and /or production problems long before real prototypes exist
- Design products faster and more cost-effectively as the costs for prototype-molding and physical testing can be reduced significantly

## DATWYLER OFFERS INDUSTRY-LEADING SIMULATION CAPABILITIES IN FOUR AREAS

### 1. Testing & Modeling

For the most accurate simulation results, Datwyler has established rigorous testing and modeling procedures which allow a comprehensive characterization of the material behavior.

### 2. Computer Aided Design

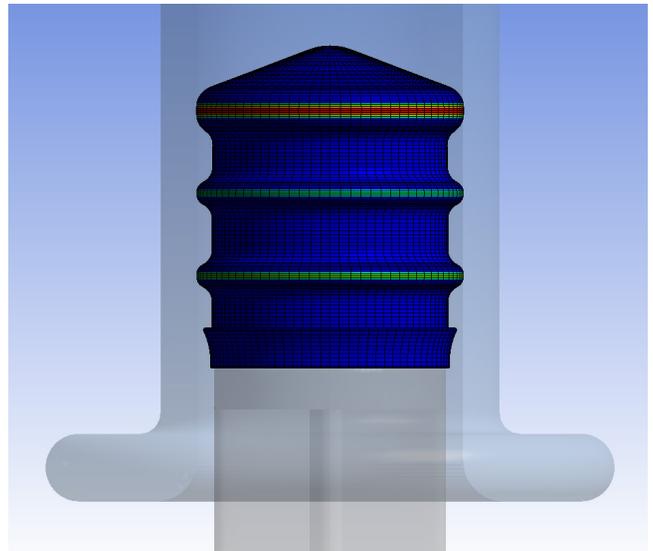
Product design and mold layout are developed and edited on a powerful CAD platform which supports fully parametrized 3D models.

### 3. Structural Mechanics

Structural mechanical analyses facilitate the systematic optimization of single parts or entire assemblies to provide best product performance.

### 4. Reducing Fluid Flow & Reaction Kinetics

The simulation of fluid flow and reaction kinetics enables the examination and optimization of mold layout and process parameters in order to ensure a reliable and cost-effective serial production.



Datwyler offers industry-leading simulation capabilities, which serve as the basis for the best product performance and a reliable serial production.

## BUSINESS CONTINUITY PLANS MINIMIZING THE RISKS FOR ITS CUSTOMERS

Datwyler takes every measure to ensure its customers have access to their products as well as a plan in place to mitigate supply risks. Datwyler's risk mitigation strategies take into account disaster risks, product discontinuity as well as regional supply constraints. By analyzing each of these areas in conjunction with its customers' supply needs, Datwyler is able to develop a joint business continuity plan to assure its customers' product availability.

### 1. Disaster Prevention and Recovery

Every Datwyler plant has a disaster recovery plan to:

- Analyze the different types of risks
- Implement preventive measures towards security, safety, and other risks
- Develop a framework to deal with unforeseen disasters

Each of these steps is an ongoing and constantly improved process to ensure that any potential issues can be resolved.

### 2. Continuous Supply

Datwyler has several production sites around the world. To ensure a continuous supply of goods, the company implements the following precautions in its sites:

- All Datwyler sites have equivalent equipment in place, allowing a fast transfer of production from one site to the other
- All key and critical process parameters are globally managed, delivering products with the same characteristics
- All tools (molds and dies) are built in-house according to the same standards

Besides this, Datwyler avoids additional risks by providing ongoing risk mitigation plans related to capacity, coated stoppers as well as raw, packaging, and auxiliary materials.

### EVERY DATWYLER SEALING SOLUTIONS PLANT HAS A THREE-STAGE DISASTER RECOVERY PLAN

Develop a framework to deal with unforeseen disasters

Implement preventive measures towards security, safety, and other risks

Analyze the different types of risks

### DATWYLER ENSURES MANUFACTURING RELIABILITY

#### CAPACITY

Most product activities only run five days a week, easily allowing for increased capacity. Datwyler has multiple manufacturing sites worldwide and capacity can be shared between plants if space is limited in its customers' local facility

#### RAW, PACKAGING & AUXILIARY MATERIALS

Risk assessment and mitigation are carried out continuously on each individual project

#### COATED SEALING SOLUTIONS

Datwyler's proprietary fluoropolymer spray coated components are currently manufactured at three different locations around the world to ensure security of supply, even in the case of unwanted events

**You can read more about the coating technology in the Coated Sealing Solutions brochure.**

**Datwyler Sealing Solutions is a leading industrial supplier and a key player in the global healthcare industry with a strong sense of future trends and the ability to set new standards. Datwyler offers state-of-the-art solutions for parenteral packaging with more than 100 years of multi-industry experience.**

Partnering with the world's top pharmaceutical and medical companies, Datwyler stands by its mission to improve patients' lives by constantly striving for zero defects in all its products. The company's state-of-the-art cleanroom manufacturing technologies exceed the most stringent industry requirements.

As a solution partner, Datwyler assists its customers in mastering the challenges of global healthcare and helps them act on opportunities of new and personal therapies.

Find out more about Datwyler's pharmaceutical and biotech solutions in other brochures:

Sealing Solutions for Healthcare  
Product Portfolio  
Sealing Solutions for Vials  
Sealing Solutions for Prefilled Syringes  
Sealing Solutions for Cartridges  
FirstLine®  
Coated Sealing Solutions  
DuraCoat™ Combiseals  
Packaging & Sterilization  
StarterPack™



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