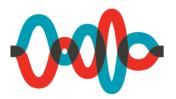


# SEALING SOLUTIONS FOR **HEALTHCARE**



### DATWYLER – WHO WE ARE

Headquartered in the heart of the Swiss Alps, Datwyler is a leading industrial supplier and key player in global markets for system-critical components in healthcare, automotive, and general industry. The healthcare market segment provides state-of-the-art solutions for parenteral drug and medical device packaging.

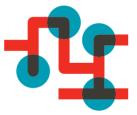


**Solution partner** Co-creating every link in the chain, from the very first idea to the moment of final delivery



#### Knowledge partner

Sharing our know-how and talent because we believe in the power of a trusting relationship with our customers



#### **Global partner**

Providing reliable solutions on a global scale throughout the entire product life cycle

### 100

years of experience of the parent company

### 7

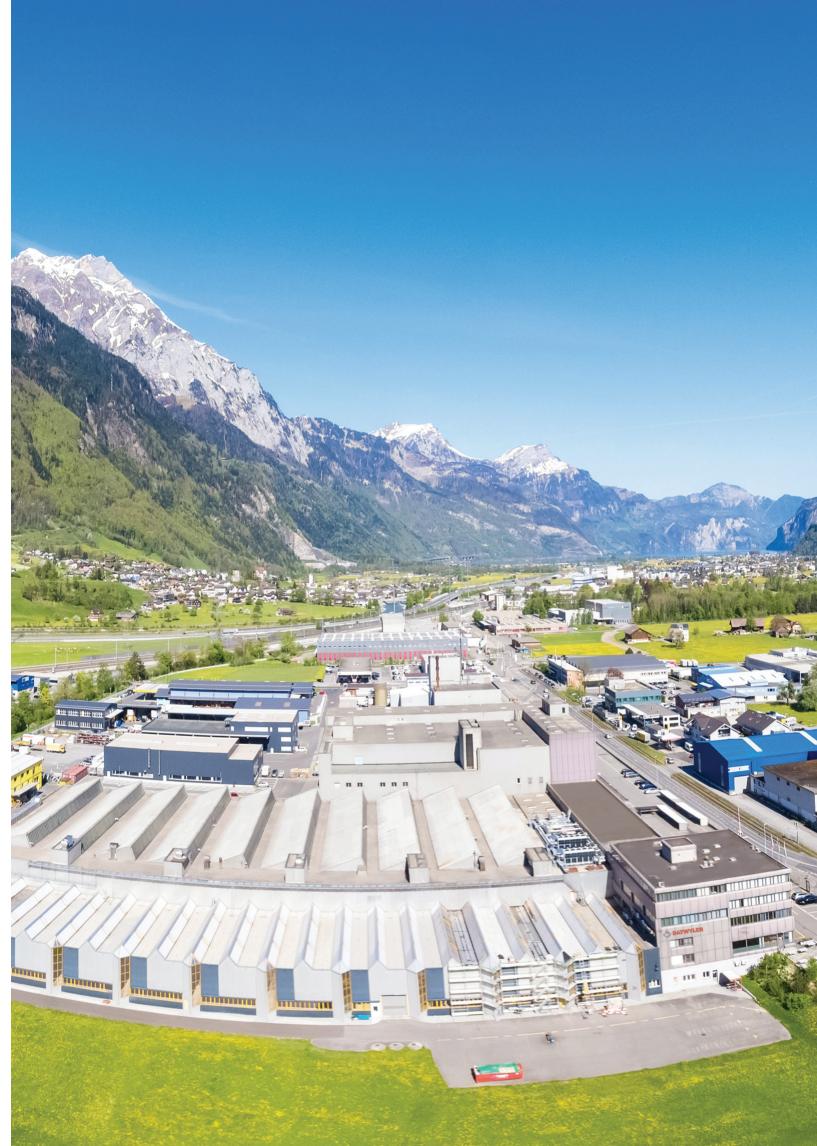
healthcare manufacturing sites on three continents

**2200** healthcare talents globally

**18** billion components every year

**600** leading healthcare customers in 65 countries

billion CHF revenue of the parent company



### OUR HERITAGE – **OUR VALUES**

Datwyler looks back on more than 100 years of innovation, benefitting our customers, employees, and other stakeholders. Over this period, Datwyler has evolved from a family-owned Swiss company into an international group. Building on our strong roots, we have developed unique values and solid foundations.

#### **VALUES FOR SUCCESS**

Our founder, Adolf Datwyler, and his sons Peter and Max Datwyler, developed and lived the values that still hold true at Datwyler today. Those values include maintaining an entrepreneurial mindset, bringing value to our customers, excelling at what we do, and being respectful to others. Together with our Code of Conduct, these values shape the culture and management at every Datwyler Group location throughout the world.

#### SUSTAINABLE AND RELIABLE

Datwyler maintains a sustainable management approach and acts as a reliable partner in its social and environmental responsibilities. This is reflected in our membership of the UN Global Compact. Our annual sustainability report in accordance with the guidelines of the Global Reporting Initiative (GRI) records our progress. With the EcoVadis audit and rating, we make our corporate social responsibility and sustainability activities available to our customers in a standardized way.

#### **HEALTHCARE – THE FOUNDATION**

With 50 years of experience in the pharmaceutical and medical industry, our product knowledge and service expertise helps make Datwyler a market leader for sealing solutions. Our efforts to constantly improve allow us to continually expand our innovative portfolio of products and services and keep our customers at the forefront of technological advancement in our industry.



WE ARE ENTREPRENEURS



WE BRING **VALUE** TO OUR CUSTOMERS



WE **EXCEL** IN WHAT WE DO



FOR OTHERS

Our values are deeply ingrained in everything we do.



### DATWYLER'S EXPERTISE – WHY PARTNER WITH US

Datwyler is a key player in the global healthcare industry with a strong understanding of the importance of high-quality products, manufacturing excellence, and continuous knowledge development. When working with Datwyler, customers can profit from our understanding in the following foundations.

#### **CUSTOMER-CENTRIC APPROACH**

From drug development and production challenges to commercial launch and ramp-up, our global multidisciplinary team of experts offers unique support to the customer. Datwyler takes an experienced holistic approach that considers all critical aspects for its customers.

#### **GLOBAL PRODUCTION FOOTPRINT**

Datwyler's production footprint is designed to provide consistent quality levels from globally harmonized sites. With three quality standards uniformly produced in three different continents, Datwyler can provide its customers with flexible supply chains to improve time-to-market and risk mitigation plans to ensure business continuity.

#### **ZERO-DEFECT PHILOSOPHY**

Facilities are designed to prevent contamination and defects, but equipped to correct them if they occur, aiming to deliver customers with the lowest possible levels of defects, crosscontamination, particulates, endotoxin, and bioburden load.

#### **QUALITY-BY-DESIGN**

Datwyler's products can play a critical role in ensuring a drug product's integrity and efficacy. That's why the company always strives to improve the way it applies Quality-by-Design principles in its design and manufacturing processes.

#### **MATERIAL EXPERTISE**

Datwyler's experts in material science develop high-performance materials and compounds which guarantee that the chemical, physical, and functional properties of the sealing parts meet the customers' exact requirements.

#### **ENGINEERING EXPERTISE**

Datwyler brings together experts in material science and development, engineering, and process automation to develop new products or re-engineer existing ones by developing tailor-made sealing solutions from prototype to large-scale production. Datwyler also believes in close collaboration with its customers: together they co-engineer the functionality and design of the customers' products by utilizing industry expertise and engineering know-how.

Datwyler not only meets the demands of current pharmaceutical and biotech trends, but goes beyond them.



### DEDICATED SOLUTIONS IN PARENTERAL PACKAGING

With a complete offering of products, technologies, and services, Datwyler meets the customers' needs for parenteral packaging – now and in the future.

#### **MEETING EVOLVING MARKET NEEDS**

In the demanding healthcare industry, parenteral packaging products must meet the highest expectations to ensure versatility. Offering long-term experience in the healthcare industry and extensive knowledge in parenteral packaging, Datwyler can both meet packaging requirements for small molecule drugs in the traditional pharmaceutical market and develop innovative biotech solutions for large molecule and highly sensitive drugs.

#### SEALING SOLUTIONS PARTNER

Datwyler believes in close collaboration with customers: a global team of experts supports customers in finding the right packaging solution. Thanks to a full healthcare offering Datywler can better assist customers during the packaging selection process. This offering includes: elastomer evaluation, assessment of necessary treatments and coating technologies, access to a full suite of value-added services, and selecting the ideal manufacturing standard for their drug product packaging.

To provide sealing solutions that set standards in the healthcare industry, Datwyler defines six components that characterize parenteral packaging to meet the customers' most rigorous requirements:

#### BROAD RANGE OF CLEAN COMPOUNDS

Product portfolio offering some of the most complex and unique elastomeric compounds in the industry

#### COMPLETE PRODUCT PORTFOLIO

Full range of sealing solutions for vials, cartridges, and prefilled syringes

#### BEST-IN-CLASS PRODUCTION TECHNOLOGIES

Manufacturing levels are designed to serve the entire pharmaceutical and biotech market

#### UNIQUE MATERIAL TREATMENT TECHNOLOGIES

State-of-the-art treatments to meet the highest demands for quality and performance

#### SPECIFIC SOLUTIONS FOR PACKAGING & STERILIZATION

High-quality packaging solutions to provide biological cleanliness to let customers concentrate on their filling processes

#### VALUE-ADDED SERVICES

Offering customers a single source solution for their packaging needs and becoming a reliable business partner with a suite of services

### BROAD RANGE OF **CLEAN COMPOUNDS**

Datwyler has the best product portfolio in the market in terms of elastomer variety and final application compatibility.

#### **PROFOUND INDUSTRY KNOW-HOW**

Our experts for material science and processing technology develop some of the most complex and unique elastomeric compounds in the industry, always answering to the most stringent quality standards and regulatory requirements. Our industry know-how enables our customers to safely and securely package innovative and sensitive drugs without compromising their safety and efficacy.

At Datwyler, we deliver the highest level of innovation, quality, and safety in the industry.



### COMPLETE PRODUCT PORTFOLIO

Datwyler is the preferred solution partner to global pharmaceutical companies. We offer one of the most extensive product portfolios for vials, cartridges, and prefilled syringes in the pharmaceutical and biotech markets worldwide.

Datwyler's experience, knowledge, and engineering expertise translates into the following product portfolio:

#### RUBBER AND ALUMINUM SEALS FOR VIALS

Produced, controlled, and tested under the industry's most stringent conditions, Datwyler's rubber and aluminum sealing solutions guarantee the highest degree of quality and reliability for a wide range of pharmaceutical and biotech applications.

#### PLUNGERS AND COMBISEALS FOR CARTRIDGES

Datwyler offers best-in-class packaging solutions compatible with different types of glass cartridges and drug applications, including insulin, hormones, and dental anesthetic.

### PLUNGERS, TIP CAPS, AND NEEDLE SHIELDS FOR PREFILLED SYRINGES

Datwyler offers best-in-class packaging solutions for a variety of syringe types and drug classes, including anticoagulant, vaccine, ophthalmic, and biotech solutions.

For more information, see the brochures Sealing solutions for Vials, Prefilled Syringes and Cartridges.



Datwyler offers a broad range of solutions for pharmaceutical and biotech applications, e.g. vials, prefilled syringes, and cartridges.

### BEST-IN-CLASS PRODUCTION TECHNOLOGIES

Datwyler offers leading packaging solutions for the pharmaceutical and biotech markets. To ensure patient safety, Datwyler's priority is to deliver safe and effective sealing solutions for drug packaging to its customers.

### For the production of parenteral solutions, Datwyler uses the following manufacturing levels to provide first-class production technologies:

#### **FirstLine**<sup>®</sup>

Datwyler's most advanced manufacturing standard. It is designed to manufacture pharmaceutical rubber components for high-end pharmaceutical and biotech markets in a fully integrated cleanroom environment conforming to the highest industry standards.

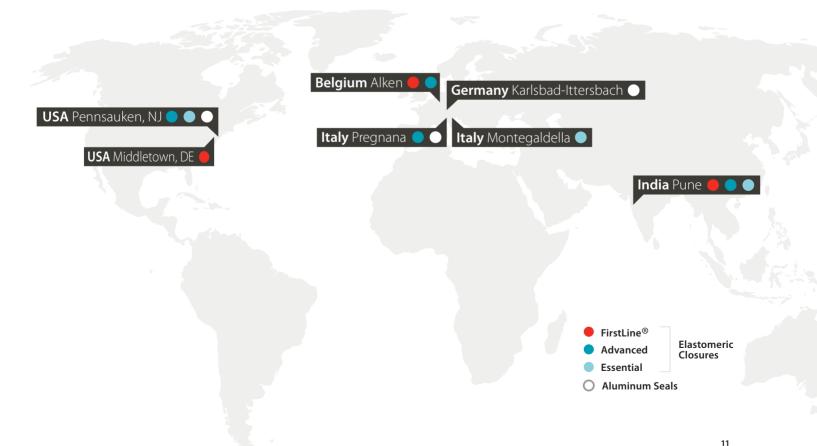
#### ADVANCED

A high-quality manufacturing standard providing a proven and reliable solution matching the quality standards and regulatory expectations needed for pharmaceutical applications.

For more information, see the brochure FirstLine®.

#### GLOBAL PRODUCTION FOOTPRINT

Thanks to its global manufacturing set-up, Datwyler guarantees consistent quality standards on a global level. With both local and regional presences in all important markets, the company meets its customers' needs for flexible supply chains and risk mitigation plans to ensure business continuity in case of emergency. To meet the needs for high-quality production all over the world and avoid long production delays due to time intensive shipments, FirstLine aligned facilities are strategically located in Belgium, India, and the United States, catering to the European, American, and Asian Pacific markets. Furthermore, Datwyler continues to invest in increasing its production quality level and capacity output.



### UNIQUE MATERIAL TREATMENT TECHNOLOGIES

Sophisticated material treatment technologies set industry standards and provide customers with components developed to meet the highest demands for quality, compatibility, and performance.

As a leading industrial supplier and key player in the global healthcare industry, Datwyler provides products with sealing materials that are as robust and clean as possible. To further ensure cleanliness, Datwyler has developed two material treatment technologies:

#### FLUOROPOLYMER SPRAY COATING

Datwyler's proprietary fluoropolymer spray coating technology is the state-of-the-art coating solution to meet the highest demands for quality and performance of highly sensitive, large molecule drugs. With the use of the fluoropolymer spray coating, customers benefit from proprietary, inert spray coating, total coverage trim edge for all designs, a covalent bond to rubber, barrier properties, and a low coefficient of friction with no siliconization needed. It is available for a variety of vial stoppers, prefilled syringes, and cartridge plungers as part of its FirstLine manufacturing concept.

#### ALUMINUM LAMINATION TECHNOLOGY

Datwyler's laminated aluminum helps reduce overall particles generated during the manufacturing process, allowing for a cleaner product from assembly to end-use. Datwyler's proprietary lamination technology is applied to aluminum to ensure a more robust and sterile product. With DuraCoat combiseals, customers can benefit from the highest quality materials, a clear reduction of particles during processing and handling, and less abrasion than standard aluminum seals.

For more information, see the brochures Coated Sealing Solutions and  $\mathsf{DuraCoat}^{\mathbb{M}}$  Combiseals



Our state-of-the-art fluoropolymer spray coating technology meets the highest demands for quality and performance for highly sensitive, large molecule drugs.

## SPECIFIC SOLUTION FOR **PACKAGING AND STERILIZATION**

Datwyler's validated packaging and sterilization solutions comprise a wide variety of applications ready for immediate use.

In light of ever-evolving requirements for drug packaging, Datwyler not only meets the demands of current pharma trends, but goes beyond them by offering ready-for-sterilization (RFS), ready-to-use (RTU), and rapid transfer port (RTP) packaging solutions:

#### **READY-FOR-STERILIZATION (RFS)**

Optimizing process efficiency and cost management. All RFS components guarantee a very high standard of particulate and biological cleanliness, giving customers the freedom to focus on their core manufacturing and filling processes.

#### **READY-TO-USE (RTU)**

Greater process efficiency and reduced total cost. RTU components not only simplify stock management and operational planning: the increased efficiency, flexibility, and security of supply chain will also result in faster lead times and a reduction of risk and labor costs.

#### **RAPID TRANSFER PORT (RTP)**

A reliable and secured product transfer solution. RTP is one of the most flexible transfer systems on the market when combined with RFS and RTU, meeting the evolving requirements of the pharmaceutical filling operations and authority regulations.

#### STEAM AND GAMMA STERILIZATION

Steam and gamma sterilization are equally viable options for most Datwyler components, allowing Datwyler's customers to meet their sterilization requirements. Datwyler products are compatible with all standard sterilization methods on the market, making it easier for customers to source components for their specific drug applications.



Datwyler has applied its expertise in RFS solutions to a platform of RTU components that minimize human intervention in the component transfer process.

### **VALUE-ADDED SERVICES**

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

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 parenteral packaging, Datwyler's team of experts is prepared to assist with:

#### LAB TESTING SERVICES

Datwyler's lab testing service begins with assisting in compound selection through questionnaires to identify the requirements for the customers' 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.

#### SIMULATIONS - FINITE ELEMENT ANALYSIS (FEA)

Datwyler offers industry-leading simulation capabilities, which serve as the basis for the best product performance and a reliable serial production. Its capabilities are divided into four areas: Testing & Modeling, Computer Aided Design, Structural Mechanics, and Reducing Fluid Flow & Reaction Kinetics.

#### **CUSTOM PRODUCT DESIGN**

Datwyler provides its customers with the opportunity to develop custom sealing solutions for their drug product platform. Datwyler calls this co-engineering. The co-engineering process incorporates three main phases: Product Design, Product Analysis, and Customized Engineering Activities.

#### **BUSINESS CONTINUITY PLANS**

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 consider 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.

For more information, see the brochure Services.

Datwyler has the research and development capabilities to partner with even the most specialized drug developers.



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:

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



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