

SOLUTIONS FOR **PACKAGING AND STERILIZATION**



READY-TO-USE AND READY-FOR-STERILIZATION PACKAGING SOLUTIONS

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

Datwyler is a leading industrial supplier and a key player in the global healthcare industry. The company offers a wide range of specialized, complex, and unique coatings, elastomer formulations, and aluminum seals that allow drug packaging and administration in the highest quality and most efficient manner.

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
- Assist its customers in mastering the challenges of global healthcare
- Help its customers act on opportunities of new and personal therapies

DATWYLER'S COMMITMENT TO QUALITY

The company's production standards are among the most advanced in the industry, assuring commitment to the highest level of quality. All Datwyler products are manufactured in the most advanced manufacturing environment, including ISO-standard cleanrooms incorporating state-of-the-art automated production cells, fully automated camera inspection, and a unique washing process. Datwyler's worldwide operations stretch across three continents and include a total of seven production sites. Therefore, the company can provide its customers with flexible supply chains to improve time-to-market and risk mitigation plans to ensure business continuity.



SAFE AND EFFECTIVE DRUG DELIVERY AND SECURE PACKAGING

Datwyler provides a unique range of healthcare sealing solutions and services for primary and secondary packaging including the most advanced elastomer formulations, proprietary coatings, sterilization options, and aluminum seals for high-efficiency production lines. Set against the background of the ever-evolving requirements for drug packaging, Datwyler not only meets the demands of current pharma trends, but goes beyond them.

Datwyler has applied its expertise in ready-for-sterilization (RFS) solutions to a platform of ready-to-use (RTU) components. In doing so, the company brings a comprehensive solution to its customers and takes full responsibility and ownership of the sterilization of the products prior to their shipment. This brings added value to the customers who consequently can redirect their resources to their core business – the manufacturing and filling of drug products.

Datwyler not only meets the demands of current pharma trends, but goes beyond them.

VALUE ADDED PACKAGING SOLUTIONS

Datwyler value addition

Bulk

Washed closures
in PE bags



RFS

Washed closures through
validated and controlled
processes in Tyvek/PE bags



RTU

Washed and sterile
closures through validated
and controlled processes
in PE/EVOH bags



RTP

Washed and sterile
closures through validated
and controlled processes
in Rapid Transfer Port bags



PROCESS EFFICIENCY AND TOTAL COST MANAGEMENT

Datwyler offers a wide variety of sterile products ready for immediate use, straight from the warehouse. RTU components simplify stock management and operational planning and also create faster lead times and a reduction of risk and labor costs through increased efficiency, flexibility, and security of supply chain.

Sterilized and vacuum packed, all RTU rubber closures can be deployed immediately in aseptic filling operations. Additionally, the vacuum packaging technique between the outer bags makes it easy to check for sterility at the point of use.

This validated RTU concept eliminates the need for:

- Washing
- Siliconization
- Sterilization
- (Re)validation of equipment and sterilization process
- Quality assurance checks of work-in-progress

Use of RTU components significantly reduces:

- Capital investment
- Manufacturing / labor costs
- Downtime
- Floor space

IMPROVED SAFETY AND RELIABILITY

Datwyler RTU solutions satisfy the strict requirements of the pharmaceutical and biotech industry meeting the EP, USP, and JP requirements and comply with the latest FDA regulatory guidelines.

RTU components include:

- Elastomeric formulations developed in-house
- Validated washing and sterilization cycles
- Certified Sterility Assurance Level (SAL 10⁻⁶) in compliance with ISO 11137
- Validated two years of shelf life
- Extractable reports
- Tamper-evident packaging validated for transportation
- Data packages on RTU products

Answering the evolving requirements of pharmaceutical filling operations and more stringent regulatory guidelines, RTU products are also available in combination with Rapid Transfer Port (RTP). By minimizing human intervention in the component transfer process, the risk of contamination is significantly reduced. In addition, the operational efficiency gets increased by facilitating routine operations.



Datwyler has applied its expertise in RFS solutions to a platform of RTU components that minimize human intervention in the component transfer process. The company takes full responsibility and ownership of the sterilization of the products prior to their shipment.



Datwyler's products are compatible with all standard sterilization methods on the market.

STERILIZATION CAPABILITIES TO MEET THE CUSTOMERS' DRUG PRODUCT NEEDS

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. Steam and gamma sterilization are equally viable options for most Datwyler components, allowing its customers to meet their sterilization requirements.

Datwyler's FirstLine Middletown facility offers validated, on-site steam sterilization. The sterilization process takes place in-line in an ISO class 5 cleanroom. Products from Datwyler's other facilities can be received in Middletown and steam sterilized in-house, further ensuring that we provide the same manufacturing standard worldwide.

Datwyler's team of experts is able to provide the appropriate data and technical support necessary to enable its customers to select the right sterilization method for their drug product. This includes:

1. Final product requirements analysis

Using a consultative approach, Datwyler gathers details on the customer's final product requirements and characteristics.

2. Process knowledge and pro/con evaluation

Leveraging Datwyler's decades of experience, the company has developed a holistic approach considering all critical aspects.

3. Providing data packages on request

Datwyler is able to provide an array of data packages detailing the compatibility of drug products and compounds before and after steam and gamma sterilization.

Following this three-step approach and considering all received elements, Datwyler can provide its customers with a shared data-driven decision.

Datwyler delivers the highest level of innovation, quality, and safety in the industry, building on more than 50 years experience in pharmaceutical industry.



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
Services
StarterPack™



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December 2021

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