

# Sealing Integrity for the Pharmaceutical Industry



Leaders in Sealing Integrity

**Garlock**

an EnPro Industries family of companies





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## *Meeting and Exceeding your **Most Rigorous** Sealing Requirements.*

Garlock® seals help make life better for millions of people around the globe. They play an important role in assuring the safety of medications, food, beverages, cosmetics and many other consumer products. Process engineers and professionals working in Quality, Operations and Maintenance trust the Garlock family of companies to develop Pharmaceutical and Bio-Pharmaceutical industry sealing solutions for a broad range of applications, including hygienic pipework, reaction vessels, blenders and mixers, ultra-pure water systems, valves and pumps.

Dependable, state-of-the-art Garlock seals, gaskets, diaphragms and valves meet key operational needs with excellent chemical resistance and remarkably long service life. Garlock is dedicated to guaranteeing the integrity and reproducibility of the products you create.



## *A Culture of Safety*

Garlock is the global leader in high-performance fluid sealing products. This leadership includes the commitment to a culture of safety and the dedication to making the world a safer, more sustainable and reliable place to live.

Our safety focus stems from our workplace culture and adherence to sealing integrity. We embrace safety both for our employees and our customers. Garlock sealing products and solutions are tested to meet or exceed industry regulatory requirements. Our goal is to go beyond compliance to set a higher standard that defines who we are and what we stand for.





## *Quality and Compliance are a Top Priority for Pharmaceutical Applications.*

In today's pharmaceutical and bio-pharmaceutical industries, cleanliness, traceability and compliance with international regulatory standards are essential for risk management. Employing durable, high-performance and precisely engineered sealing solutions is imperative to meeting these goals and preventing process material contamination.

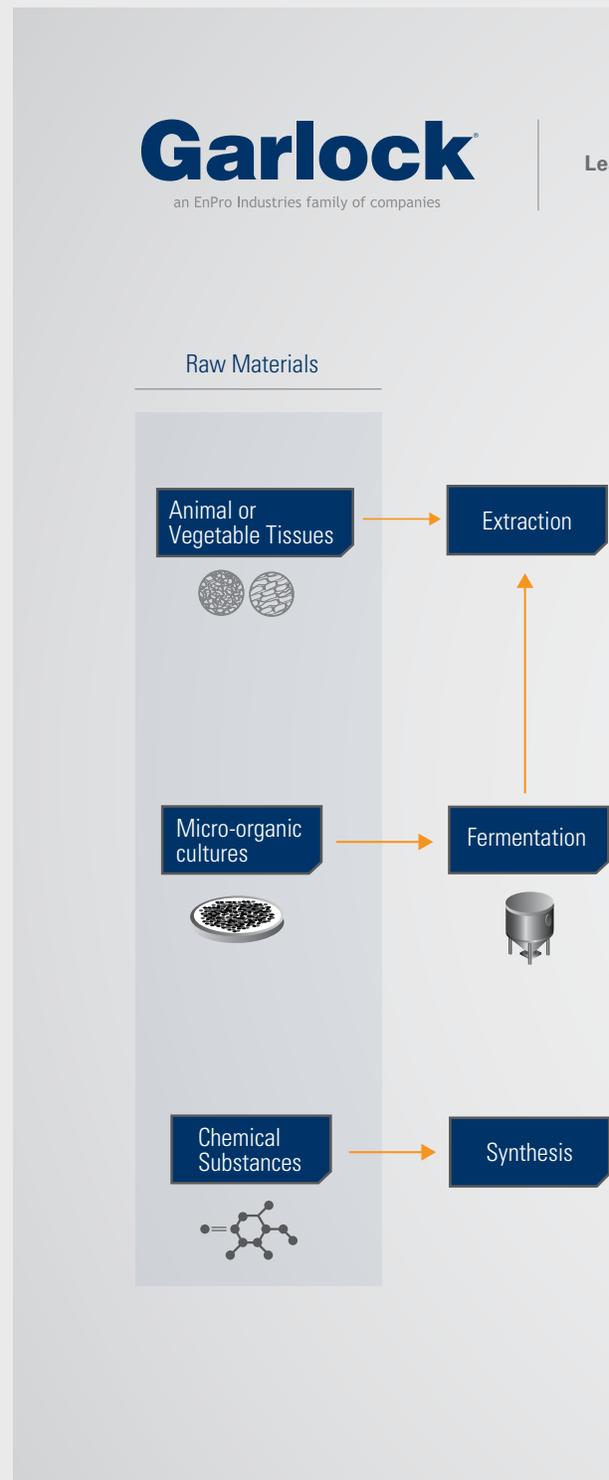
Garlock assists in this critically important task with sealing products that conform to the highest international regulatory standards, including:

- FDA 21 CFR 177.1550 for fluorocarbon plastics
- FDA 21 CFR 177.2600 for elastomers
- (EU) 1935/2004
- 3-A sanitary standards 18-03 and 20-27
- USP Class VI and Chapter <87> and <88>
- NSF/ANSI standards 51 and 61 for food equipment materials and drinking water systems

Pharmaceutical and bio-processing equipment represents a broad range of applications and operating conditions. Garlock's seal designers and engineers are constantly innovating better ways to comply with the full spectrum of regulatory requirements.

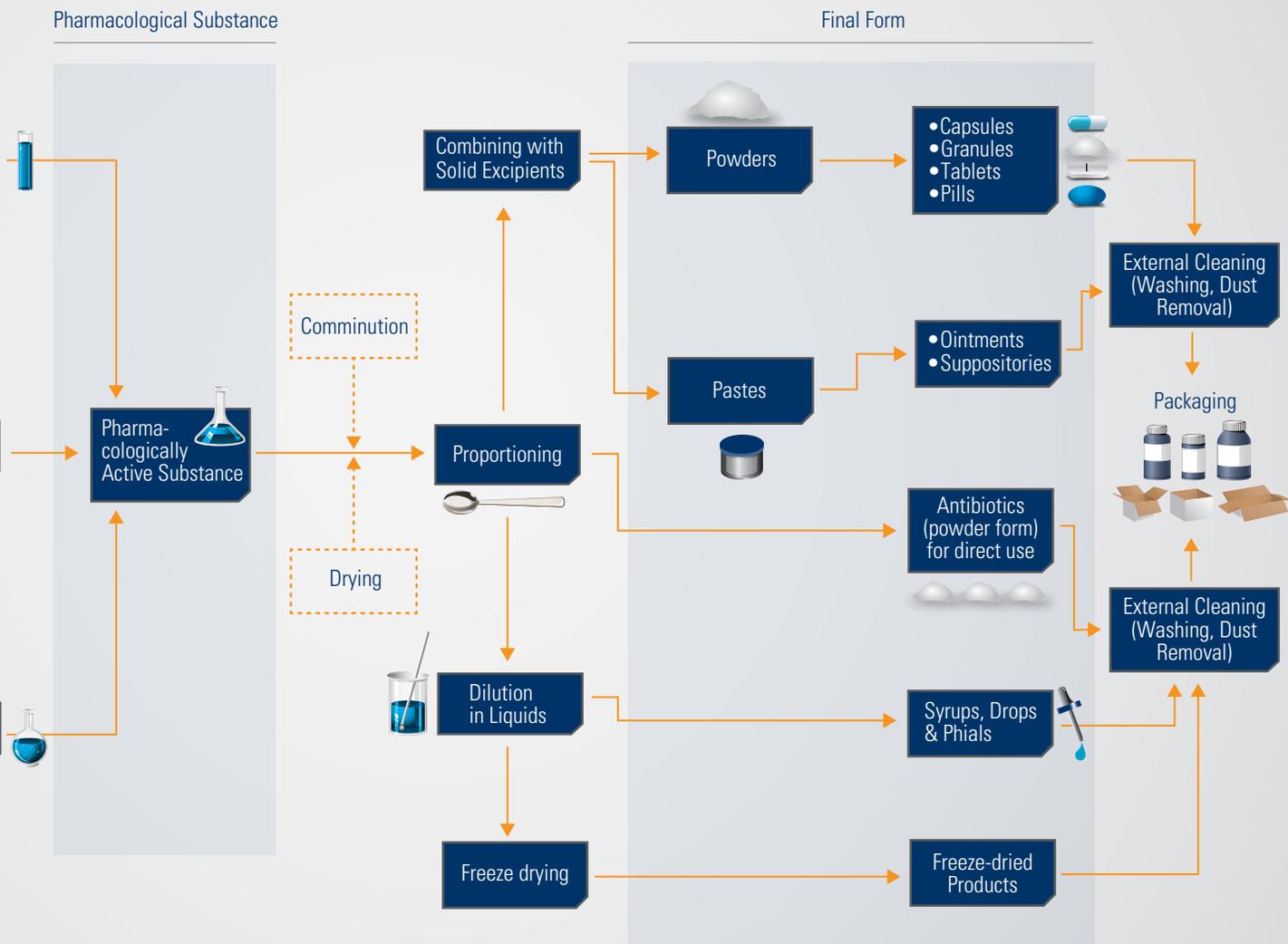
# Sealing Products for the Pharmaceutical Industry

From raw materials to final packaging, Garlock engineers and manufactures a comprehensive range of sealing solutions specifically for the varied conditions and materials used in pharmaceutical and bio-pharmaceutical production. Our applications engineers and technical experts work in close partnership with our customers to understand the complexity of their operations and the diversity of their sealing challenges; only then do we begin to prescribe specific products to meet their requirements.



- 1 GYLON® standard gaskets and GYLON BIO-LINE® sanitary gaskets are well-suited to production of APIs (active pharmaceutical ingredients) and intermediates, with excellent temperature and chemical resistance in the most aggressive of CIP/SIP regimes.

# Pharmaceutical Process Overview



**2** The wide range of final formulation processes calls for both fluid and powder sealing solutions on both static and dynamic applications. Products such as PS-SEAL® and KLOZURE® bearing isolators all provide excellent compatibility and durability in any number of challenging applications.

**3** Fill and finish operations demand some of the most critical conditions in the whole pharmaceutical process. GYLON® diaphragms are ideal for aseptic valve applications, while GAR-SPRING seals provide reliable shaft sealing on filling carousels.

## Key

### Sanitary Gaskets

BL GYLON BIO-LINE®

### Inflatable Seals

IS CEFIL'AIR® or AirLock

### Gaskets

GY GYLON®

SS STRESS SAVER®

### Dynamic Seals

PS PS-SEAL®

GS GAR-SPRING

### Bearing Isolators

IG ISO-GARD®

### Butterfly Valves

BV GAR-SEAL or STERILE-SEAL

### Diaphragms

DPM GYLON® Diaphragms

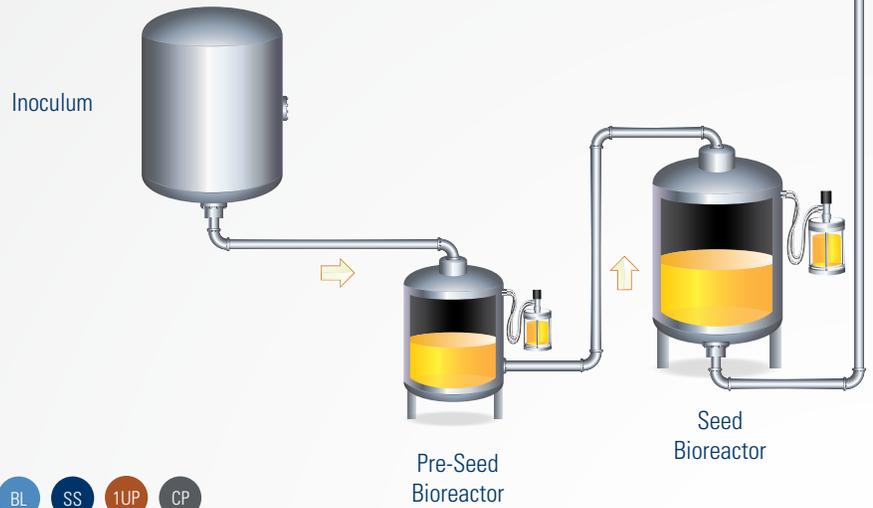
1UP GYLON® ONE-UP® Pump Diaphragms

### Expansion Joints

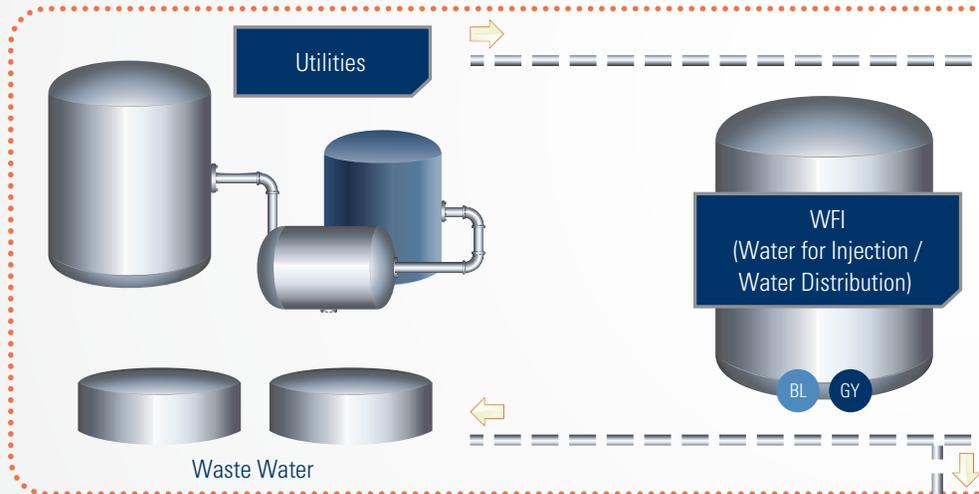
EJ GUARDIAN® 200, 200HP, and EZ-FLO®

### Compression Packaging

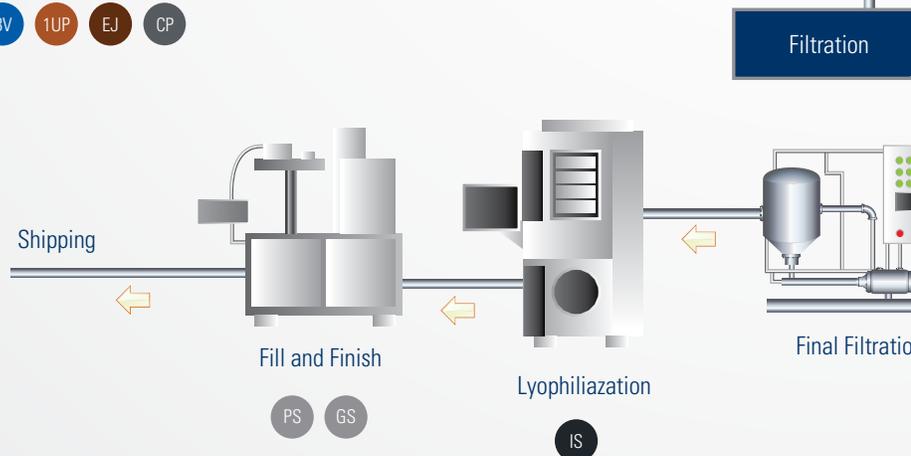
CP PTFE Packing (Styles 5904/5906)



GY BL SS 1UP CP



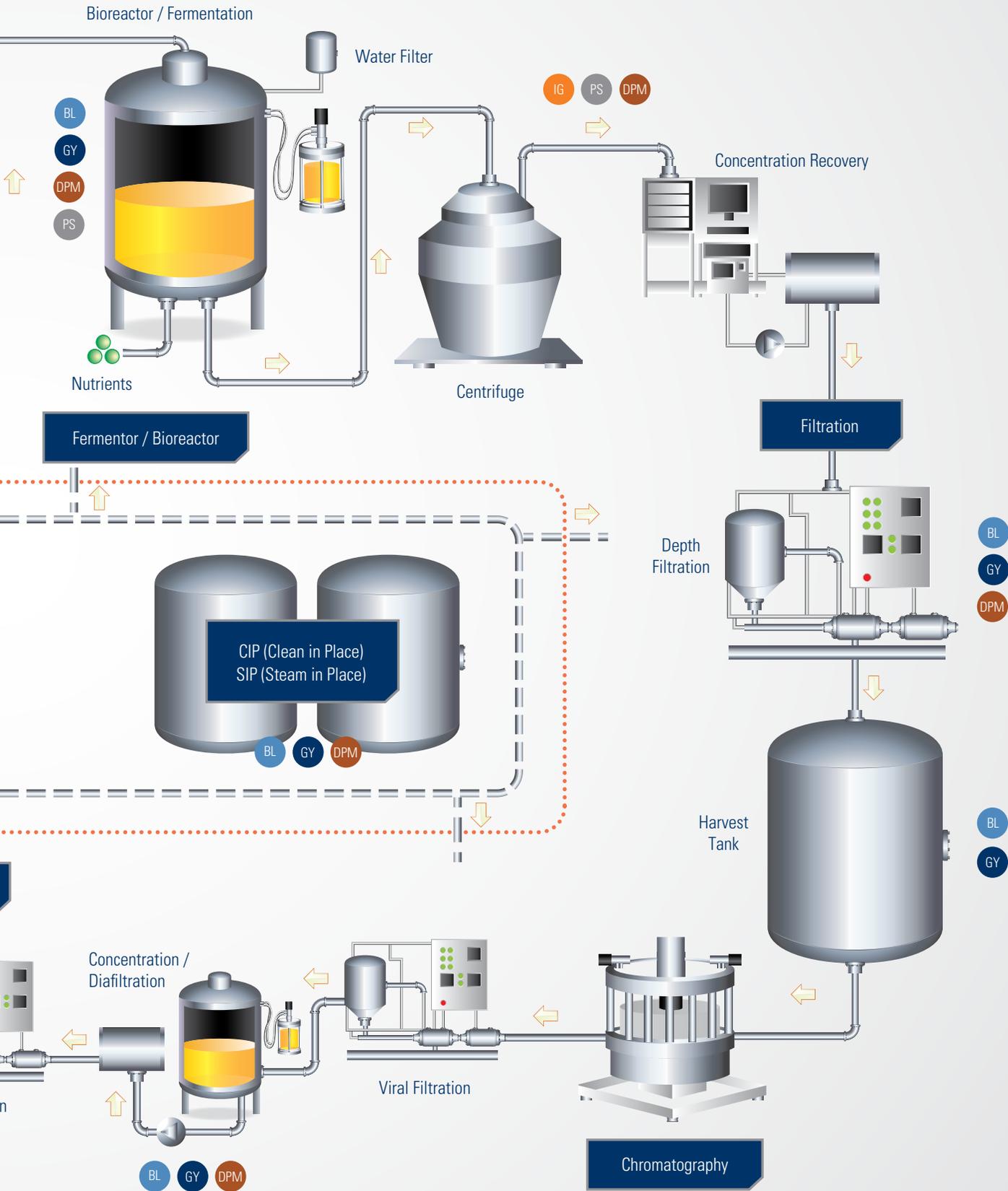
BV 1UP EJ CP



PS GS

IS

# Bio-Pharmaceutical Manufacturing Product & Application Recommendations



## Sanitary Gaskets - GYLON BIO-LINE®

### Performance materials for demanding applications

GYLON BIO-LINE® PTFE seals offer an alternative to traditional elastomer materials and better withstand the harsh conditions found in many pharmaceutical applications. GYLON BIO-LINE® seals also resist intrusion, which can lead to material contamination and flow irregularities.



#### GYLON BIO-PRO®

GYLON BIO-PRO® gaskets are pre-formed to fit tri-clamp type joints precisely and ensure a smooth 'no trap' internal surface. Dimensionally stable over a wide range of process temperatures, GYLON BIO-PRO® gaskets do not creep or relax and lose their high-integrity seal. Meets EN 1935/2004, USP Class VI, FDA compliant and KTW approved. Seal dimensions in accordance with DIN 32676, DIN 1850, ISO1127, ASME BPE – 2009, ISO 2852, SMS 3019.



#### GYLON BIO-ASEPT®

For aseptic flange connections in accordance with DIN 11853 and DIN 11864 (Form A), GYLON BIO-ASEPT® seals offer high stability and a specific elasticity. Our seals are pre-formed and stress controlled for solid sealing in piping systems. High performance PTFE sealing materials prevent chemical degradation or brittleness, even under ever-increasing process and sterilization demands.



#### GYLON BIO-ECO®

The necessity for adequate sealing stress and simultaneous recovery makes GYLON BIO-ECO® the ideal solution for couplings in accordance with DIN 11851 and SMS1149. All of the disadvantages associated with standard elastomeric seals regarding temperature, chemical resistance and re-usability are eliminated by the modified PTFE material. GYLON BIO-ECO® seals are available in all dimensions without inner collar (M1) or with inner collar (M2).



# Butterfly Valves

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## Quality regulation for maximum productivity

Regulation of caustic, abrasive and aggressive chemicals and materials can prove challenging in pharmaceutical operations. Garlock's GAR-SEAL and STERILE-SEAL butterfly valves provide the performance and maintenance features needed to ensure material integrity and maximize uptime.



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### **GAR-SEAL**

GAR-SEAL valves are used for accurate control, throttling and shut-off duties where corrosive, abrasive and toxic media must be reliably controlled. GAR-SEAL butterfly valves offer reduced maintenance requirements and increased operational reliability over competitive products.



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### **STERILE-SEAL**

STERILE-SEAL valves are used in the pharmaceutical and bio-pharmaceutical industries to maintain a sterile environment without the need for unnecessary and costly overhauls and replacements. The special characteristic of this valve is its external sterilization capability. The design allows the critical "dead" areas of the valve, along with the disc, body liner and seals, to be steam sterilized without the risk of contaminating the material being processed.



# Gaskets

## Positive Seals and Proven Reliability

Our gasketing products are offered in a wide range of materials, including GYLON® modified and restructured PTFE gaskets, an industry standard for resistance to aggressive chemicals. A patented heat welding process enables the production of one-piece gaskets instead of separate segments spliced together.



# Gaskets



## **GYLON®**

GYLON® gaskets deliver improved performance over conventional PTFE. GYLON® advantages include reduced creep relaxation and the ability to withstand a wide range of chemicals for extended service life in a wide range of applications.



## **GYLON® Style 3504 STRESS SAVER®**

Since 1996, the Garlock family of companies has successfully sealed low load flanges with our STRESS SAVER® family of products. The molded raised ribs help to create a tighter seal by concentrating the compressive load, making STRESS SAVER® ideal for lightweight piping. Our new Style 3504 GYLON® STRESS SAVER® combines these proven sealing advantages with the performance characteristics of the industry recognized GYLON® 3504.



## **STRESS SAVER® XP**

A single piece molded design made from a high performance proprietary blend of fluoroelastomers, STRESS SAVER® XP is suitable for use in potable water, steam and most chemical applications and is FDA compliant. This formulation outperforms traditional fluoroelastomers in severe chemical and steam applications that require improved heat resistance.



## **Premium Rubber**

Garlock premium rubber gasketing sheets are manufactured with a wide range of natural and synthetic rubbers, including 8316 FDA compliant EPDM. They can be deformed, but not reduced in volume. Highly impermeable Garlock rubber gasketing can serve as a tight barrier against the infiltration of gases or liquids.



# Dynamic Seals

## Specialty seals for challenging applications

Garlock's dynamic seals are engineered to meet the demanding temperature and chemical requirements of challenging and specialized pharmaceutical applications, including bioreactors, centrifuges and fill and finish operations.



### P/S®-II Multi-Lip Seal

This high-pressure multi-lip cartridge seal is ideal for sealing viscous materials in a variety of chemical processing applications. It is suited for pressures up to 150 psi (10 bar) and vacuums of 28 inches Hg (711 mm), and can withstand temperatures up to 300°F (149°C). It is also field repairable.



### 3-D Mixer Seal

Featuring a cartridge-style design, the 3-D Mixer Seal compensates for extreme shaft movement, can run dry, and can handle up to 1.000-inch of total indicated runout (TIR), compression and elongation. Custom designed for each application, these seals are rated to 300°F (148.8°C), vacuums of 28 inches Hg (711 mm), and pressures up to 150 psi (10 bar).



### GAR-SPRING

GAR-SPRING products are suitable for a wide variety of uses including Rotary and Static applications. GAR-SPRING is primarily PTFE, energized by either springs or elastomer material. GAR-SPRING is designed to withstand temperature extremes ranging from cryogenic temperatures up to 340 °C. Available in sizes from 2mm I.D. up to 2000mm.



### PS-SEAL®

High performance PS-SEAL® products operate with a sealing lip of modified PTFE, making them highly elastic and flexible with a very low coefficient of friction. They suffer little wear and require no metallic spring element. PS-SEAL® is specially designed for reliably sealing rotating shafts with high peripheral speeds, high pressure, temperature fluctuations and aggressive media.



## Bearing Isolators

### Exceptional fluid sealing for demanding applications

Garlock bearing isolators feature a labyrinth design that forms a non-contacting seal with no wearing parts for exceptional service life and contaminant prevention. Outboard and inboard drain grooves collect and expel contaminants through drain ports to achieve unmatched contaminant prevention and lubricant retention.



#### ISO-GARD®

ISO-GARD® bearing isolators provide excellent chemical resistance within a wide temperature range, making them suitable for bearing protection in many applications. A press fit design allows for ease of installation without the use of tools, reducing production downtime and saving maintenance costs. As with all Garlock Isolators, ISO-GARD® comes in a variety of configurations; both flanged and non-flanged designs are available.



# Inflatable Seals

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## Reliable performance in changing environments

Garlock's inflatable seals feature unique mechanical and chemical properties that make them ideal solutions to a wide range of pneumatic sealing challenges in pharmaceutical applications.



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### CEFIL'AIR®

CEFIL'AIR® seals have been designed to maintain seal integrity in the most critical and challenging applications. They are expanded and retracted by a pneumatic process, and their patented design withstands temperatures from -100°C to +250/280°C, and pressures from  $10^{-1}$  to  $10^{-3}$  mm Hg to several bar. CEFIL'AIR® seals are available in circular or rectangular form, in over 150 different profiles.



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### AirLock

A proven solution for sealing against infiltration by fluids, gases, powders and granules, AirLock also serves as an environment seal in a multitude of applications where a variable sealing gap is present. Manufactured in a range of elastomers including FDA compliant silicone, AirLock can be manufactured to any length and joined, shaped and vulcanized to produce the desired seal.

# Diaphragms

## Innovative designs for long life & less maintenance

Garlock's proprietary materials and designs and high-quality construction give our diaphragms exceptional service life and reduced maintenance for a wide variety of pharmaceutical applications. From pure PTFE to one-piece bolt-on PTFE-bonded rubber diaphragms, if you have a difficult or critical application, Garlock has the diaphragm to meet your needs.



### **GYLON® ONE-UP® Pump Diaphragm**

Made using our exclusive GYLON® PTFE Diaphragm material and a proprietary EPDM rubber backing, this product has the same patented rib construction of our standard industrial ONE-UP® and complies with FDA regulations.



### **GYLON® PTFE Diaphragm Style 3522**

Exclusive to Garlock, this proven product is made using a proprietary process that optimizes quality and uniformity. Through the use of the best available technology, GYLON® PTFE diaphragms offer the longest cycle life in the industry, and continue to outperform all competitive materials.



### **High-Performance Rubber Diaphragms**

Offering a variety of compounds to meet your needs, Garlock's high-performance rubber diaphragms comply with the strictest standards. We have compounds that comply with FDA standard 21CFR177.2600 and NSF 61.



# Expansion Joints

## Highly engineered joints for increased piping safety

Garlock expansion joints offer superior performance, reliability and service life. This in turn improves plant safety and increases the mechanical integrity of equipment.



### GUARDIAN® 200 and 200HP

Garlock GUARDIAN® 200 and 200HP expansion joints consist of a chemically resistant FEP liner that is mechanically bonded to an abrupt arch. An achlorobutyl cover and blue protective coating add resistance to environmental contaminants.



### GUARDIAN® Style 306 EZ-FLO®

Garlock GUARDIAN® 306 EZ-FLO® spool-type expansion joints feature an FEP lining that is fused to the body of the expansion joint. This product is designed for the pharmaceutical industry, where it has an unequalled ability to resist corrosive attack at normal or elevated temperatures and pressures.



### Style 214/215

These PTFE concentric spool-type flexible couplings are designed to reduce noise and compensate for expansion, contraction and minor piping misalignment in chemical processing systems. The convolution shape provides extra long flex life at high temperatures, and the PTFE body withstands corrosion, water, steam, and most chemicals and gases.



# Compression Packing

## Cutting edge technology for changing demands

PTFE compression packing is known for its exceptionally high resistance to chemicals and low friction, and provides excellent performance in terms of leakage control, service life and dependability. Garlock's compression packing is rigorously tested to ensure reliable, cost-effective sealing in valves, pumps, agitators and other rotary equipment.



### PTFE Packing Style 5904/5906

Style 5904 is made from high purity PTFE filament lubricated with mineral oil – both of which conform to USDA and FDA standards. It is also highly chemically resistant and suitable for use in caustic service. Style 5904 is recommended for use in rotary food processing equipment such as pumps, dryers, blenders, mixers and cookers as well as acidic mining pumps.





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Garlock Family of Companies  
1666 Division Street  
Palmyra, New York 14522 USA

1-800-448-6688 | 1-315-597-3216  
Fax: 1-800-543-0598 | 1-315-597-3039



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

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