

# ***Mechanical Seal Guidelines for Pharmaceutical Applications***

## ***Introduction***

The pharmaceutical industry demands creative sealing solutions for its unique products and manufacturing processes. Increasingly strict government and public requirements for product purity and emission controls drives the market toward an ever-increasing demand for mechanically sealed rotating equipment. Compression packing has become all but obsolete in the pharmaceutical industry.

It is the tendency of industry to apply established products to new types of equipment and new applications. This philosophy exists in the mechanical seal industry. The intent of the sealing industry is to offer crossover designs to the pharmaceutical industry building on existing proven designs. It has been found that the pharmaceutical industry is unique enough, and large enough, to demand special design features for their equipment not found in other industries.

Bioprocessing is a special group within the pharmaceutical manufacturing community. The bioprocessing group specifically processes living cells. This results in a batch process in which there are at least three different applications for every mechanical seal installation.



This paper will focus on top entry mixers. However ideas and concepts presented here may be applied to other types of equipment. This paper contains several topics about the pharmaceutical industry. Those topics are;

- Typical process flow chart
- Cryogenic Applications
- Bioprocessing
- Cleaning and Sterilization
- Design Considerations.
- Typical Sealing Applications

The intent of the paper is to introduce the reader to pharmaceutical sealing considerations and to make the reader comfortable with his or her understanding of the subject and the associated language used in the industry.

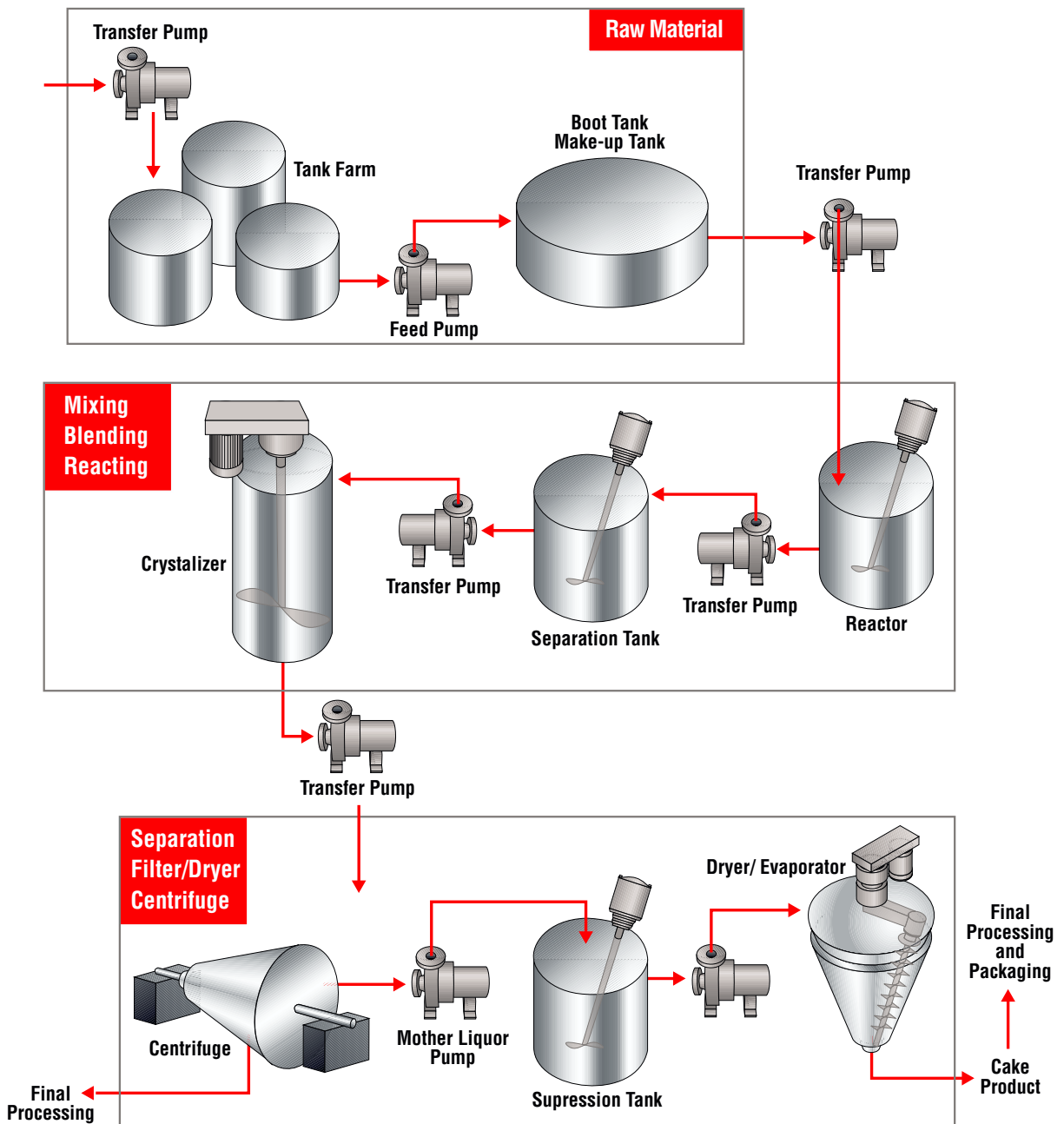
### Typical Process Flow Chart

A typical flow chart for a pharmaceutical plant may be seen in Figure 1. This is a very general flow chart and is not necessarily typical for every manufacturer. Notice

that the flowchart depicts a process similar to the manufacture of any product in the world. That is, first raw material must be gathered to a central location near the manufacturing point.

Typical Pharmaceutical Production Process

Figure 1



Manufacturing an active pharmaceutical ingredient (API) may involve simple mixing or it may involve complex chemical reactions. In the case of biopharmaceutical processing, living organisms are grown in tanks where the organisms are fed nutrients and oxygen at an optimum rate for growth and reproduction.

Once mixing, blending, reacting, or growing is complete the products must undergo separation or purification; the desired product must be isolated and collected from the bulk process materials. This step can be accomplished, depending on the process, by filters, centrifuges, or precipitation. The separation process for biopharmaceuticals is more complex and requires a different science than chemistry.

Once the API has been separated from the process it must be prepared for consumption. Whether the product is to be injected, ingested, or topical, it is now becoming more important to maintain cleanliness and sterility. Final purification of the product is done to remove trace amounts of impurities. Once the manufacturer of the final product is convinced of the purity of the product they will prepare the product for consumption. The final form may be a powder, pill, cream, or liquid. The product will then be packaged and numbered for traceability.

Naturally the steps described above are very general and vary infinitely in detail. There are wide variations in pharmaceutical manufacturing from product to product; unlike for instance petroleum refining where the technology and methods are well known and largely consistent throughout the world. But even then there are similarities in pharmaceutical plants from plant to plant where generalizations may be made.

### Cryogenic Applications

Pharmaceutical producers are constantly looking for new ways to enhance safety and economy of production for their products. That means that new extremes of pressure and temperature are being evaluated by both equipment and pharmaceutical manufacturers. Typically process pressures and temperatures tend to rise to new heights, but now pharmaceutical plants are asking for equipment to contain process temperatures lower than ever before. It is not uncommon to design to temperatures as low as minus one hundred and fifty degrees Fahrenheit.

There are several reasons why cryogenic operation may be considered for a process condition. One reason is that cryogenic temperatures slow the process reaction to a manageable rate. Another reason is that liquid used in the process reaction will not flash or evaporate at these dramatically reduced temperatures; this may reduce the need for high pressures to maintain a liquid state in the process. Also cryogenic temperatures can slow bio-activity thus reduce risk of bio-pollution in the process.

In the chemical and refining industries it has been normal to manage process temperature extremes by utilizing double mechanical seals with flush Plan 54. The Plan 54 external flush is provided at an appropriate pressure, temperature, and flow rate to moderate the temperature in the seal cavity; thus maintaining good lubricating properties while protecting the seal components from extreme temperatures.

Double mechanical seals are used in the pharmaceutical industry for a variety of reasons. Because of the ever pressing demand for pure product and simple equipment, dry running single and double seals are emerging as a strong preference in this industry. Some of the design and material considerations when sealing cryogenic equipment are as follows;

- O-rings harden and become embrittled as their temperature decreases. They cease to remain elastic as temperatures drop below 0°F (-18°C).
- O-rings have a high coefficient of thermal expansion. This means that as temperatures decrease the O-ring will not maintain a proper squeeze for proper operation. The O-ring will contract faster than the surrounding metal while at the same time hardening due to the low temperature.
- Fits of sleeves, shrouds, collars, and housings will loosen due to large temperature gradients across the parts.
- Interference fits between dissimilar materials may loosen.
- Freezing and moisture around the atmosphere side of the seal will cause hang-up of pieces that are expected to have slight accommodating motion.
- Condensation and freezing of condensate in the dry seal housing.

Based on the above partial list of cryogenic design considerations, the following set of guidelines helps establish some design rules for cryogenic seal operation. The biggest consideration is the temperature limit of the elastomers. The following addresses temperature only;

Temperature Range: 0°F (-18°C) to 70°F (21°C)

Acceptable Elastomers Based on Temperature: EPR, fluorelastomer, perfluoroelastomer, buna

**Note:** Conventional wet or dry mechanical seals are acceptable in this temperature range.

Temperature Range: 0°F (-18°C) to -40°F (-40°C)

Acceptable Elastomers Based on Temperature: EPR, custom fluorelastomer, buna

**Note:** Conventional wet or dry mechanical seals are acceptable in this temperature range. Care must be taken to insure that barrier fluids are compatible

with low temperatures. The use of a thermal spool and/or a wet seal with flush plan 54 may drive the elastomers into an acceptable temperature range.

Temperature Range: -40°F (-40°C) to -200°F (-130°C)

Acceptable Elastomers Based on Temperature: none

**Note:** A thermal spool under the seal must be used. The spool in conjunction with a flush plan 54 will raise the temperature at the secondary seals enough to use a conventional wet or dry mechanical seal. Care must be taken to insure that barrier fluids are compatible with low temperatures. The use of a thermal spool and/or a wet seal with flush plan 54 may drive the elastomers into an acceptable temperature range.

The simplest and most efficient method to insure that the elastomers are kept warm enough is to install a thermal spool between the mixer flange and the seal canister. This spool is similar to a stuffing box jacket but is positioned between the vessel and the seal in a strategic location. The intent of the spool is to interrupt heat flow to or from the seal into of from the vessel. It may be considered to be a thermal dam, or an insulator.

Any fluid pumped through the spool will act as a heat flow interrupter. If there is concern that the spool fluid might freeze then oil, glycerin, glycol, or aqueous solutions of glycerin or glycol may be used. While a properly designed spool can significantly interrupt heat flow through the seal housings the shaft remains an avenue through which heat can enter or leave the seal cavity. Design ‘tricks’ must be used to help counter heat transfer through the shaft.

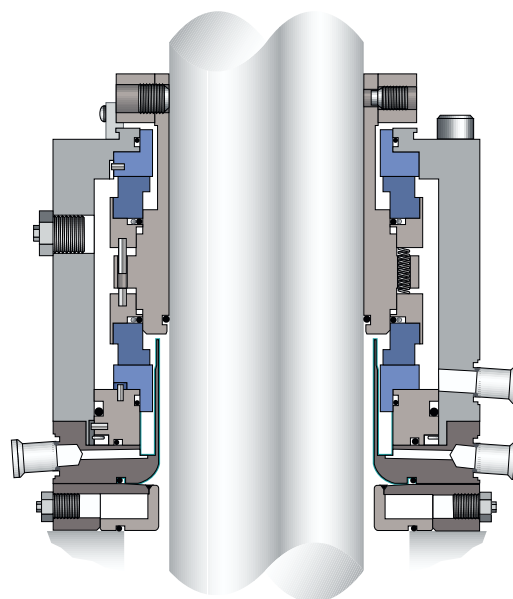
### Bioprocessing

Bioprocessing is unique because, as the name implies, living organisms are being farmed and harvested. The vessel conditions during processing are not demanding and well within the capabilities of even the lowest technology seal. However great caution must be exercised with these applications because the seal design and manufacturing techniques for these seals are a great departure from the ordinary. Also while the application seems innocuous it must be noted that the vessel processing operation is only a distraction from the actual difficult part of the application; CIP and SIP.

The mechanical seals that have been used in bioprocessing in the past are increasingly seen as dirty designs; they have many cracks and crevices in which organisms may hide and reproduce. They are often thought of as Clean-Out-of-Place (COP) seals. The COP seal is removed, cleaned, and sterilized between batches. Sometimes COP is performed between every batch. This is a very expensive procedure and automatically creates questions about the sterility of the seal and tank when the seal is reinstalled. This requires the sterilization of the seal and vessel once reinstalled. The expense of this labor intensive process clearly points out the value of a seal capable of CIP and SIP without removal from the vessel.

### Dual Seal with Thermal Spool

Figure 2



A seal that can be reliably cleaned (CIP) and sterilized (SIP) between batches without removal is an economic advantage both in time and labor, to say nothing of confidence for maintaining the sterile condition of the equipment. In other words, a properly designed seal will increase the repeatability of CIP and SIP while minimizing downtime of the equipment. This is all doubly important for the bottom entry mixer configuration that seems to be a standard in the bioprocessing industry.

### Cleaning and Sterilization

Cleaning and sterilization create operational conditions that must be taken into account when selecting a mechanical seal. The CIP process performed between batches can utilize a variety of chemicals that will contact with the inboard mechanical seal. Typically these chemicals will be mild acids or caustics at elevated temperatures of approximately 176°F (80°C). Therefore the seal materials must be capable of tolerating those chemicals and temperatures.

During the SIP process the seal will be exposed to steam temperature of approximately 278°F (131°C). Minimally the steam will be introduced into the vessel for a designated period of time to obtain a designated target temperature of the sterile boundary surfaces. Seal designers must take note that it has become very common to introduce steam into the double seal cavity for sterilization.

To understand the levels of ‘clean’ it is necessary to define some common word used in the pharmaceutical industry. Most common are the words clean, sanitary, and sterile.

Clean means free from dirt, stain, impurities, and generally unsoiled. This is the easiest level of cleaning to accomplish. It can be accomplished with water and solvent flush. Usually the condition of clean can be measured by visual inspection. Mechanical seals can be cleaned safely and easily will little need to anticipate damage to the seal's ability to properly perform.

Sanitary relates to health. To sanitized means to be made free from elements that endanger health. The word sanitary is often associated with the words asepsis and hygienic. This means that all harmful living organisms have been killed or removed to a degree that the remaining organism cannot produce disease or sickness. A state of sanitary cleanliness is more difficult to obtain in a mechanical seal.

To become sanitary the seal must be cleaned in a manner that assures that harmful organisms have been purged from all surfaces, cracks, pools, and reservoirs that naturally exist in mechanical seals. Some of the methods used to produce a sanitary condition in a mechanical seal can cause damage to the sealing surfaces or the materials from which the seal is made. The seal designer must take care to understand the cleaning method to be used and thus design the seal configuration and materials to tolerate those conditions.

Sterilization is the most difficult level of cleaning to obtain. To be sterile is to be free of living organisms. It is difficult to establish and maintain a certifiable state of sterilization for the same reason that the state of sanitary cleanliness is difficult to obtain; there are many cracks and crevices in a mechanical seal where organisms can hide. It is impossible to design a mechanical seal where all cracks and crevices have been designed out of the seal.

The method of sterilization is a more damaging process than the process used to obtain cleanliness or asepsis. During the design and selection of materials for the seal it is essential that the designer be aware of the user's intent for sterilizing the mechanical seal. That way the seal design may reflect the best selection of configuration and materials to tolerate the harsh steam sterilization.

A cleaning cycle will usually include the three following steps;

1. CIP fluid is sprayed around all contact surfaces using spray balls in the mixing vessel. The goal is for the stream of fluid to impact all surfaces to take advantage of fluid inertia scrubbing. Spraying is typically performed at elevated temperatures to accelerate the effectiveness of the CIP fluid. When spraying has been completed the vessel will be drained as completely as possible.
2. Deionized water flush will then be sprayed into the vessel and the chemicals from CIP and loosened debris will be thoroughly washed away.
3. The vessel will be sealed and steam will be injected into the vessel. The vessel will be steamed until all surfaces reach a target temperature for a target time. This includes the mechanical seal. Additionally it must be remembered that many users wish to concurrently SIP the seal barrier fluid area. They believe the bugs that might be left in the seal cavity will be forced across the inboard seal faces and into the vessel during operation.

## Design Considerations for Mechanical Seals in the Pharmaceutical Industry

Whether cleaning, sanitizing, or sterilizing equipment with mechanical seals, the design methods used to make the mechanical seal receptive and tolerant of cleaning is essential. There is a wide variety of opinion in the marketplace about what features are necessary for a properly designed mechanical seal. Because of this it is important to understand the specific needs of the particular user and properly transmit those needs to the seal designer. A review of common design features used in seals used in pharmaceutical applications immediately follows.

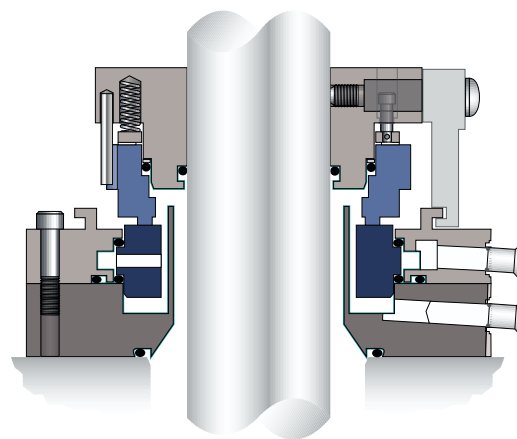
### Debris Well

This device is also known as a 'sanitary feature' even though it has less to do with asepsis than with debris. The debris well is designed to catch wear particles from the sliding faces. The debris collects in the debris well. When the batch is finished the debris may be swept from the area by ports arranged for flushing with water or steam. Naturally the ports are normally closed during operation. Ideally there is a low-point port that is sloped down for complete drainability.

The debris well is common device but many seals are designed without this feature. It is important to be specific about including this feature, or not, in the design.

VRA with Debris Well

Figure 3



### Surface Finish

A fine surface finish is typically required on equipment where CIP and SIP occurs. The surface finish requirement exceeds normal seal surface finishes. The very smooth surface resulting from hand polishing and electropolishing aids in cleaning and sterilizing the equipment. Residue is more easily cleaned from a very smooth surface.



A machined surface finish of 63 Ra is easy to obtain on a metal lathe. Even a finer surface of 32 Ra is relatively easy to obtain when using good machining practices. However to obtain the surface finish of 15-25 Ra, which covers 95% of the product contact surface requirements, demands extra steps.

To obtain a 20 Ra surface finish requires that very good machining methods be used. However, a machined surface will exhibit microscopic tears, rips, and rolls of metal straight off a lathe; even when the surface finish appears to be meet finish specifications! All mechanical polishing provides the same surface condition; ripping and tears in the metal.

Electropolishing will improve the finish. With the use of chemicals and electricity, slight amounts of material will be removed from the surface of the metal making it microscopically smooth and featureless, and very difficult for biomass to cling to!

There is disagreement between pharmaceutical users as to what portion of the seal must be polished. It is important to determine the company's philosophy and pass that information on to the seal designer. It is also important to note that there are materials used in the mechanical seal that can not be electropolished. Best efforts are made to provide the specified surface finishes when and where called for.

### ***Sloping Surfaces***

It is desirable for all surfaces that contact product or barrier fluid to be sloped. This increases the effectiveness of the CIP and SIP process. This allows for quicker and more complete drying and minimizes pooling of liquid in cracks and crevices.

### ***Modified O-ring Grooves and Drainable Gaskets***

O-ring grooves are a common location for pooling of liquid that cannot be easily flushed out or cleaned. When possible the O-ring grooves can be designed in a manner that minimizes pooling area and exposes the O-ring and groove to cleaning fluids, sterilization, and draining.

This feature is a compromise of design characteristics and the seal designer uses this feature only if the feature is requested.

### ***Seal Designs***

Flowserve offers a complete range of single, dual, dry contacting, dry non-contacting, and liquid lubricated seals that may be used in the pharmaceutical industry. Flowserve has developed relationships and alliances with major equipment OEMs that produce custom equipment for the pharmaceutical industry.

Flowserve currently designs and provides seals for mixers, filter dryers, centrifuges, media mills, rotary filters, rotary dryers, conical dryers, choppers and various other specialty equipment. OEM names such as Pfaudler, Lightnin, Pro-Quip, Rosendmund, Cogium, Carr, are among the OEMs that Flowserve serves every day. Applications encountered are water filtration, fermentation, separation, homogenization, evaporation, biowaste, WFI, slurries and powders.

The following seals may be purchased as standard offerings. However they may be customized with any of the previously mentioned modifications to make them more pharmaceutical appropriate and to fit the xspecific need of the user.

### ***M-Series***

The standard M-Series of double mechanical seals are built on a chassis that allows the conversion from one design philosophy to another. There are three distinct designs within this family of seals. A liquid lubricated, a dry contacting, and a dry non-contacting seal.

### ***MW-200***

Double wet seal requires a liquid barrier fluid.

Barrier Pressure: up to 500 psi (35 bar)

Temperature: -40° to 500°F (-40°C to 260°C)

Speed: 0 to 225 RPM

### ***MD-200***

Double dry contacting seal requires gaseous pressurized barrier fluid.

Barrier Pressure: up to 125 psi (8,6 bar)

Temperature: -40° to 300°F (-40°C to 150°C)

Speed: 0 to 225 RPM

**ML-200**

Double dry non-contacting seal requires pressurized gas barrier fluid.

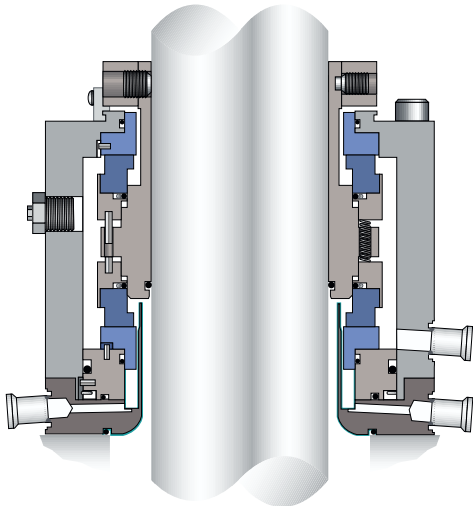
Barrier Pressure: up to 150 psi (10,3 bar)

Temperature: -40° to 500°F (-40°C to 260°C)

Speed: 0 to 500 RPM

ML-200

Figure 4



**QBW**

Double dry contacting component seal requires pressurized gas barrier fluid.

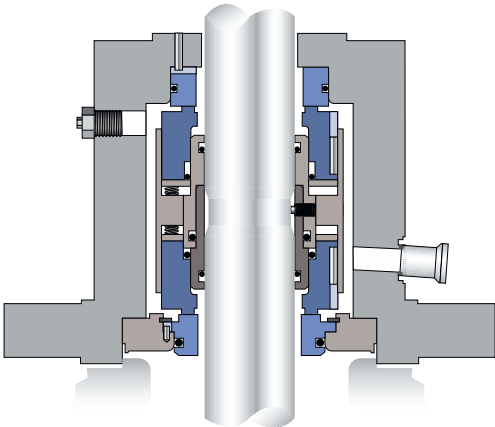
Barrier Pressure: up to 125 psi (8,6 bar)

Temperature: -40° to 300°F (-40°C to 150°C)

Speed: 0 to 225 RPM

QBW

Figure 6



**Other Seal Designs**

**Single VRA**

Dry contacting seal

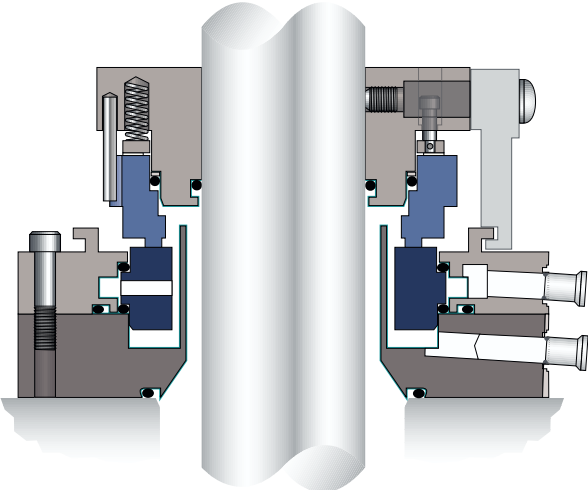
Pressure: up to 200 psi (13,8 bar)

Temperature: -40° to 250°F (-40°C to 121°C)

Speed: 0 to 350 RPM

VRA

Figure 5



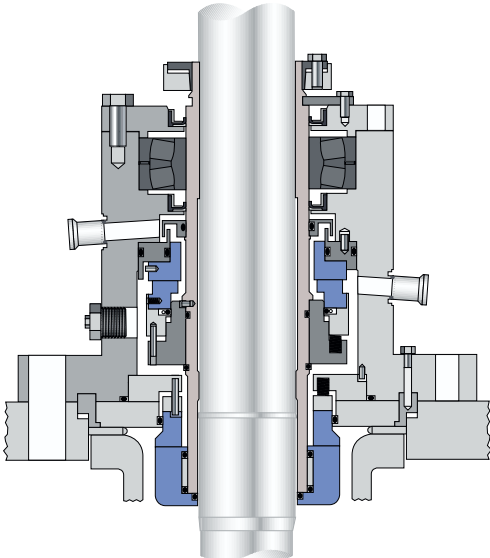
**MixerPac 2570**

DIN double non-contacting requires pressurized gas barrier

Barrier Pressure: vacuum to

MixerPac 2570

Figure 7



**ST**

Double wet mechanical seal specifically designed for bottom entry vessels in biopharmaceutical applications

Barrier Pressure: up to 88 psi (6 bar)

Temperature: -13° to 392°F (-25°C to 200°C)

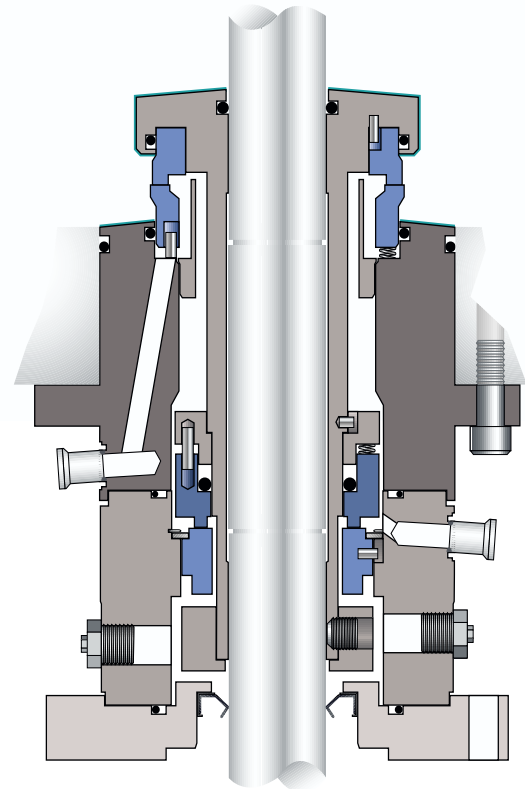
Speed: 0 to 1000 RPM

The following list of options are available to turn standard sealing products into a custom pharmaceutical seal. Not all options are available to all seal types. Consult Flowserve for details

1. Certifications for materials and finishes
2. Surface finish enhancement for wetted areas of the seal
3. Sloped surfaces for enhanced drainage
4. Electropolishing for wetted surfaces
5. Passivation for wetted surfaces
6. Special face material combinations
7. Sanitary fittings with BPE compliant attachment to the seal cartridge
8. Bearing may be requested for the cartridge assembly
9. Bearing grease may be specified by customer.
10. Special O-ring lubricant may be specified by customer

**ST**

Figure 8



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**USA and Canada**

Kalamazoo, Michigan USA  
Telephone: 1 269 381 2650  
Telefax: 1 269 382 8726

**Europe, Middle East, Africa**

Essen, Germany  
Telephone: 49 201 31937-0  
Telefax: 49 201 2200-561

**Asia Pacific**

Singapore  
Telephone: 65 6544 6800  
Telefax: 65 6214 0541

**Latin America**

Mexico City  
Telephone: 52 55 5567 7170  
Telefax: 52 55 5567 4224