**Mechanical Seal Guidelines for Pharmaceutical Applications**

**Introduction**

The pharmaceutical and bio-pharmaceutical industry is an industry with economic potential for mechanical sealing solutions. It is also an industry that is unique both in its product and its manufacturing processes. Historically the sealing industry has focused on the chemical and petroleum industries. But as Government regulations for both product purity and emission control becomes tighter, there is an ever-increasing interest in mechanically sealing equipment that has in the recent past been sealed with compression packings.

It is the tendency of industry to attempt to apply established products to new types of equipment and applications. This philosophy was no different in the mechanical sealing industry. The intent of the sealing industry has been to provide a crossover product line to the pharmaceutical industry. It has been found that the pharmaceutical and bio-pharmaceutical industries are unique enough, and large enough, to demand special design consideration. And as the mechanical seal industry learns more about the needs and demands of the equipment and processes, it can be expected that more mechanical seal designs will be developed to meet the needs of this vibrant and growing industry.

This paper contains several topics about the pharmaceutical and bio-pharmaceutical industry. Those topics are:
- Typical Process Flow Chart
- Cryogenic Applications
- Cleaning and Sterilization
- Design Considerations
- Seal Designs
- Typical Sealing Applications

The intent of this paper is to introduce the reader to pharmaceutical and bio-pharmaceutical sealing considerations, and make the reader comfortable with his or her understanding of the subject and the language used in the industry.
Typical Process Flow Chart

A typical flow chart for the pharmaceutical industry may be seen on Figure 1. Note that this flowchart depicts a similar process common to the manufacture of any product anywhere in the world. That is, first the raw materials must be gathered to a location within a useful proximity to where the processing will occur.

Typical Pharmaceutical Production Process

Typical Pharmaceutical Production Process
Once there is reasonable access to the raw materials, the raw materials are combined and processed. Combining and processing may be simply mixing, or reacting chemically, or in the case of bio-pharmaceuticals, living organisms are grown. In the case of cultivating a vessel full of living organisms, the organisms must be fed and held at very exacting pressures and temperatures. This step is typically carried out in a mixer or reactor.

Once the mixing, precipitating, chemical reacting, or growth is complete, the useful product must undergo separation. This is the part of the process where the undesirable components of the reaction, mixing, or cultivating must be separated from the useful components and discarded. The desirable components must move on to the next step. The separation can occur in a filter/dryer, a centrifuge, or an evaporator.

The product from separation may be processed again to remove additional impurities, in which case it may go through additional mixing and separation steps. Wherever it goes, at some point it has been processed to an acceptable purity, and it must be packaged for shipment. At this point it may be stamped into pills, used as filler in capsules, become an injectable fluid, bottled, or bulk shipped to another plant as a raw product for some other process.

The steps shown above are highly simplified. Keep in mind that there are wide variations in each pharmaceutical plant process. Unlike the petroleum refining where the systems and fairly similar throughout the world, pharmaceutical processing is as unique and varied as the number of products in the world marketplace. However, despite the variations, there are other similarities that are consistent from plant to plant!

**Cryogenic Applications**

Pharmaceutical producers are constantly searching for new methods to economically produce their product. This means that new extremes of pressures and temperatures are being evaluated by both pharmaceutical and equipment manufacturers. Process pressures and temperatures are rising, and it is now common to be asked to seal low temperatures that were previously believed impossible to seal. Temperatures as low as minus one hundred, two hundred, and even three hundred degrees Fahrenheit are being considered as necessary process temperatures.

There are a few reasons why cryogenic operation may be considered for a process. One reason is that cryogenics slows the process reaction to a manageable rate so precise reactions can be produced. Another reason is that the liquids used in the reaction will not flash or evaporate at dramatically reduced temperatures, so high pressures are not necessary to keep the liquid in a liquid state.

In the chemical or refining industries it has been somewhat normal to manage extremes of temperature by utilizing double seals with and API Plan 54 external flush to moderate the temperatures in the seal area. In extremely hot applications in the refining industry single bellows seals are used with a steam quench to remove the build-up of oxidized hydrocarbon, or coke. While these methods have been successful in the chemical and petrochemical industries, these techniques are not as accepted in the pharmaceutical industry. The pharmaceutical industry is moving away from double wet seals because of contamination issues, and much of the specialty pharmaceutical equipment is top entry gaseous phase seal operation, making single bellows seals generally unacceptable.

New sealing methods and materials must be sought out for the constant push toward cryogenics. Some of the considerations for cryogenics are:

- O-rings harden and become embrittled as their temperature is decreased. They cease to remain elastic as temperatures drop below zero Fahrenheit.
- O-rings have a high coefficient of thermal expansion. This means that as the temperatures decrease, the o-ring will not maintain the proper squeeze for proper operation. The o-ring may actually shrink much faster than the metal components around it that it may lift off the metal surfaces all together.
- Fits of sleeve, shrouds, collars and housings may loosen up as there is a large temperature gradient across the seal and seal components.
- Interference fits between dissimilar materials may loosen.
- Freezing of moisture around the atmosphere side of the seal, causing icing on the seal components that are supposed to remain mobile.
- Condensation and freezing of the condensate in the dry seal housing.

Based on the above partial list of cryogenic design considerations, the following is a current guideline that establishes some design rules for cryogenic seals. The biggest consideration is the temperature limit of the elastomers.
The following addresses the consideration of temperature ONLY.

Temperature Range: ambient to 0°F
Acceptable Elastomers Based on Temperature:
- EPR, Viton, Kalrez, Buna,
- Fluorosilicone, Silicone,
- Aflaz, Chemraz

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

Temperature Range: 0°F to -40°F
Acceptable Elastomers Based on Temperature:
- EPR, Buna, Fluorosilicone,
- Silicone

Notes: Conventional wet or dry mechanical seals are acceptable in this temperature range.
Care should be taken to make sure barrier fluids are compatible with low temperatures.
The use of a heating spool and/or wet seal with API Plan 54 may drive the acceptable elastomers into one temperature range up.

Temperature Range: -40°F to -100°F
Acceptable Elastomers Based on Temperature:
- Fluorosilicone

Notes: Conventional wet or dry mechanical seals are acceptable in this temperature range.
Care should be taken to make sure barrier fluids are compatible with low temperatures.
The use of a heating spool is recommended but not required unless problems occur with the seal at low Temperature. A wet seal with API Plan 54 and a heating seal may drive the acceptable elastomers into one temperature range up.

Temperature Range: -100°F and below
Acceptable Elastomers Based on Temperature:
- Fluorosilicone

Notes: Wet mechanical seals are acceptable in this temperature range only when a heating spool and API Plan 54 and/or heating coils in the stuffing box around the seal are used. Care should be taken to make sure barrier fluids are compatible with low temperatures. These applications should be referred to Flowserve Kalamazoo Engineering.

The simplest and most efficient method to keep the elastomers warm enough to operate is the insertion of a heating spool between the seal housing and the vessel.

This spool acts like stuffing box jacket but is located in a manner to keep the heat from moving from the seal housing and into the vessel. The spool requires a heating fluid to be pumped through it. The heating fluid can be water at sixty degree Fahrenheit. Or if freezing the water is a concern, then oil, glycol, glycerin, or any combination of these can be used to provide the thermal barrier between the vessel and the seal.

It must be noted that the spool acts as an insulator to keep the heat from being sucked out of the seal housing and seal cavity through the vessel walls. This does not account for the heat conducting through the shaft and down into the vessel. However, there are steps that can be taken to minimize the effect of heat conduction down the shaft.

One step is to move the seal up the shaft toward the bearings as far as possible. The addition of a spool assists in this move. It is also useful to design in as many ‘air spaces’ under the sleeve and around the housings as possible. Air is a poor conductor of heat, so any dead air spots assist in reducing heat transfer. It is also a good idea to make the heating spool inside diameter as close to the shaft as possible so there may be some radiation of heat from the spool to the shaft.
Cleaning and Sterilization

Cleaning and sterilization is a key consideration when designing equipment to operate in a pharmaceutical plant. Proper cleaning plays an important role in pharmaceutical manufacturing. The methods used to establish a clean manufacturing environment vary from system to system and from company to company. But the goal is always the same, to acquire the level of cleanliness necessary to maintain a high product quality while minimizing costs.

To begin to understand the concepts of cleanliness, it is necessary to define some of the common words used in the pharmaceutical industry. Most important are the words clean, sanitary, and sterile.

Clean means free from dirt, stain, or impurities and generally unsoiled. This is the easiest level of cleaning to accomplish. It can be accomplished with water or solvent flush. And the condition of clean can often be measured by visual inspection. Mechanical seals can be cleaned safely and easily with little anticipated harm to the seals ability to perform properly.

Sanitary relates to health. To be sanitized means to be 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. A state of sanitary cleanliness is more difficult to obtain in a mechanical seal. The seal must be cleaned in a manner that assures that harmful organisms have been purged from all of the surfaces, cracks, pools, or reservoirs that exist in a mechanical seal. This level of cleanliness is more difficult to insure as there are many areas in a mechanical seal for organisms to hide and reproduce. Some of the methods used to produce asepsis in a mechanical seal can cause damage to the mechanical seal. Care must be taken at the design stage of the equipment to understand the methods that will be used to obtain a sanitary mechanical seal. Materials and design features should be selected with sanitary cleaning in mind.

Sterilization is the most difficult level of cleaning to obtain. To be sterile is to be free of all living organisms. It is difficult to establish and maintain a certifiable state of sterilization for the same reason the state of sanitary cleanliness is difficult to obtain. There are many cracks, crevices, and pools in and on a seal that have the potential for incubating living organisms. And the methods for killing these living organisms is even harsher than the methods used for obtaining sanitary conditions. The seals can be damaged in the process of sterilization. Care must be taken to insure that during the design stage of the equipment that the sterilization method is known and understood by the seal manufacturer so that the potential for damage may be minimized, and confidence that sterilization has been obtained is maximized.

Some common methods used to acquire the desired level of cleanliness or sterilization follow. Keep in mind that it is best to know this information before recommending a seal design and seal materials. The two methods listed below are assumed to occur between batches when the product has been removed from the equipment.

- One method of cleaning and sanitizing a vessel is to use a caustic and/or an acid to remove residue from the vessel. The acid and/or caustic can be sprayed around the insides of the vessel with strategically placed spray balls. These balls are placed so all parts of the vessel are brought in contact with the chemical. In many cases the spray will, at least in a form of mist, migrate up the shaft and wet the inboard portion of the seal. This can be considered a CIP (Clean In Place) process in preparation for the next batch of product. The seal manufacturer may be asked if it is acceptable to flush the inner seal area, or even between the seal, with the cleaning chemical. Naturally, depending on the chemical, this may or may not be acceptable.

- Another method of cleaning, sanitizing, or sterilizing a piece of equipment is SIP (Steam In Place). A couple methods may be used to introduce the steam to the vessel depending on the saturation temperature required and the level of cleanliness or sterilization desired. Again, the seal manufacturer may be asked if it is acceptable to flush the inner seal area, or to actually have steam run through the seal chamber for cleaning purposes.

Generally speaking there is a correlation between temperature and temperature saturation time used in cleaning equipment. If the target temperature of the equipment is 80-90°C (176-194°F), then it is likely that a sanitary state is required for this particular process equipment. When attempting to reach a sanitary state, the temperature time seems to be less critical.

When sterilization is required it is common for the pharmaceutical manufacturer to saturate the equipment to 121°C (250°F). The goal is to raise the temperature of all components in the equipment that may harbor organisms that could be introduced to the
next process. Here the minimum time is critical. And it may be requested to run steam through the seal cavity for a designated time to completely saturate the seal cavity with heat. Naturally here it is critical to have the proper materials for contact with steam. It is best to avoid any fluoroelastomers under these conditions.

**Design Considerations Pharmaceutical Ready Seals**

Whether cleaning, sanitizing, or sterilizing equipment, the methods that will be used on the mechanical seal, and the resulting selection of design characteristics and materials, is critical. This subject requires discussion before the design selection begins.

**Design Considerations**

You have read above that there are special design considerations when dealing with cryogenics and sterilization. There are a few additional design considerations that are useful when dealing with the pharmaceutical industry.

**Debris Well**

This device has also been called the ‘sanitary feature’ even though it has less to do with asepsis than with debris. The concept is that a ‘cup’ is formed inboard of the seal faces. This cup arrests debris that may come from or pass through the seal face and holds the debris until the next cleaning of the equipment. The debris well is normally configured in a way that liquid or steam can be directed though it causing the inner seal faces to be quenched with the cleaning or sterilizing media. The debris well has a low point drain.

**Surface Finish**

A surface finish requirement is typically called out for equipment which will operate as a sanitary or sterile vessel. A very smooth finish aids in the cleaning, sanitation, or sterilization of the equipment. Residue is more easily removed from a smooth surface, and the elimination of cracks and crevices in the surface finish makes it impossible for bacteria and other living organisms to infiltrate and cling to the surface.

Surface finishes are described with ‘Ra’ numbers. A 65 Ra finish is relatively easy to achieve with good machining practices. Even a much smoother finish such as the 32 Ra finish can be achieved on the lathe with additional care. However, the desired finish is a 20 Ra. The 20 Ra finish will satisfy 95% of the equipment finish requirements. This finish can be achieved mechanically by polishing while the part is still on the lathe. Also additional smooth finish quality can be achieved with electropolishing.

**Sloping Surfaces**

All surfaces in the seal and on the vessel side of the seal should be sloped and drainable with low point taps. This allows for more complete cleaning and drying. The goal is to have no pools of liquid remaining after cleaning, sanitizing, or sterilization that might harbor and encourage bacteria growth.

**Drainable Gaskets**

Grooves that hold o-rings should be configured in a manner that makes them as completely drainable as possible. It is acceptable and necessary to open clearances on grooves that retain the O-ring as long as there is no threat of O-ring extrusion.

**Seal Designs**

Flowserve offers a complete range of singe, dual, dry contacting, dry non-contacting, and wet seals for the pharmaceutical and bio-pharmaceutical industry. Flowserve has developed relationships and alliances with pharmaceutical manufacturers and major equipment OEMs that produce custom equipment for the pharmaceutical industry.

We currently design and provide seals for mixers, filter dryers, centrifuges, media mills, rotary filters, conical dryers, choppers, and other specialty equip-
We work with OEMs such as Pfaudler, Lightnin, Chemineer, DeDietrich, ProQuip, Scott, 3V-Cogium, Rosenmund, Nettco, Carr Separations, and many others.

Applications that are encountered are water filtration, fermentation, separation, homogenization, crystallization, evaporation, and biowaste. These may include ultra-pure water, or heavy, almost dry slurries and dry powders.

The major seal designs now available are:

**MW-200**
Double wet seal in standardized and convertible package
- Pressure: 500 psi
- Temperature: -40°F to 500°F
- Speed: 0 - 225 rpm

**MD-200**
Double dry contacting seal in standardized and convertible package
- Pressure: 125 psi
- Temperature: -40°F to 300°F
- Speed: 0 - 225 rpm

**ML-200**
Double dry non-contacting seal in standardized and convertible package
- Pressure: 150 psi
- Temperature: -40°F to 300°F
- Speed: 0 - 500 rpm

**Single VRA**
Single Outside contacting dry seal
- Pressure: 200 psi
- Temperature: -40°F to 250°F
- Speed: 0 - 300 rpm

**Pharmaceutical Ready VRA**

**Pharmaceutical Ready QBW**
**ST**
Double liquid lubricated contacting seal. Specifically designed for bottom entry vessel applications.

- **Pressure:** 50 psi
- **Temperature:** -40°F to 300°F
- **Speed:** 0 - 1800 rpm

**Pharmaceutical Ready ST**

For additional information on these and other Flowserve seals, contract your nearest Flowserve Sales and Service Representative or Authorized Distributor.

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