



Flow Solutions Division

BW Seals

Durametallic Seals

Pacific Wietz Seals

Pac-Seal

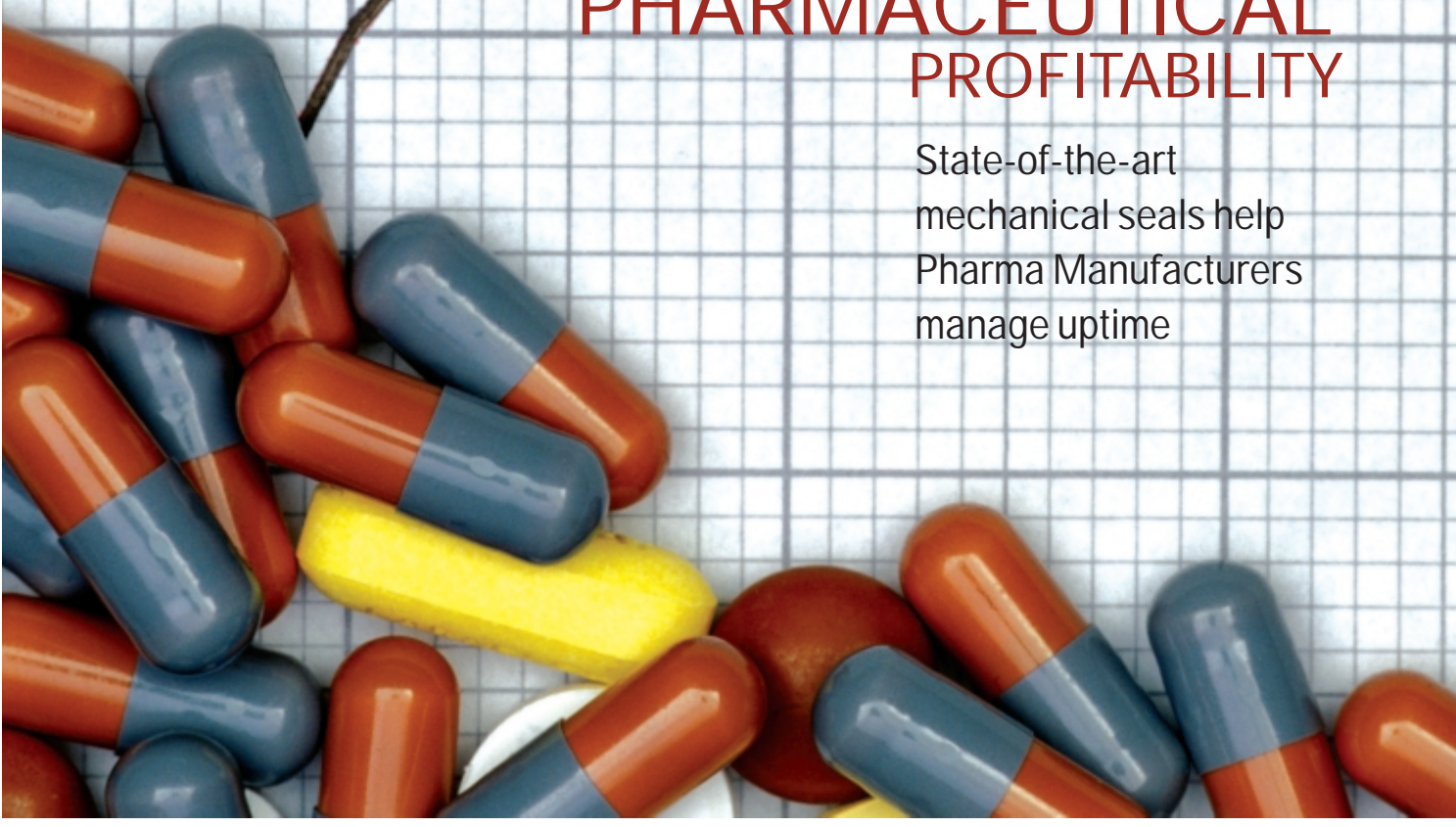
Face to Face

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THE SEALING TECHNOLOGY MAGAZINE

ENSURING PHARMACEUTICAL PROFITABILITY

State-of-the-art
mechanical seals help
Pharma Manufacturers
manage uptime





ENSURING PHARMACEUTICAL PROFITABILITY

The value of a vessel's contents is not a good guide for seal selection. Pharma manufacturers must also consider uptime.

Chemical manufacturing requires the standard repertoire of chemical engineering know-how and process hardware. From fertilizer to pharmaceuticals, each processing line uses similar pumps, mixers, vessels and reactors. However, one significant difference between producing ordinary chemicals and life-saving drugs is the degree of cleanliness and sterility imposed on the latter. A contaminated batch of drugs can't be reprocessed if a mechanical seal fails.

Fighting the tide

Time moves in only one direction, and that presents a particular difficulty for the pharmaceutical industry. The moment a research lab secures a patent on a new drug formulation, the clock starts counting down the 17 years it takes for the protective cloak to vanish. Bringing the newly patented pharmaceutical to market requires that it undergo a rigorous FDA testing regimen, an activity that can consume a large part of the limited window of opportunity the patent provides.

Perhaps years later, if the trials prove successful, the drug company has relatively little time left to recoup its research and development costs. While their patent protection is in effect,

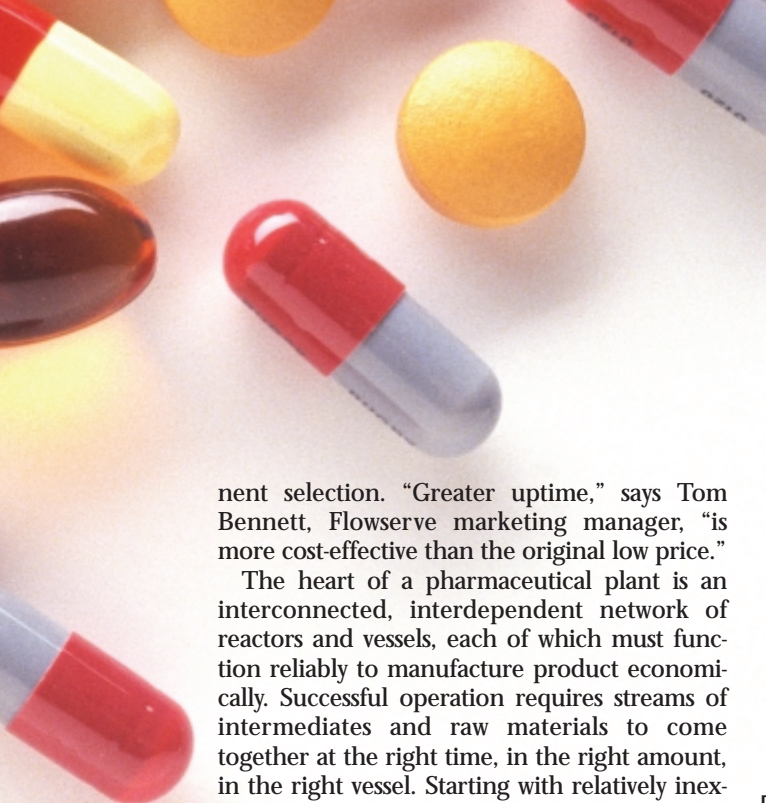
pharmaceutical companies routinely bestow a high degree of care and maintenance on the equipment that produces the new drug and its revenue stream.

When the protection expires, however, the formulation enters the public domain. Manufacturers of generic drugs are then free to make the same material. An increased supply in the marketplace tends to drive down the price either manufacturer can demand. With the basic economics so dramatically changed, it's natural for the drug's developer to start cutting costs, perhaps by switching to less expensive hardware and alternate raw materials.

Doing the math

Applying a cost-cutting strategy to specialty items, such as mechanical seals for top entry mixers, can backfire. First of all, the cost of a mechanical seal is a tiny fraction of the total installed cost of a processing line. Second, the cost of a seal is small compared to the value of the contents in a reactor or mixer, which can be worth thousands of dollars per pound.

Instead, traditional engineering economics, and its long view that accounts for the relationship between purchase cost and operating cost, should be the final arbiter in matters of compo-



PREFERRED PRODUCTS FOR THE PHARMACEUTICAL INDUSTRY

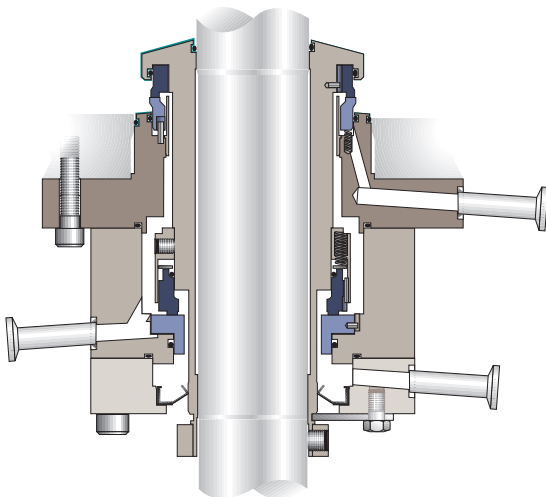
Historically, the sealing industry has focused on the chemical and petroleum industries, but there is increasing need for products specific to the pharmaceutical/biotech industry. Interest is growing in alternatives to the compression packings commonly used for mechanically sealing mixer equipment. At Flowserve's Flow Solutions Division, ongoing R&D programs have resulted in proven products that meet these special needs. Visit www.flowserve.com/seals for more information.

- ST—double liquid lubricated contacting seal specifically designed for bottom entry vessel applications.
- QBW—A double dry contacting seal.
- VRA—A single, outside, dry-running pusher seal designed specifically for use in top-entry agitator/mixer services.
- ML-200—Mixer seals configured to operate with non-contacting gas barrier technology.
- MD-200—Mixer seals configured to have contacting faces operated with a gas barrier.
- MW-200—Mixer seals configured to operate with a liquid barrier.

ment selection. "Greater uptime," says Tom Bennett, Flowserve marketing manager, "is more cost-effective than the original low price."

The heart of a pharmaceutical plant is an interconnected, interdependent network of reactors and vessels, each of which must function reliably to manufacture product economically. Successful operation requires streams of intermediates and raw materials to come together at the right time, in the right amount, in the right vessel. Starting with relatively inexpensive raw materials and intermediates, the plant adds value by processing them into a final product that's more valuable than the sum of its parts.

The natural tendency is to use the highest quality seals for vessels that process expensive materials, while those that process lower-cost materials are equipped with low-cost seals. It looks good on paper, but ignoring seal reliability is false economy. When margins are thin, a tolerance for unplanned downtime is an extravagance no plant can afford. A seal failure in an upstream vessel handling low-cost material initiates a chain of events that halts production of the high-value final product. Overall, the value of a vessel's contents isn't a good guide for seal selection.



The Flowserve ST seal is a double, liquid-lubricated contacting seal designed specifically for bottom entry applications.

Designed for success

Using a seal specifically designed for the pharmaceutical industry, however, is a way to ensure success. For years, Flowserve has offered its QB series seals for API and ANSI pumps. These standard single, balanced, multi-spring pusher seals are available in single and dual seal configurations for general service, primarily in the petrochemical and chemical industries. The QB seals are API 682-compliant and boast a solid history of success with environmentally restricted products that must meet EPA and OSHA regulations.

Given QB's success in chemical plants around the country, Flowserve engineers believed strongly that they would serve equally well in the pharmaceutical industry. Although they will seal and perform well in that venue, they faced one major hurdle for use in drug manufacturing: they simply don't comply with FDA standards.

Reacting to the perceived market need, the Flowserve engineering and design teams in Kalamazoo, Mich., rose to the challenge. They modified specific elements and features of the standard QB seal to bring it into compliance with FDA standards. When tested, the prototype seal hit a home run in its first turn at the plate in a pharmaceutical beta site.

Buoyed by the success of that collaborative effort, the design team refined the prototype into a new product, the Flowserve ST seal. It's a double, liquid-lubricated contacting seal designed specifically for bottom entry applications. The ST seal joins a lineup that includes three other Flowserve mixer seals (liquid barrier, contacting gas barrier and non-contacting gas barrier) used successfully in pharmaceutical companies around the world. As Bennett summed it up, "Inlet to outlet, we cover all of a plant's seal needs—and the pharmaceutical industry is no exception." ■

SEALING PHARMACEUT

Five factors for selecting seals for top entry mixers.

While other segments of industry have slowed, the pharmaceuticals industry is currently enjoying growth. There are many unique types of equipment in a typical pharmaceutical plant, but the top entry mixer remains the most commonly sealed equipment, superseded only by the pump. As we learn and understand the unique requirements of the pharmaceutical mixer we can design refinements into the basic mechanical seal that will help our pharmaceutical customers maximize operational MTBPM. To intelligently select and design these features into the mechanical seal requires that we understand five operating conditions that affect the operational success of a mechanical seal.

Cryogenics

Unlike the chemical processing industry, the pharmaceutical industry sometimes requires their equipment to operate in the cryogenic regime. This is usually done to control vapor pressures or reaction speed while minimizing the risk of introducing biological infection into the batch. While most seal components tolerate cryogenic temperatures well, elastomeric secondary seals have difficulty tolerating cryogenic temperatures. Perfluoroelastomers become brittle below 0 °F. Special compounds of fluoroelastomers can tolerate temperature down to minus 40 °F. EPDM elastomers regularly extend the lower temperature limits to minus 40 °F and tolerate steam cleaning, but they have a narrower band of chemical compatibility than a typical fluoro or perfluoroelastomer. Careful consideration must be used when selecting secondary seals to be used in cryogenic applications.

Debris

The product in a typical top entry mixer in the pharmaceutical industry tends to be an intermediate product. The vessel normally will be sterilized or chemically cleaned between batches, but it is also very important to keep any seal contaminates out of the batch during the process run.

To avoid product contamination from the

seal requires prevention of the normal day-to-day seal wear debris from falling into the vessel. Another concern is that if there is a seal failure the accelerated wear rate will introduce large amounts of debris to the batch and perhaps ruin the batch. The debris well, a passive cup-like device below the seal's wearing surface, is the most common method of collecting the debris before it falls into the batch. The assumption is, of course, the debris falls into the debris well due to gravity. Any collected debris in the debris well is swept away between batches using gas or liquid in any number of flush configurations.

Deflection

Top entry pharmaceutical mixers have one or two impellers attached to long shafts. They are easy to seal, as long as the mixer design adequately addresses run-out, squareness and vibration. A rigid shaft and mounting platform greatly contributes to the life and success of a mechanical seal.

There are many factors that can contribute to shaft runout and perpendicularity problems during operation. Highly viscous products, filling or emptying the tank during shaft rotation, manufacturing tolerances, thermal expansion, pressure deformation, and sparging are all examples of conditions that can modify the relative position between the equipment shaft and seal mounting plate during operation.

At elevated temperatures and pressures the single most destructive form of misalignment is the lack of perpendicularity between the centerline of rotation of the shaft and the seal mounting plate. There are seal designs, such as flexible stator designs, that minimize the affect of perpendicularity due to manufacturing and assembly tolerances. Operational perpendicularity issues are generally not resolved with seal design.

Increased shaft runout (dynamic motion of the shaft in the radial direction) induces a pendulum-like motion through the mixer

Mechanical Top Entry Mixers

bearing, which degrades the perpendicularity of the mating surfaces at the seal. As mixer pressures and temperatures increase, along with requirements for decreased leakage and increased seal life, shaft run-out and squareness have become known as vitally important to the success of the mechanical seal.

When the seal manufacturer must provide a bearing in the seal package the size and cost of the package increases. The trick is to know and design for the direction and magnitude of the forces the bearing and seal housing must withstand. The fact that the seal contains a bearing does not alleviate the mixer manufacturer from providing an otherwise concentric and perpendicular seal platform.

It is important to recognize that the mixer design, including the size of shaft, may be modified for competitive reasons.

Temperature Control

The double wet seal that uses flush Plan 54 with water, ethylene glycol or oil as a barrier fluid has been widely accepted in the mixing industry. The double wet seal tolerates transient temperature and pressure swings and maintains an absolutely positive seal between the vessel and the atmosphere. The liquid barrier fluid makes it easy to control the seal cavity temperature. In hot applications, the barrier fluid flow keeps the seal's O-rings lubricated and cool. Under cryogenic conditions, barrier fluid flow keeps the seal faces and O-rings at an acceptably warm temperature. Moderation of the temperatures at the inboard o-rings nearest the source of heat or cold enhances the seal reliability.

Another temperature control used in conjunction with flush Plan 54 includes a cooling coil or a cooling jacket around the seal. In extreme temperature cases the jacket helps the Plan 54 flush system pull heat out of the seal area.

A cooling spool is a type of cooling jacket that is installed between the seal housings and the mixer vessel. When extremely high or low temperatures are present in the mixer vessel

the spool moderates seal cavity temperature by physically blocking heat flow from or to the seal cavity. The spool is an extremely effective method for maintaining the elastomers at moderate temperatures. With a spool and jacket working in unison to moderate temperature in the seal cavity the pressurized barrier system can often be simplified to a simple pressurized, no flow, system.

Materials of construction

The most common metal used for mechanical seals in the pharmaceutical industry is 316SS. This alloy has a good blend of strength, weldability, chemical resistance, and economy. If added corrosion resistance is called for, upgrading to alloy C-276 is common. C-276 is a thermally stable, high nickel alloy with good thermal conductivity. Another suitable alloy is 20 SS.

When used in extreme temperature applications seal designers must account for thermal expansion and contraction of all materials applied to the seal. The wider the range of temperatures the more important it becomes to consider the thermal properties of the seal materials and how they interact with the mixer materials.

Metals may be purchased to conform with GRAS (Generally Regarded as Safe for incidental product contact) and may be electropolished and passivated.

Face materials may include combinations of carbon graphite, silicon carbide, ceramic and tungsten carbide. Of these, only carbon is considered to be soft. One face of a dry running contacting seal will usually be carbon, while liquid-lubricated seals can use any combination, of hard-on-hard or soft-on-hard faces. Seal specifications should state if material certification is required.

Secondary seals and gaskets also may be fabricated from GRAS compounds (Generally Regarded As Safe). Pharmaceutical applications don't necessarily require GRAS material of construction, so specifications from the buyer should be clear in stating the requirements for o-ring material certification. ■

FLOWSERVE READY FOR OVERSEAS MARKETS

A new “three-in-one” concept infiltrates the European and Asian markets for double mechanical seals.

In Europe, double mechanical seals conform to the requirements of Deutsches Institut für Normung (DIN). This is the German national standards organization that cooperates with the International Organization for Standardization (ISO) in the development of international standards. In Europe, and especially Germany, the DIN standards serve a function similar to that of the ANSI standards in the U.S., according to Gordon Fagg, FlowServe pharmaceutical industry specialist, based in the U.K. In the U.S., products that conform to the ANSI standards have become almost like commodity products. The situation is different overseas.

Original equipment manufacturers in Europe produce high-quality processing equipment, such as mixers and agitated vessels, for sale worldwide. Each mixer is custom-engineered and fabricated with components that conform to DIN standards. But, conforming to DIN standards does not imply dimensional standardization, as it does here.

Vessel design

There are three places an agitator can be installed on a vessel. The top-mounted agitator accounts for an estimated 90 percent of the installed base. In this configuration, the seal typically resists only the vapors in the freeboard volume of the vessel. When installed on the bottom of a vessel, the agitator seal must keep the process liquid contained. Finally, for the agitator mounted in the sidewall of a vessel, the seal holds back vapor or liquid, depending on the depth of the contained fluid. There are three seal types that can be used on agitators:

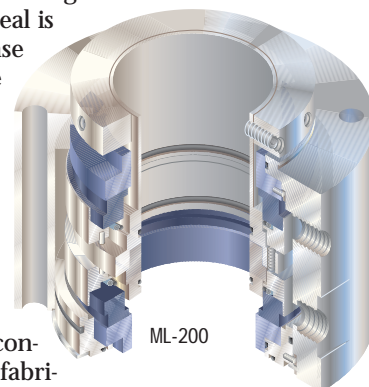
- Wet seals (MW-200).
- Dry contacting seals (MD-200).
- Dry non-contacting seals (ML-200).

A wet seal in a top-mounted mixer holds back vapors because the pressure applied to the barrier fluid inside the seal exceeds the pressure in the vessel. The pressurized barrier fluid can migrate across the seal face and weep on the inside of the vessel. Designers use a sanitary gland or a debris well to capture such leakage. It

can also be drained periodically using suitable piping and valves.

Dry, non-contacting seals on bottom-mounted agitators present a different problem. A process upset can force process fluid between the seal faces. No longer separated by a thin layer of gas, the seal faces come into contact with each other, thus compromising the primary seal. The outboard seal is now the primary defense against leakage until the seal cartridge is repaired.

Side-mounted agitators use either dry contacting or wet seals. Dry running seals use pressurized dry nitrogen, although some processes and applications need humidified nitrogen to maximize seal life. The faces in a dry contacting seal are generally fabricated of carbon and a preferred hard face. Since the faces physically touch each other in service, wear always produces some minute level of fine carbon particulates. Some industries, such as pharmaceuticals, cannot tolerate any level of contamination. If carbon dust is unacceptable, the best option is a gas, non-contacting seal.



Retrofitting

Although German designers prefer wet seals, end users may find it necessary to use other styles. Even some European OEMs are slowly migrating to dry, non-contacting seals. Nevertheless, like every mechanical component, sooner or later a seal needs to be replaced. In Europe, retrofitting a DIN-based agitator seal requires physical measurements of the old unit before a new unit can be selected.

Flowserve is the only supplier offering the three styles of seal that can be installed in the same cartridge housing. Users of DIN standard seals now can change seal types without having to modify the agitator or vessel. The Flowserve Series M DIN standard seals are currently available in sizes from 40 to 220 mm. ■

Global Presence, Local Support

Globally, Flowserve Flow Solutions Division operates nine regional, state-of-the-art manufacturing facilities to provide sealing solutions as a single resource for the improvement of end user customer rotating equipment operations. In conjunction with its alliance customers, the Flow Solutions Division has improved operational efficiencies to world-class standards.

Unlike traditional purchasing agreements, the Flowserve strategic alliance concept is a reliability-focused process to help keep customer equipment running and plants operating. The alliances begin with a complete survey of all the customer's rotating equipment and application variables.

Flowserve alliance programs are focused on optimizing seal and rotating equipment performance, achieving dramatically improved MTBF, reducing inventory through standardization and driving down total costs associated with rotating equipment.

The result: Fewer equipment failures, less downtime, less inventory, and increased overall profitability.

To meet the end user need for cost reduction, increased seal life and minimal downtime, the Flow Solutions Division has over 35 Quick Response Centers (QRCs) located in strategic areas around the world. Typical facilities are equipped with modern manufacturing capabilities that include seal repair and reconditioning, as well as the ability to design and produce complete seals.

QRCs are staffed with knowledgeable Customer Service Representatives to expedite the customer's needs and delivery requirements. Application Engineers are ready to assist in seal and system recommendations, on-site troubleshooting and failure analysis. ■

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Increase your production reliability while reducing product contamination with Flowserve sealing solutions.

The products and expertise to keep you up and running

We know that keeping your pharmaceutical process equipment operating while keeping product contamination to a minimum is your utmost concern. At Flowserve, we have a complete range of sealing products that have been accomplishing this in plants around the world.

We offer a range of mixer seals for dry or wet running applications as well as dry nitrogen barrier gas seals, both contacting and non-contacting. Based on years of research and lab testing, our products are designed for your production criteria, including features that reduce process equipment downtime and maintain strict quality standards such as:

- CIP - clean in place seals
- electro-polished finishes
- sterilizable seals
- sanitary designs
- seals constructed of FDA acceptable materials
- seals designed for mixers, centrifuges, dryers, fermentors, and stills



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