Mechanical Seal & Material Selection for Mixer, Reactor and Filter dryers in the Pharmaceutical Sector

Process containment and reducing the risk of product contamination are key requisites for pharmaceutical production equipment. Yet the industry is notoriously averse to change when it comes to the selection of mechanical seals and seal materials, says John Smiddy managing director at SMIDDY (IMSC) Ltd. (independent mechanical seal consultant). He explains how, although often overlooked, seal and component selection can be central to improving the reliability of rotating equipment, as well as reducing the risk of process contamination and delivering long-term savings.

There are two core concerns common to almost every pharmaceutical company – process **containment** to prevent leakage to the atmosphere and minimising the risk of **product contamination**.

The pharmaceutical industry can be commended for its adherence to the regulations relating to the manufacturing of active pharmaceutical ingredients (APIs) and implementing current good manufacturing practices (cGMP) when purchasing equipment such as a new mixer, reactor, or a dryer. However, when it comes to considering the design and composition of the sealing components on such equipment, they seem perfectly content to accept outdated and inefficient technology over advanced, industry-compliant modern sealing solutions which are proven to eliminate leakage and reduce the risk of product contamination.

There are various reasons for this, not least the simple fact that many companies are reluctant to embrace change. This is partly because the subsequent need to amend change control is deemed too onerous, and partly simple force of habit.

Then, there is the fact that mechanical seals are a comparatively small component whose significance in overall capital expenditure for a project can be easily ignored. This leads to old and outdated mechanical seals and support systems, routinely specified as a result of inadequate engineering research regarding the specification of more up-to-date seal technology.

Current good manufacturing practice (cGMP) is about using the current best available technology. Mechanical seal technology that was good five years ago, may not be the best available and cost-effective technology for today's applications.

The upshot of this is that a pharmaceutical plant can have a range of equipment including critical assets – even a modern asset - fitted with original equipment manufacturer (OEM) sealing technology which is often more than 25 years out of date.

A typical example would be a single balance seal with seal face materials made from poor quality carbons, ceramics, or Ni-resist materials, or where PTFE wedges are used as the primary sealing element.

PTFE wedges are fast-wearing and unreliable. They seal directly to the shaft, fretting against it and causing damage which allows a process to leak.

The risk of contamination is in-built. Seal failure is swift and inevitable. And yet the typical response to such failures is to replace the exact same seal onto the exact same point on the already damaged shaft, creating a downward spiral of repetitive seal failures.

It's hard to imagine many of these outdated seals are still being used today, even on new equipment. The mechanical seal might not be the primary concern when buying a new mixer, but once that mixer is out of warranty the seal becomes far more important in terms of its impact on overall reliability. Therefore, when purchasing or upgrading equipment, best-in-class companies place equal importance on specifying the correct sealing solutions and material selection as they would for a mixer, reactor, or dryer.

Several options are available to the pharmaceutical company seeking to achieve zero emissions and minimise contamination risk.

Firstly, Mechanical seal selection should incorporate the most up-to-date seal technology most suitable for the application. Using seal technology to guarantee a high level of process containment. Double balanced seals or seals that work under pressure and vacuum conditions, recognise the pressure-to-vacuum operating changes, which prevent the seal from leaking. They can also be made from more hygienic designs, so are ideally suited to environments requiring high levels of hygiene.

Wet Seal Technology:

The wet seal is the most common sealing solution on pharmaceutical production lines. These are normally pressurised using barrier fluids API Plan 53A, such as food-grade oil, solvents, or purified water, supplied to the seal faces via a support system. When using food-grade oil as a barrier fluid, the viscosity of the oil has a direct relationship with the successful operation of the seal. – too thick and it will force the seal faces apart, increasing barrier fluid leakage to the process.

Barrier fluid seal support systems, API plan 53A use a seal pot-vessel to contain the barrier fluid, these seal pots can be a more serious weak spot in terms of process contamination. All mechanical seals leak a tiny amount of barrier fluid. Barrier fluid finds its way across the inboard seal faces into the process, so the cleanliness of the fluid and its container is crucial.

Barrier fluid generally sits at a temperature of 30/40°c - an ideal breeding ground for bacteria. If barrier fluid is not changed frequently, it quickly becomes impure. Ideally in this sector and depending on the application, barrier fluid should be changed every day; in reality, it can be months before it is replaced with clean fluid.

Traditional seal pots -vessels are difficult to inspect, access ports are small - you need a camera to view the interior - so there is no guarantee they're 100% clean and free of contamination. The first sign of contamination of the barrier fluid will be noticed at the seal pot.

Mechanical seals and seal support system designs, along with seal pot inspection at intervals are very important when it comes to carrying out risk assessments to prevent process contamination.

However. It could not be more obvious – if the barrier fluid is discoloured, - black colour, it is a clear sign of contamination.

The case against using wet seal technology, therefore, begins to mount. However, the right wet seal technology combined with a well-maintained barrier fluid system can mitigate the risk of mechanical seal leakage and the risk of process contamination.

Modern double-balanced mixer seals made from (FDA) compliant materials, used with correctly specified barrier fluids, eliminate seal leakage beyond the accepted levels.

Most importantly, using the most up-to-date designed seal pots -vessels, specifically designed for pharmaceutical and -hygienic applications, are now available from various suppliers. They can be disassembled for easy inspection and cleaning between batches.

Dry Gas Seal Technology

Dry gas seal technology presents several options to combat the risk of process contamination. Traditional gas seal designs, contacting and non-contacting seal face technology, and more recent designs especially for the pharmaceutical industry chemical resistant lip seal technology. The barrier used between the inboard and outboard seals is a pressurised gas, normally N2, not the traditional liquid barrier.

Material selection is a critical part of the specification when it comes to dry gas contacting seal face designs. Carbon impregnated with molybdenum disulphide (MoS2) which comes to the surface once heat is generated, is a good choice (application dependent), much like perspiration coming to the surface on the palm of one's hand is enough to keep the seal faces lubricated.

Dry gas contacting seals can perform better and run longer than some wet seal designs while removing the risk of process contamination from liquid barrier fluids.

Test results have proven, some dry gas contacting seals working on mixers and reactors at a maximum duty of 25 bar m/s will work for approximately 8,000 hours. Bearing in mind that most mixers in the pharmaceutical sector operate at between 1-5 bar m/s, which translates to approx. 50,000 hours on normal duty. It also means that seal life can be predicted based on the running conditions.

The support system for dry gas seals is a simple, easy-to-read display panel, representing another significant advancement for reliability engineers. The panel is simple to read, with visible gas flow indicators, a flow switch, and a pressure switch, which are designed to alarm on a seal upset condition or pre-empt a possible seal failure condition. It is hard to believe, but pharmaceutical companies will happily spend anything from €10,000 to €50,000 on a dry gas seal provided by OEMs, which often comes without a display panel. Ask yourself, if you bought a new car and there was no display panel on the dashboard, would you drive it?

Dry Gas Non-Contacting Seal Face Designs:

The faces of dry non-contacting seals are laser etched allowing gas between the faces to prevent contacting when rotated; they hover above each other. They work well on mixers and reactors, however, they are extremely sensitive to running conditions. If the gas supply is lost for any reason and the seal faces touch while rotating, the seal faces will be permanently damaged. Gas pressure and flow must be consistent, and equipment perfectly aligned. In certain applications, sub-micron particles in the process can migrate across the seal faces causing seal failure.

All this begs the question, why choose this sealing technology? The answer is that, because the seal faces are non-contacting, there is no risk of carbon black shedding material which may cause process contamination and discolouration.

This seal can operate at higher speeds and accept most ATEX conditions because the seal faces do not generate heat on rotation. This type of seal should always be selected with awareness of its flaws. Non-contacting seal face designs, used under the right process conditions and with the correct seal support systems, can be an effective sealing solution. However, in my experience, it is difficult for plants to maintain the correct and ideal running conditions, so it is difficult for this option to be recognised as a reliable seal solution across many applications.

Gas Chemical Resistant Lip Seal designs:

In recent years, Gas Lip Seal designs are making a big impact in the pharmaceutical sector. New lip seal technology has proven to be very successful.

This seal design provides the ultimate solution, zero risks of process contamination, accepts poor alignment and running conditions, long-lasting self-lubricating chemical resistant lip seal designs.

The seal design operates with a pressurised N2 gas barrier and a gas panel which always indicates the seal condition.

There is a large selection of brands to choose from, all providing unique features for the pharmaceutical sector.

Conclusion:

So, which sealing solution should the judicious purchasing or engineering department select for their application?

All seal designs have limitations, and some designs are more suited to different applications.

e.g Hot applications, Powder applications, High pressure, etc, tec.

The key point is, make sure your engineering department is engaged in the selection process, and always look beyond single-source supply.

There are fantastic seal designs available and compliant for pharmaceutical applications, which provides improved seal performance and improved equipment reliability.

The improvement in reliability has been huge – increasing Mean Time Between Failures (MTBFs) from one year to five in many cases – and costs have not risen in line with these advances. Surely that is reason enough for the pharmaceutical industry to not just accept, but to embrace, change, engage and review the most up-to-date seal technology most suited for your applications.

Please contact SMIDDY (IMSC) Ltd to review your mixing applications.
We have lots of available options when it comes to Repairing and Selecting new Mixer Seals along with a suitable Seal Support System.

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