Responsive innovations help minimize production costs and simplify operations
Regeneron Pharmaceuticals, Inc. purchased a new bioreactor skid and had the same high expectations that surround any major process improvement. During initial start-up, it became apparent that the vessel would not maintain sterility reliably due partly to the bottom entry agitator seal. The reactor was, to use the word of the facilities’ engineering supervisor, Kyle Cherry, “problematic.” Undisrupted production did not begin until shortly after the agitator shaft seal was replaced with a custom-engineered design from the Flow Solutions Division of Flowserve Corporation.

Both the OEM seal and the Flowserve replacement featured a dual mechanical seal to protect the sterility of the cell culture medium and a secondary sealing device to protect the gearbox. “The difference, Cherry says, is that the OEM seal had cleanability issues, compounded by an inability to maintain a sterile environment.”

“The main issue with the OEM seal had to do with the sterilization requirement not being observed and sealing integrity being compromised,” says Cherry. The orientation of the seal faces was not suitable for complete sterility. In addition, the port locations were not optimal for complete evacuation of air and partially caused the inner seal to run in a vapor. Clean steam was used for sterilizing the bioreactor and a moderate flow rate of clean steam-condensate was the barrier fluid to the mechanical seal assembly, depending on the phase of production. Sterilization of the interior vessel bore cannot be compromised. Once this requirement has met validation, the bioreactor must cool to a temperature appropriate for introducing the cell culture medium.

Leaks are not sterile
Both dual mechanical seals had seal faces backed up by a spring-loaded mechanism. In each case, the spring-loaded primary seal face was inside the bioreactor, a typical configuration that couldn’t be avoided, Cherry says. However, with the OEM seal, the single coil spring and elastomer bellows were also inside the bioreactor. The multiple crevices and incomplete drainability compromised the bioreactor’s clean-in-place and steam-in-place procedures.

The design pressure of the clean steam-condensate barrier fluid maintains a uniform thin film of condensate to lubricate both sets of primary sealing faces and prevent the cell culture medium from entering the atmosphere within the suite. A more serious problem with the OEM seal was regulating the barrier fluid pressure. If the differential pressure was too great, the inboard seal would not seat properly causing above normal leakage into the bioreactor.

Another problem, Cherry says, was that the OEM lip seal that was supposed to protect the gearbox “failed frequently.” The fit would cause a slight score mark beneath the sealing member and over time would not maintain a seal in the event the dual seal weeped. This condensate weepage entered the gearbox and created the risk of agitator failure and additional maintenance cost.

The solution
“Flowserve customized a model STW seal to address the repetitive seal failures,” says Cherry. First, the new seal was designed as a dual cartridge seal that not only mounted directly to the gearbox but also to the bioreactor’s mounting pad. Part of the challenge was the European design and the transverse angle of the drive that required detailed field measurement for proper fit and function. Installing the seal as a complete unit provided numerous advantages—a complete cartridge that could be aerostatically pressure tested to insure integrity before
installation, no handling of integral sealing components, and fewer components to stock and maintain. Relocating the springs outside the process media and contouring critical sealing components to resist pooling in areas where cell growth is not acceptable fostered complete cleanability and sterility. The addition of a flexible stator design compensated for misalignment and mixing anomalies that may occur under normal operation. These were critical design advantages inherent with the Flowserve STW seal.

The seal is engineered to maintain absolute containment of the clean steam condensate during each phase of production. By incorporating an internal flow deflector, the primary seal is adequately lubricated to eliminate dry run conditions. And finally—a BEARING GARD II was added to eliminate condensate weepage from penetrating the gearbox.

The selection
When asked how Regeneron had come to choose Flowserve, Cherry responded that Flowserve had provided engineered sealing solutions for several bacterial fermentation reactors projects over the years, and those had performed as promised.

Because the reactor was too large for a magnetic drive, this created the need for a mechanical seal. Another point, Cherry says, “is that this is a bottom-entry agitator at a slight transverse angle. The previous Flowserve projects were for top-entry agitators. But this did not seem to be a problem for them.”

The level of reliability needed for mammalian reactors is high and positive containment is critical since the seal is in contact with the process medium. Yet Cherry also says that with the Flowserve seal, along with some small piping modifications and procedural changes, “We are able to maintain sterility for extended periods.”

When asked how big a challenge it was to solve these problems, Cherry replied, “It was an ongoing challenge for us, but John Hayes, Flowserve’s District Manager, worked closely with the technicians and engineering department on the field retro-fit and came up with the solution.”
At the Syracuse, N.Y. Bristol-Myers Squibb plant, it was time for a seal change. The equipment had been there since the mid-1940s. In addition, says Mark Mascari, senior process engineer, a new pharmaceutical formulation was being developed, and there were concerns about purity and product release. Mascari, whose responsibilities include troubleshooting, upgrading equipment and systems, and optimizing processes, adds that price, reliability, maintenance and convenience considerations led to the decision to upgrade to a Flowserve MSS split seal.

Bristol-Myers Squibb, one of the top five pharmaceutical companies with revenue of $20 billion a year, has more than 70 buildings on its Syracuse campus. About 750 people work in three divisions—research, development and manufacturing—with 300 in the manufacturing area.

One 45,000-sq. ft. building rises three stories to enclose a 40,000-liter fermenter installed in the 1940s. The fermentation process has a capacity of about 500,000 gallons per week.

“The basic issue was that standard packing could not hold product leakage to below detectable levels,” Mascari says. He explains that although packing is cheap, it can wear and form gaps.”

“The alternatives,” he continues, “came down to different kinds of mechanical seals. In a new installation, you would probably put in a double mechanical seal. As a retrofit, it means we would be pulling off a gearbox the size of a small car, a 150-hp motor, and a 30-ft. shaft. The cost to install a regular mechanical seal would be huge compared to the cost of the seal. By putting a split seal on the existing equipment, you avoid the need to move the gearbox.”

“What the single mechanical seal allowed,” Mascari continues, “is to achieve a better seal without the expense of a conventional non-split mechanical seal. Price is also a major driver. For upgrades, you’re looking for a quick payback.”

Mascari added, “You don’t want a product that’s going to require a lot of maintenance that can wipe out your savings. The plant is running at full capacity. Downtime is a major obstacle to avoid. We work hard to eliminate downtime, so reliability is important.” On the subject of reliability, he adds that, “The new seal has been in place about a year and a half and there has been very little maintenance. We’re pleased about that.”

Although mechanical seals were clearly a better choice, not all brands are equal, Mascari asserts. “Our plant engineers determined that Flowserve best addressed our twin concerns of purity and release.”

Service was another consideration. “Because of some hygiene concerns, we needed to keep the material inside the vessel,” says Mascari. “So after the installation, we checked to make sure the seal performed as designed and we were satisfied. During the installation, Gordon Molampy, the Flowserve representative and David Shepardson, the local distributor with Sealing Devices, came out several times to respond to our concerns. We got the service we expected.”

When asked if there was some way to quantify the results of the new seal, Mascari responds, “The final selection involved a combination of factors. Seal quality was primary, certainly, but we also looked at the best offering in terms of price, reliability, convenience and service. We believe we made the right choice with Flowserve.”
Every year Shell Chemical Company’s Geismar, La. plant produces from 400 to 500 million pounds of ethylene oxide, ethylene glycol and higher olefins and detergents (HODER), which are used as a base stock for soaps. Most of the 520 employees are involved in operations. The plant posts metrics so employees can see the cost per pound of product, fixed costs—actual versus budgeted and controllable unbudgeted loss that result from equipment failure.

Proactive maintenance is a necessity. “Everything has a finite life. It’s not going to last forever,” acknowledges Chuck Lickteig, the plant’s senior mechanical engineer—rotating equipment. “Today, 80 to 90 percent of the work is planned. Three years ago, only 30 percent was planned.” The plant’s maintenance department championed the shift in thinking that led to this improvement.

In addition to mean-time-between-repairs, Shell tracks total cost per pump-year to support resource allocation decisions. The metric restrains them from increasing run time 50 percent by tripling spending. Cost per pump-year has been dropping, while reliability has increased. To ensure interplant comparability, the company publishes standards detailing what constitutes a pump repair and how to report it. Shell also benchmarks seal performance.

The alliance

“When Shell partnered with Flowserve, we wanted operations and maintenance closer together, we wanted better linkage,” said Jim Miley, Flowserve’s District Manager. When the alliance concept was first floated, there was skepticism. “The alliance was driven from the corporate level,” reports Lickteig, who accepted the concept after he realized what it could do to improve reliability.

The alliance started in April 2000. “If you don’t have a champion to make the process move forward, it stagnates,” advises Lickteig. “Most people, even the few that were reluctant, see the advantages in the alliance. When benefits accrue, they jump on board.”

According to Lickteig, Flowserve brings direct benefits. The biggest advantage he cites was seal standardization. Finding commonalities reduced the number of part numbers to be stocked.

Another alliance benefit Lickteig sees is training classes, taking place in the plant’s control room and lasting from one to two hours. Craig Brown, Flowserve Regional Reliability Engineer and Miley are dedicated to improving reliability through training. Topics include selection, installation, troubleshooting, failure analysis and site-specific issues. Flowserve conducts 24 classes yearly. Employees can learn something and start applying it immediately.

A third alliance benefit is the Flowserve field organization. During its 30 years of operations, there have been numerous changes in plant processes and equipment. The product mix evolves, equipment and pump requirements change. Flowserve engineers review operating variables to select the optimum seal. This relieves Shell of a major burden.

The problem pumps—bad actors—have a mean-time-between-repairs of less than one year and an annual repair cost above $4,000. “Before the alliance, we made little progress addressing bad actors because individuals were responsible,” says Lickteig. “Now, it’s the Alliance Implementation Team, comprised of Shell and Flowserve people, that focuses on bad actors. They use a systems approach. That is the key change.”

Shared risk—another change

When something changes, the team addresses it together. Shared ownership and peer pressure is another alliance outcome. “That’s the reason we made such great steps in the bad actor area,” said Lickteig. “We reduced the number and cost of bad actors in the olefin area by 50 percent in one year. Our pump repair cost dropped by $200,000. The alliance pays for itself.”

“Jim has done a lot of the legwork and he really came through on this,” said Lickteig. “Our intent is to reduce cost and improve reliability and Jim will end up earning less at this plant.” Looking at the big picture, Jim probably isn’t too concerned.
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