

EnviZion® Hygienic Diaphragm Valves

Major pharmaceutical company undergoes critical valve upgrade

A multinational pharmaceutical company manufactures a high-volume injectable at a facility in Ireland. Every 2½ days a batch is produced that is worth millions of euros. For this reason, any downtime imposed on the operation is extremely undesirable.

In fact, 36 diaphragm valves on a process line located above the operation's six bioreactors had been causing issues for years. But in order to avoid shutting the process down, no work had been done on them, or on the actuators and pipework, since the system was installed in 2002. Over that period, the original fasteners and valve diaphragms had become damaged and worn. And so, within three to six months of a diaphragm replacement, the seal would usually fail.

The process liquid was sodium hydroxide, which presented a significant health and safety issue. Whenever personnel entered the area, it was necessary for them to wear hazmat suits and breathing equipment. Drip pans to catch the contents were installed by the company as a temporary solution, but replacement was clearly overdue and highly warranted.

The ITT Impact

The pharmaceutical company received an upgrade to EnviZion diaphragm valves, which solved their seal failure problem while enabling future diaphragm replacements to be made much more rapidly.

Upgrading to EnviZion valves

When the final decision was made to replace the valves, functional equivalence was essential. So the company requested a quote for an in-kind replacement. However, they also recognized this as an opportunity to upgrade to next-generation valve technology. Therefore, the company agreed to consider a second quote that included ITT's EnviZion hygienic valves.

The reason for this recommendation was two-fold. First, the EnviZion valve design provides a reliable seal. PTFE suffers from cold flow, so under high pressure and temperature it wants to become flat again. In conventional four-bolt valve designs, the clamping force of the bolts combats this tendency. But over time this force decreases because of wear to the parts, which means that leaks can occur, particularly during changing thermal cycles. EnviZion, on the other hand, contains an integrated thermal compensation system that exerts a constant force around the edge of the diaphragm that is totally independent of whether the valve is heating or cooling down—thereby reducing the possibility of leaks and batch contamination essentially to zero.



Active Thermal Compensation system assures contamination free shell seal

Upgrading to EnviZion valves (cont.)

Second, with EnviZion valves, diaphragm replacement can be accomplished much more quickly. With its exclusive mount and turn design, diaphragms can be changed in three minutes or less—whereas conventional designs on average require 23 minutes. No tools or torquing are needed and installations can't be done wrong.

The EnviZion valves quoted higher than the in-kind replacements, but analysis indicated that, owing to the faster diaphragm replacement times, the company would earn back the difference after just one scheduled maintenance. What's more, this cost advantage would continue to grow over the life of the valves. Not surprisingly, the decision was made to move forward with EnviZion valves.



EnviZion valves reduce the time to replace diaphragms to less than three minutes

A challenging installation

The replacement valves were specified to match the existing installation's flow chart characteristics, which ensured that all cleaning and process systems remained unaltered. It was also important to be certain prior to installation that the new hardware would fit in the space available and matched the existing pipework connections perfectly. This was made more challenging by the fact that the valves were housed in a maze of pipework that included supply, utility and process lines.

In addition, because the original valves were non-standard, the EnviZion replacement valves needed to be custom-configured. This involved 3D modeling, drawings and extensive physical checks before the new designs were finalized. While the ITT team was at it, the orientation of some valves was altered to make them easier for technicians to access during future maintenance. And replacement of existing obsolete switch packs with the next generation Sitomatic VC9000 enhanced the overall reliability of the installation.

No loss of production

Perhaps the most challenging requirement of all was the need to complete installation of the valves within a very tight time window. With a total of six bioreactors, as batches go through, two are scheduled to be cleaned with four operating at once. In order to not disrupt production, ITT needed to fit installation into the time gap when two bioreactors were down.

The first valve, which was finished on a Friday, was hand-delivered from England to the site in Ireland for installation the very next day. The shortest window for valve replacement that ITT had was 36 hours, so the team worked around the clock. In that time, ITT assisted in cutting out the old block valve, fabricated a new one in, cleaned the line, passivated it and got it all checked and ready to go in. Since passivation takes 12 hours, the actual space of time was shorter.

In the end, all installations were completed with no disruption to production whatsoever. Unreliable seals have been eliminated. The scheduled replacement periods for diaphragms can now be increased, from one year to eventually three years or more.



Seal issues were eliminated after the 36 EnviZion valves were installed

Future plans

Following the success of these installations, another group of 54 valves at the company's facility are slated for replacement with orders placed. Additionally, two new CIP skids with approximately two hundred valves are planned.

The EnviZion valve platform was developed with one overarching goal—to reduce the total cost of ownership. And for this customer, everything's gone to plan. They are very pleased with the valves, which are performing brilliantly. The company's team received a coveted quality award. And it's clear to everyone that along the way ITT has gone way above and beyond.