White Paper

Unlocking Efficiencies in Plant Processing Equipment

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Establishing preventative maintenance frequencies and new emerging hygienic diaphragm valve technologies can significantly reduce plant downtime resulting in big savings

In the biotechnology and pharmaceutical processing industries, maintaining diaphragm valves is considered the primary bottleneck of the maintenance process. A typical diaphragm change-out can easily take a full week of plant downtime, resulting in significant hours of lost productions time. Properly changing valve diaphragms is a tedious process and typically takes a team of maintenance technicians to get the job done on time. Time studies have shown that it takes on average twenty-three minutes to complete the installation and fastener torque process for a single valve. As large BioPharm plants typically have thousands of hygienic diaphragm valves installed, the number of hours to change our the entire system can be significant (over 300 hours for a plant with 1000 valves)

Leaders on the plant floor need to understand each piece of equipment in their system and be on the lookout for efficiencies and ways to lower total cost of ownership (TCO). In evaluating their TCO, they must take into account capital costs including installation and validation, operating costs, maintenance costs in both personal, training and materials and periods of production downtime. Implementing a preventative maintenance program and incorporating evolving enhancements in valve designs into a plant system can have significant financial implications on the bottom line. Extending the time between diaphragm change outs and shortening maintenance shutdown periods can result in a plant being online for longer periods of time with reduced operating costs and huge efficiency gains.

Typical Maintenance Challenges for Hygienic Diaphragm Valves

Diaphragms are the most critical component within a hygienic valve and are one of a few soft parts requiring regular maintenance. A valve diaphragm is constantly challenged since it must function as both a static seal (shell seal) and a dynamic seal (seat shutoff). Seal integrity in both of these sealing duties is critical to the BioPharm process as seal joints are a primary opportunity for process contamination. The diaphragm also provides positive shut-off between process-fluids and must maintain its integrity and guarantee trouble free and predictable performance. One unplanned mishap can result in a bad batch causing significant monetary losses for a manufacturer. In the bioprocessing

industry diaphragms and other soft parts such as gaskets and o-rings face constant fluctuations between steam sterilization and cold processing temperatures. These significant thermal cycles substantially affects the life cycle performance of the seal. The plant staff must be aware of the lifecycle and plan for future maintenance before a seal failure which can result in a costly leak and contamination.

One of the most common pitfalls seen in plants today is a poorly planned maintenance schedule, or even the absence of a plan. The time and costs associated with installation and maintenance for hygienic valves are primarily related to ensuring that the body to valve bonnet joint is properly torqued. In most cases process components can not be maintained at all during the process so quite often a special thermal cycling may be required prior to releasing the process to production. Maintenance personnel must be trained to ensure that the integrity of the diaphragm is maintained throughout this process. Diaphragms are often degraded if a retorque is done too frequently. According to the American Society of Mechanical Engineers Bioprocessing Equipment (ASME-BPE), dynamic sealing solutions must be retorqued to handle temperatures up to 300^{o} F, accommodating the associated thermal swing in a typical production cycle. This process helps avoid systematic leakage and ensure that the equipment is cleaned and sterilized.

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A significant amount of time and materials is required to maintain diaphragm valves in BioPharm facilities. A preventative maintenance program can decrease plant down time and deliver savings.

Typical plant shutdowns can vary widely, but it is common for a plant to be shut down for a week or more for routine maintenance activities. This can entail changing out diaphragms and o-rings and maintaining sanitary clamps and pumps. Once a diaphragm valve is installed, torque and retorqued, it must be constantly monitored to ensure the highest hygienic standards are being met and to catch any possible faults in a valve's seal integrity. This process can happen in rolling manner across small portions of the facility's system semi-annually or annually. However, the water system in a plant usually requires maintenance every few years and can result in a complete plant shutdown.

From installation, to monitoring and control, the process of maintaining a diaphragm valve through its total lifespan can cost hundreds of thousands of dollars. Thankfully, new advances in the bioprocessing industry have created highly engineered technologies to impede these costly challenges, and create a more streamlined, easy-to-use diaphragm valve with virtually no leakage.

Benefits of a Preventative Maintenance Program

Most BioPharm plant environments utilize bioreactors as the primary production method for products. The cell culture manufacturing process typically requires an organism that was chosen to produce the drug and is maintained in solution under exacting temperature and pH conditions best suited for the organism to produce the desired output. These processes can take roughly 7 – 31 days to finish a batch and it is critical to keep the process sterile so that the product is not contaminated. This requires a lot of steam sterilization and leak free valves and piping joints. The hygienic valves in this environment usually require regular maintenance including diaphragm change out where a torquing procedure and loosens and compresses the seal. PTFE diaphragms with separate elastomer backing cushions are considered the diaphragm of choice for these highly steamed applications due to their longevity in steam. Unfortunately where PTFE diaphragms excel in temperature resistance, their lack of resilience make them notoriously difficult to achieve and maintain a high integrity seal. The sealing capability of the PTFE is constantly degraded as the process goes through thermal cycles. A typical valve can endure hundreds of thermal cycles in its maintenance lifecycle.

The amount of maintenance time and materials needed is significant. Sometimes due to these pressures plants will try to stretch out diaphragm change out times in order to reduce TCO. Other companies don't have a plan and wait until failure. However, in most other instances there is a set process that is scheduled and it is a predetermined length. The key in this process is having a thorough understanding of your system and implementing a preventative maintenance program that is efficient and reduces risk. By understanding and properly evaluating cycle rates and process flow, one can develop a preventative maintenance frequencies program to extend the time period before touching the diaphragm in a valve. The key is gaining a thorough understanding of cycle events, the effects on the soft parts within the valve and creating a PM schedule that reduces unplanned failures.

Mitigate Risk in a Preventative Maintenance Program

Most preventative maintenance programs are done by calendar because they have numerous processes where soft parts must be scheduled for removal based on general wear and tear. Typically, companies will plan to change a process every six months to a year. There are also some companies that do not have maintenance frequencies and let them go until the end of a product's life. This can be

ITT Engineered Valves helps companies determine a maintenance schedule specific to their needs that maximizes the preventative maintenance interval.

risky as contamination may occur resulting in a contaminated batch and unplanned plant shutdown each costing thousands or millions of dollars of lost production. More progressive companies are working with organizations, like ITT Engineered Valves, to determine a maintenance schedule that is specific to the customer's needs and maximizes the PM interval while maintaining it within the mean time between failure (MTBF) time frame and averting failure.

One such organization is a major global pharmaceutical company whose elastomers were attributed as root causes in contamination failures. Furthermore, the plant experienced over fifty unplanned work orders for elastomer change outs in just one year. The plant was also planning on adding a second product line and needed to support an anticipated twenty percent increase in run-rate challenging the existing elastomer lifetimes for diaphragms and gaskets. The plant's leaders desired a predictive model for all future change outs with improved reliability. ITT Engineered Valves was brought in and worked with the staff to develop a strategy to mitigate future risk. Partnering throughout the process, they focused on uncovering solutions to overarching challenges, worked to extend the change out frequency and produce an educated PM schedule.

In the plant, the soft parts within the hygienic valves were exposed to multiple cleaning and sterilization cycles. Alkaline or acidic media and valve actuations were also present in the environment. During the assessment, they evaluated diaphragms and gaskets in over eighty five systems. It was evident that the wide array of processes had different effects on the diaphragm life expectancy. Chemistry, PH, temperature, steam exposure and valve actuation cycles all needed to be considered. Utilizing ITT's substantial amount of proof testing, the performance of diaphragms in similar conditions could be predicted. In some cases alternative diaphragm material was recommended for particularly difficult applications. In short the in-depth analysis of the process allowed the plant to focus on the critical applications and extend the PM frequency of the less stringent applications. The result was increased production capability, reduced maintenance and labor time, and overall big financial gains were realized in total cost of ownership. The increased production capability can now be used to bring another product into production and diversifying the drug product portfolio, which is extremely important in the highly competitive drug industry.

Impact of Valve Design on Maintenance Schedules and TCO

Hygienic valve designs have evolved over the years to meet the needs of the bioprocessing and pharmaceutical industries. Most products today have four bolts to attach the body, diaphragm, and bonnet, and maintenance can be time intensive. Within this design are the soft parts which typically account for roughly half of all maintenance. The hygienic diaphragm valves require additional man power to install and take up to a week for planned shutdowns with substantial time required for careful maintenance and fastener torquing. The importance of an efficient and innovative valve design cannot be understated. Imagine a plant with 500 valves that need diaphragms changed and the time and the manpower to complete this task on a regular schedule. Sometimes the valves can be difficult to maneuver and require two people to take apart and reinstall properly. Other times special tools are needed for valves that are difficult to access due to tight constraints.

Seventy five percent of hygienic diaphragm valves are fitted with Polytetrafluoroethylene (PTFE) diaphragms, which is a fluorocarbon resin that is chemically and temperature resistant to most BioPharm processes. The PTFE diaphragm typically use an elastomeric backing cushion that allows for some, but not much “spring” force in the diaphragm joint during a production cycle. These valve systems must go through the torquing process twice; once when installed, and once after one thermal cycle.

Advances in emerging technologies do not require any retorquing because they have a consistent sealing force during thermal cycles. One such design features a live loaded seal joint that provides a more predictable seal performance and extended PM frequencies. These new dynamically loaded diaphragm joints prevent seal integrity loss during the thermal swing. The dynamic loading can withstand the changes in dimension during cycles. The valve joint is quickly assembled once, and has complete seal integrity without needing tools and no torqueing is required for the life of the valve diaphragm. The evolution in hygienic valve design can deliver huge reductions in maintenance time by reducing diaphragm change out time, removing special torque procedures, and eliminating special thermal cycling. This reduction in maintenance time can save hundreds of thousands of dollars annually by reducing plant downtime.

Conclusion

Advancing technology in valve design, combined with an educated preventative maintenance frequency program, can significantly decrease plant down time and deliver huge TCO savings to the biotechnology and pharmaceutical processing industries. The diaphragm plays a critical role within hygienic valves primarily in preserving the integrity of the seal, avoiding leaks and keeping out contaminants. Best practices for maintaining the integrity of your valve can help organizations reduce risk, gain plant uptime and reap the associated financial benefits all by gaining a better understanding of predicting when a valve will eventually falter. This knowledge provides the intelligence to develop a

preventative maintenance schedule supporting the exact frequencies. While it's not yet possible to have a "zero-leak" facility, the future has a promising outlook.

About the Author

Paul McClune is the Global Product Manager for ITT's Engineered Valves and has been with the company for 14 years. Paul has extensive experience in assessing bioprocessing applications and developing predictive and preventative maintenance programs. As a 10 year member of the ASME Bioprocessing Committee Paul helps guide the Biopharm industry in the proper use of hygienic diaphragm valves. Paul's knowledge of the requirements of the industry and his technical background has lead to numerous product developments for Engineered Valves. Paul is currently leading the development efforts of a new product platform focused on reducing total cost of ownership for the customer.

About ITT and ITT Engineered Valves

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ITT Engineered Valves provides essential equipment in industries ranging from mining to biopharmaceuticals, from nuclear operations to oil sands. With 65 years of experience in valve development, design, manufacturing, installation and automation, product offerings include market-leading industrial knife-gate and sanitary diaphragm valves.