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# Maintaining Hygienic Diaphragm Valves

## A process-specific preventative maintenance program improves productivity and reliability.

The biopharmaceutical industry relies on hygienic diaphragm valves for its demanding process applications due to a unique need for cleaning and draining and for pressure and temperature capabilities. Over the past 40 years, the basic design of such valves has remained the same: body, diaphragm, topworks, and four fasteners (see **Figure 1**). Properly installing and maintaining these valves requires experienced personnel and stringent maintenance practices to assure consistent and reliable valve performance.

### Preventative maintenance benefits

Facilities can cut costs and decrease downtime through preventative maintenance, which involves a schedule and process for maintaining equipment; preventative maintenance is particularly important when it comes to valves. Although it can take hundreds of hours a year to properly maintain hygienic diaphragm valves, resulting in thousands of dollars of maintenance cost and lost hours of production, the primary function of a maintenance program is maximized production up-time, reduced planned and unplanned man-hours of labor, and early detection of diaphragm failure. Many plants fail to have a maintenance schedule for their hygienic diaphragm valves and may even wait until a piece of equipment fails before performing any maintenance at all--resulting in a costly and lengthy plant shutdown.

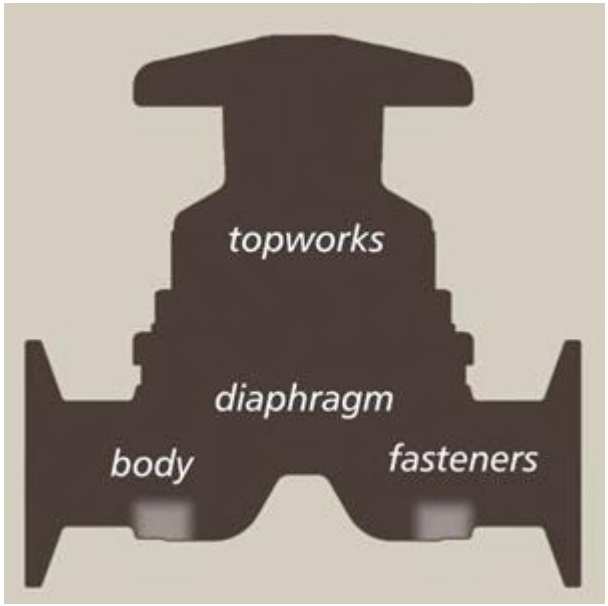


**Figure 1. Design of a hygienic diaphragm valve. Figure is courtesy of the author**

Failure of the diaphragm, which will occur if it is not replaced on a routine basis, will most likely contaminate the process somewhere along the process lines. In many cases, the three major types of failures include valve leakage (fluid leaks between diaphragm and valve body to atmosphere), complete diaphragm rupture (diaphragm tears allowing process fluids to escape through the valve bonnet), and diaphragm tears (diaphragm tears allowing process fluids to escape through the valve bonnet).

The result of these failures can be loss of product. In addition to the product that leaks out, a leak can put the entire batch at risk because of possible contamination entering the system. A diaphragm rupture can introduce contamination from the non-sterilized internals of the valve topworks, allowing the product to come into contact with greases and other contaminating liquids. Diaphragm tears can cause contamination from fluids that get entrapped in the diaphragm tears.

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Diaphragm tears can be especially insidious; because the pressure boundary of the diaphragm is not breached, the in-line instrumentation does not detect a system problem. Many times, all of the process fluids produced from the time of detection of the problem may be recalled or put on hold for testing.

Valve leakage can also result in lost production time and an additional need for maintenance and time to clean up the equipment and repair the leaking valve. Additionally, valve leakage can cause potential safety risk, including employee exposure to dangerous process fluids, steam leaks, clean-in-place fluids, and dangerous organisms.

Preventative maintenance can help maintain these seals and decrease the risk of leakage. Ultimately, detecting failures before they occur can result in improved sterility and minimized risk of contamination, and therefore, reduced maintenance hours and commissioning. Additionally, going through the process of preventative maintenance reduces the need for managers to unnecessarily replace valves or react to potential problems that can occur, resulting in greater efficiency, reliability, and ease of use.

The keys to proper valve maintenance are knowing the steps involved in maintaining valves and implementing a preventative maintenance plan that works for a particular facility and application.

## How to maintain hygienic diaphragm valves

Hygienic valves act as both the static seal (shell seal) and a dynamic seal (weir shutoff). They are often exposed to harsh chemicals, high temperatures, and high pressures, resulting in high amounts of wear and tear and an increased need for routine maintenance. Proper valve maintenance requires several steps by the maintenance team to ensure that the valve will function to its full potential.

**Valve assembly/installation.** One of the most important parts of maintenance is proper assembly during the diaphragm change-out process. If the valve is not assembled properly, it can leave room for batch contamination, poor valve performance, and short lifecycle. Proper diaphragm installation per manufacturer's instructions is essential. If installed improperly, excessive force during operation can result in diaphragm damage. Fluids can then pass through the closed valve or, in the worst case, cause catastrophic failure that results in process fluid contamination and leaks. Torqueing and retorqueing are also important steps in the assembly process that can often lead to seal failure, by either making the seal too tight or too loose for proper performance.

**Replacing the diaphragm.** Another aspect of valve maintenance is knowing when a replacement diaphragm is needed. To make sure valves do not fail, some companies change out their diaphragms on a regular basis (e.g., every six months), regardless of whether or not it is needed. Facilities that use diaphragms with a shorter life expectancy, such as rubber-type diaphragms, may be more likely to perform require more regular changes. However, consistently replacing diaphragms with no signs of failure can cost plants unnecessary expenses and time. Knowing the signs of valve failure is also essential to maintaining a facility's valves. Physical signs that a valve or diaphragm needs to be replaced are excessive wear, corrosion, or fluid leakage.

## Factors to consider

Because of the wide range of applications and conditions within the pharmaceutical processing industry, preventative maintenance programs should be built up over time and should be specific to the application. Programs can vary widely from one plant to another.

There are many factors to consider when facilitating a preventative maintenance program. The biopharmaceutical industry is fairly unique in that valves are used in many different applications with different exposures to temperatures and harsh fluids. Different applications for valves can include steam-in-place (SIP) or high-temperature sterilization; cleaning in place (CIP) where caustics and acids act as detergents; cold processing where purification is usually below ambient conditions (2-8 °C typically); and purification processes, such as chromatography and filtration. Many of these processes run in sequence or through the same pipes, which means the valves are exposed to a wide range of application temperatures and conditions.

Other factors that affect valve performance and maintenance include the amount of exposure time to liquids and steams, the type of diaphragm (one-piece vs. two piece diaphragm), and the thermal cycle (the swings between minimum and maximum temperature). Diaphragms and other soft parts, such as gaskets and O-rings, often face fluctuations between steam sterilization and cold-processing temperatures in the biopharmaceutical industry. A typical valve undergoes hundreds of thermal cycles in its maintenance lifecycle, which can affect the valve seal and ultimately the product. As thermal cycles increase, the valve diaphragm is continually being compressed and relaxed, resulting in thinning of the diaphragm. These dimensional changes create less seal contact and will eventually result in valve leakage to the atmosphere. Although some leaks can be addressed with re-torqueing, most end-user procedures do not allow valves to be re-torqued after the process has been released to production.

Thermal cycle performance has been a significant topic for the biopharm industry for some time. The American Society of Mechanical Engineers Bioprocessing Equipment Committee, which drives many of the industry best practices, has developed a test procedure that will help the end user determine the potential performance of a given seal/diaphragm in these varying conditions. This “Appendix J” test (1) allows seal/diaphragm manufacturers to rate the performance of their elastomers based on a standard test protocol. This testing is currently non-mandatory and is in its infancy of adoption by the end users in the industry. Eventually these Appendix J ratings will provide end users a consistent basis to assess expected life expectancy with regards to thermal cycle performance.

Many of the forward-thinking pharmaceutical companies are now partnering with valve manufacturers to assess maintenance frequencies. With proper application data, including temperature, pressure, process fluid data, and exposure times, valve manufacturers can help develop a maintenance program that aligns with the risk profile of the end user. In this way, the end user can save unnecessary maintenance costs and production down time, ultimately reducing their total cost of ownership of the process system.

## Improved valve designs

In recent years, the design of the hygienic diaphragm valve has been optimized to increase productivity, ultimately advancing maintenance practices in biopharmaceutical facilities. New valve technology, for example, can reduce average diaphragm replacement time from 23 minutes to three minutes and total maintenance time from hundreds of man hours to just a few hours, hence reducing maintenance cost by more than 90% (2). Preventative maintenance practices and more innovative technology, such as valves that do not require tools or re-torqueing, are preventing the potential of human error and making processes safer and more efficient. Improved designs can help meet the biopharmaceutical industry’s growing demand for increased productivity, extended maintenance intervals, and reduced operating costs, in conjunction with an effective preventative maintenance program.

**References**

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