Case Study

ITT
ENGINEERED FOR LIFE

Engineered Valves

EnviZion® Hygienic Diaphragm Valves
Biopharm valve reliability: Solving the caustic challenge

Anyone that has been around biopharmaceutical processes very long, has dealt with a caustic process leak. The main culprit is Sodium Hydroxide (NaOH), which is one of the most effective cleaning compounds used in the industry for Clean in Place (CIP) protocols. It is also one of the most problematic.

Sodium Hydroxide is a “slippery” chemical that will find the smallest leak path. This characteristic makes it more difficult to seal than air or water. It creates problems since most system integrity tests involve pressurization with water or pressure decay with air.

There is nothing more frustrating to process engineers than having a system pass the system integrity tests and then waking up one day to the dreaded caustic residue eminating from valves and other process components.

A top pharmaceutical company was experiencing this phenomenom and frustration on a consitent basis. One process was more problematic than others. A fermentation reactor that produces a critical vaccine was exhibiting these deposits of dry NaOH residue on every production batch.

The company’s Reliability Engineers conducted an indepth root cause analysis to get to the bottom of the issue. They determined that the primary cause of the leaks was the physical/chemical nature of the caustic solutions. Capillary action had caused water and sodium hydroxide ions to seep along the boundary between the valve and diaphragm. Thermal cycling was a major contributing factor, with 200 thermal cycles per batch in their process.

EnviZion valve solves the caustic challenge

The company reached out to ITT Engineered Valves for a solution to the valve leakage problem. ITT visited the site and inspected the non-ITT valves, control automation software, and overall process to identify all aspects of the problem.

Since the chemical/physical nature of the Sodium Hydroxide could not be changed, the valve performance had to be upgraded to alleviate the issue.

The existing 4-bolt valve shell seal was not capable of remaining leak tight with the “slippery” NaOH and the large number of thermal cycles degraded the shell performance over time.

ITT recommended the EnviZion valve platform with an integrated thermal compensation system to solve the performance issue.

ITT’s EnviZion valve – manual and actuated options

The ITT Impact

The Pharma company upgraded to ITT’s EnviZion valve, which completely eliminated the caustic valve leaks and batch contaminations, dramatically reducing maintenance time and investigation costs.

EnviZion valve solves the caustic challenge (cont.)

The EnviZion valve platform was designed to reliably address the common issue of diaphragm valve sealing performance over thermal cycles regardless of process chemical or temperature conditions.

The EnviZion valve platform features:

- Integrated Thermal Cycle Compensation System, which exerts a constant force around the edge of the diaphragm whether the valve is heating up or cooling down
- A fastener-less, tool free desing that requires no torquing or re-torquing of fasteners
- A seal design that minimizes product entrapment and maximizes valve cleanability
- An exclusive mount and turn design allows diaphragms to be changed in 3 minutes or less

Even though the company's problem valves were welded into place, the value of the EnviZion valve performance was compelling. The customer decided to cut out the existing valve and install an EnviZion valve to evaluate the performance.

ITT Engineered Valves designed and manufactured an EnviZion valve to drop in and replace the problematic valves.

After more than a year of in-process service and multiple production batches the EnviZion valves have totally eliminated the caustic leaks and batch contaminations. What's more, the company experienced a dramatic reduction in maintenance time and investigation costs associated with this problem application.

The EnviZion valve once again demonstrated it's value to improve performance, reliability and profitability… Solving the Caustic Challenge.