

# One Up On Performance

Dan Fischer, Ampac Fine Chemicals

**Simply changing to a new pump diaphragm made a dramatic difference in this contract manufacturer's process performance.**

**A**mpac Fine Chemicals (AFC) is a leading U.S. contract manufacturer of active pharmaceutical ingredients and registered intermediates. Our company, which is a wholly-owned subsidiary of American Pacific Corporation, is headquartered in Las Vegas, NV, with production facilities in Rancho Cordova, CA, twenty miles east of Sacramento.

Our technology platform has been built over 50+ years of experience in the development of energetic chemicals, cytotoxic chemicals and pharmaceutical fine chemicals. Our products are used in the development of pharmaceutical formulations for the treatment of diseases in cancer, antiviral and central nervous system therapeutic areas, among others. Due to the highly specialized nature of these products, they can be very costly.



**The Ampac Fine Chemicals plant, located in Rancho Cordova, CA.**



**The Ampac fine chemicals plant in Rancho Cordova makes active pharmaceutical ingredients and registered intermediates by using more than 80 air-operated diaphragm pumps to process organic chemicals such as methylene chloride and ethyl acetates with abrasives.**

## The Situation

The use of pumps in our manufacturing processes is very important, and the precision of this equipment is critical to ensuring the consistent quality and integrity of the finished product.

More than 80 air-operated diaphragm (AOD) pumps are used onsite, pumping a variety of organic chemicals such as methylene chloride and ethyl acetates with abrasives. The operating environment and typical characteristics include:

- Inlet air pressure: 60-psi
- Discharge pressure: various
- Temperature: negative 10-deg F to ambient
- Lowest outside temperature: +30-deg F

## The Challenge

During a plant visit conducted by the west coast field sales manager of W.L. Gore (Elkton, MD) and his

authorized distributor, Valley Rubber & Gasket Co. (Sacramento, CA), they noticed that several AOD pumps were in the process of being rebuilt.

For us, it is critically important that these AOD pumps be in perfect operating condition, since the intermediate batches being manufactured have such high market values. Any premature diaphragm failure – or worse, foreign particles generated by a faulty diaphragm – would be serious cause for concern for our plant's O&M staff.

Naturally, equipment rebuilding is something maintenance personnel would prefer not to be doing, but it is a necessity. One of our products utilizes methylene chloride and/or toluene at negative 10-deg F and has a coarse, gritty consistency. It turned out that the elastomers on the two-piece PTFE diaphragms that were previously used in the AOD pumps could not handle the cold temperatures and the abrasives.

This problem had caused the diaphragms to fail within the first one or two manufacturing batches, and had been persistent and serious enough that the engineering and O&M teams were actually considering shifting to a completely different fluid transfer technology.

## The Solution

A solution was proposed to change to the GORE™ One-Up Pump Diaphragm, a new one-piece composite design pump diaphragm with proprietary PTFE on the wetted side that would allow us to continue using the same Wilden® and Versamatic® pumps that are currently online in the plant.

The proposed diaphragms are made with EPDM backings and have been engineered to provide long-life service in high-pressure pumping applications (head pressures of 250-psig (17-bar) or greater) involving corrosive or caustic media. As it turned out, the recommended diaphragms are perfectly suited to handle the media at the required low temperatures.

Constructed from a unique two-in-one proprietary design that is a considerable advancement over conventional PTFE materials, these pump diaphragms are strong and deliver significantly longer service life, as well as provide greater flex life. Moreover, the two-in-one construction of the pump diaphragms meant that installation was easier and faster, with our maintenance crew no longer having to apply joint sealant on two diaphragms.



**The unique two-in-one construction of the pump diaphragms makes installation easier and faster for maintenance personnel. With their advanced design, these pump diaphragms are strong, delivering significantly longer service life and greater flex life.**



**These process vessels are used for handling specialized pharmaceutical intermediates at the Ampac fine chemicals plant in Rancho Cordova.**

Before deciding to install the pump diaphragms throughout the facility, we conducted tests on one of the pumps. The subsequent testing (and failure) of alternative diaphragms eventually resulted in the two-in-one diaphragms being designated as the units to be used on all AOD pumps handling all process fluids – not just the most difficult, coarse ones.

## Results

For us, the switch to the two-in-one pump diaphragms has resulted in several important improvements in plant efficiency, processing effectiveness and risk avoidance, including:

- Significantly longer diaphragm life has resulted in lower replacement parts costs. (We exceeded our goal of achieving diaphragm longevity of at least 10 batches on a campaign.)
- Less maintenance downtime.
- Eliminating the potential for catastrophic diaphragm failures that could result in losing an entire batch of expensive pharmaceutical intermediates due to contamination.

That's not all. Because quality control is a critical factor in our pharmaceutical manufacturing processes, we must interface with FDA audit teams that inspect both the procedures and the paperwork. The fact that these pump diaphragms are coded by lot number makes traceability much easier, in case this information is ever needed.

## P&S

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