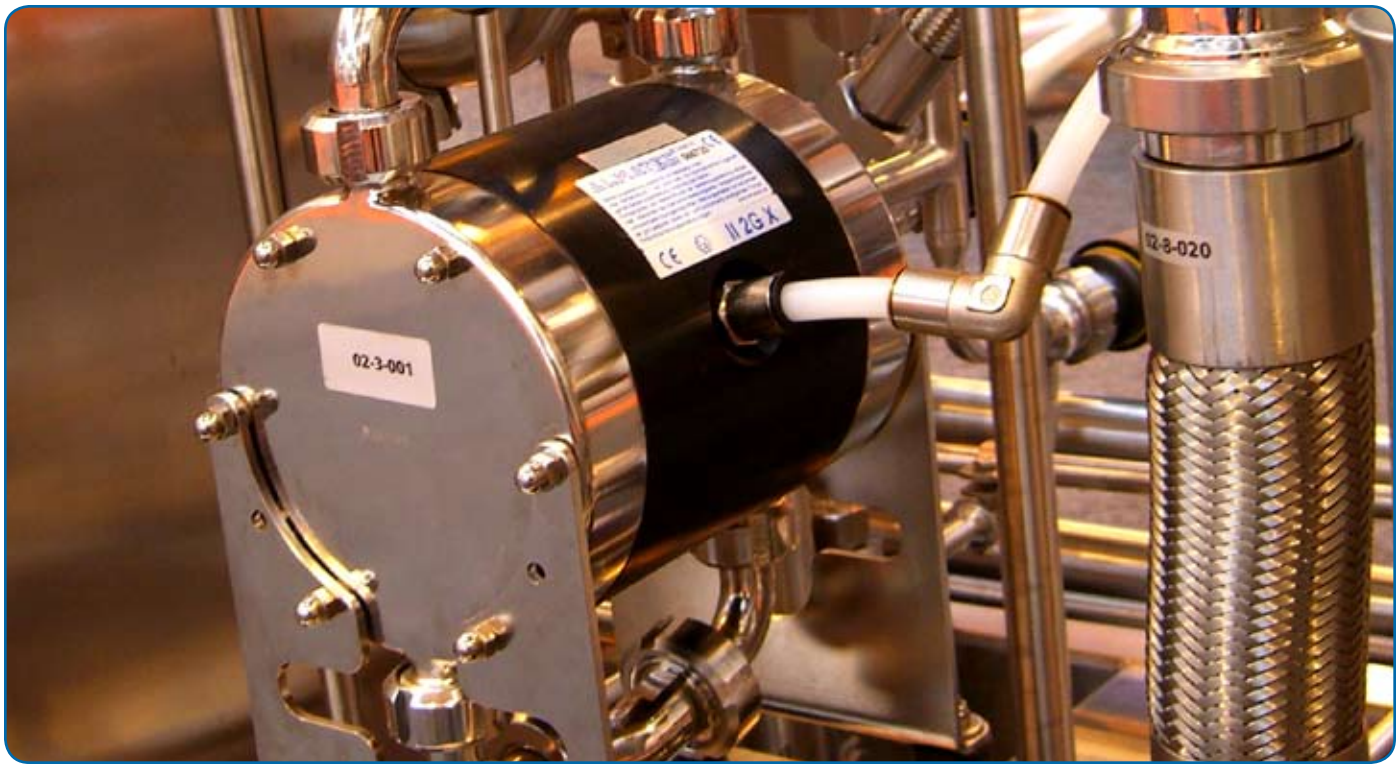
The Perfect Prescription

AODD PUMP TECHNOLOGY HAS BECOME A FORCE IN THE MANUFACTURE OF PHARMACEUTICALS

By Wallace Wittkoff



None other than the ancient Greek philosopher Plato is credited with coining the phrase, "Necessity is the mother of invention," meaning that "a need or problem encourages creative efforts to meet the need or solve the problem." It's unknown whether that phrase was going through Jim Wilden's head as he watched water from a ruptured pipe gush into a shop at a steel factory in San Bernardino County, CA, some 50 years ago. Legend has it, however, that a foreman who was trying to plug the leak and, using Mr. Wilden's nickname, yelled to him, "Hey, Slim, you would make a million dollars if you could invent a pump to get this stuff out of here."

From that simple tongue-in-cheek exclamation an entire industry would blossom, as Wilden went to work doing just that, and in 1955 he had the solution—the air-operated double-diaphragm (AODD) pump, a technology that was said to have been "conceived out of necessity, born in the arms of innovation, and inspired by sheer will and determination." After several years of trial and error, Wilden developed a pump that had the right air valve and diaphragms needed, and was tough and versatile enough, to meet the stringent demands of the mining and heavy-construction industries, where the need to pump water, slurry or any finely divided substance such as cement is an ongoing requirement.

First, Do No Harm

While the earliest AODD pumps were born of the need to remove water or other liquids from where they didn't belong, over the years AODD design has been modified to fit the operational parameters of many other industries. One of these industries is the manufacture of pharmaceuticals. As it turns out, the diaphragm pump already have a cousin in the industry, the diaphragm valve. So with a few innovations and enhancements for ultra-sanitary conditions needed by the pharmaceutical industry, the diaphragm pump is now an attractive option for many fluid transfer needs. These processes—and the products they produce—have to meet a wide array of regulations and certifications that ensure that they are being performed in a high-purity environment. Among the

regulations that AODD pumps can satisfy are those from EHEDG, 3A, CE, ATEX, USP Class VI and FDA CFR 21.177. This includes a validation package with mill, 3.1b, polish, passivation, and classified area use certifications.

Wilden AODD pump and dampener used in a health care process application.

The liquids—which can run the gamut from extremely shear-sensitive to extremely viscous—and semi-solids can range from liquid glucose to polymer slurries. Pharmaceutical and biochemical fluids currently pumped. with diaphragm pumps include: blood and by-products, live cell cultures and vaccine producing solutions, egg emulsions for vaccine production, pill coatings, eye care solutions, fluids for oncology, specialized disinfectants, nutraceuticals, vitamins, topicals (creams/lotions), filter media and many more. The use of AODD technology can guarantee their safe transfer during the production process.

According to Hoover's Inc., which analyzes companies and industries that drive the economy, there are as many as 1,500 companies in the United States that manufacture and market pharmaceuticals (defined as "a compound manufactured for use as a medicinal drug"), with combined annual revenue of more than $200 billion. Needless to say, these numbers indicate that the manufacture of pharmaceuticals is one of the lynchpins of the American economy. The actual creation of pharmaceuticals involves one of three major methods: synthesis (using chemical reactions to build a drug from simpler components); extraction (using solvents to remove and purify a drug from a natural source); or biotechnology (using methods such as gene-splicing or the production of antibodies using mouse or human cells).

No matter the method used to produce pharmaceuticals, the actual manufacturing process is a precise one that must be performed under demanding, exacting conditions, often in a cleanroom environment that prohibits instances of product leakage, fouling or cross-contamination.

There is good reason for the fast adoption of AODD pump technology in high-purity processes: its close operational relationship to the well-known and well-regarded diaphragm valve. The diaphragm valve has long been the valve of choice in these types of applications because of its high product containment and cleanability traits. These are also traits that AODD pump technology boasts, along with a seal-less stem and shaft-free product-side environment.

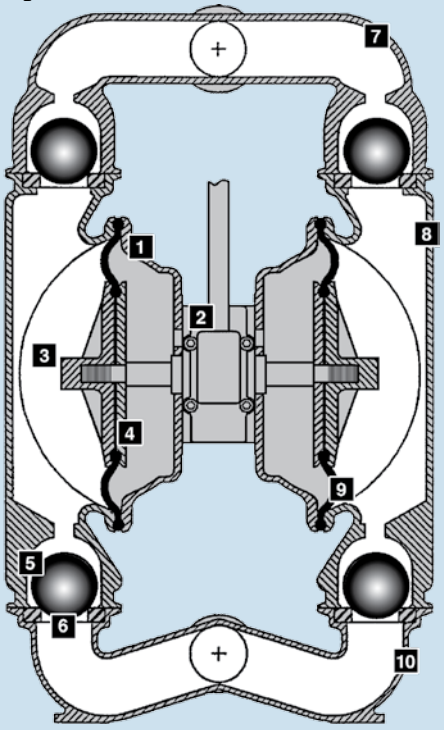
Specifically speaking, AODD technology is a boon to pharmaceutical manufacture in a number of crucial areas, including:

- **Sterile Product Transfer —** AODD pumps remove the need for gas-purge systems in continuous processes because the technology allows both the filling and emptying process to occur at the same time while keeping the product contained and pure.
- **Process Flexibility —** AODD pumps can handle highly variable process conditions found in many hygienic applications.
- **Sampling —** Complex pharmaceutical processes under very strict conditions require frequent and multi-point sampling. AODD pumps provide the ability to extract these samples while maintaining a high degree of containment and avoiding cross-contamination.
- **Clean In Place —** The AODD pump's self-priming, dry-running and seal-less design is ideal for CIP operations.
- **Chemical Feed —** This is a traditional role for AODD pumps as their seal-less design and reliable product containment ensure safety when handling volatile or potent chemicals.
- **Ingredient Unloading** — Because they self-prime, run dry and have negative suction lift, AODD pumps meet pharmaceutical-validation requirements and can be applied where needed.

Inside An AODD Pump

The uncomplicated design of AODD pumps features few moving parts, and those that do move have very simple, specific tasks:

1. **Air Chamber —** Houses the air that powers the diaphragms
2. **Air Distribution System —** The heart of the pump, it is the mechanism that shifts the pump in order to create suction and discharge strokes
3. **Outer Diaphragm Piston —** Connects the diaphragms to the reciprocating common shaft and seals the liquid side from the air side of the diaphragm
4. **Inner Diaphragm Piston —** Located on the air side of the pump, it does not come in contact with the process fluid
5. **Valve Ball —** Seal and release on the check-valve seats, allowing for discharge and suction of process fluids to occur
6. **Valve Seat —** Provide the ball valves a place to check
7. **Discharge Manifold —** Allows fluid to exit the pump through the discharge port, which is typically located at the top of the pump
8. **Liquid Chamber —** Separated from the compressed air by the diaphragms, it fills with process fluid during the suction stroke and is emptied during the discharge stroke
9. **Diaphragm —** Acts as a separation membrane between the process fluid and the compressed air that is the driving force of the pump. To perform adequately, diaphragms should be of sufficient thickness and of appropriate material to prevent degradation or permeation in specific process-fluid applications.
10. **Inlet Manifold —** Allows fluid to enter the pump through the intake port located at the bottom of the pump



- **Product Recovery and Semi-Solids Removal —** Again, the AODD pump's dry-run, self-priming and full product containment makes it ideal for use in most filtering or separation processes.
- **Chromatography, Separation, Purification and Filter Feed —** These processes often require shear-sensitive transfer and constant pressure feed, traits found in AODD pumps. Extracting delicate cell structures from centrifuge discharge is a good example.

Regarding maintenance, simplicity defines the cleaning and maintaining of these pumps. In the highest hygienic configurations, these pumps are designed to clean-in-place so that manual labor and contamination risks do not occur. However, at the same time, these pumps have been purposely to be simple to disassemble either for manual cleaning procedures or routine maintenance.

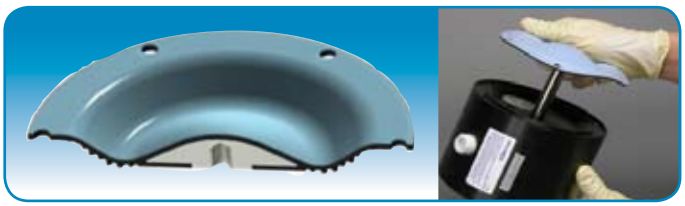
Additionally, as biopharmaceutical processes evolve, more attention is being paid to optimizing them. The separation of mechanical and utility functions is an example of area/floor space optimization. AODD pumps can be split so that the "power side" is mostly located remotely in an unclassified area and the fluid end can be placed in a classified area, with only an instrument air-supply line connecting the two. This means that electric motors, oil-filled gear cases and greased bearings no longer need to be located in the clean area, raising the level of hygiene and reducing the risk of product contamination.

How AODD Technology Works

AODD pump lines used in pharmaceutical manufacture need to meet a series of strict specifications in materials of construction and design. As such, the heart of the system remains the revolutionary air-operated double-

diaphragm technology. At their simplest, AODD pumps are classified as reciprocating, positive-displacement-style pumps. The pump operates by displacing fluid from one of its two liquid chambers upon each stroke completion. To operate correctly, AODD pumps require a precise amount of pressure (measured in pounds per square inch) and air (measured in cubic feet per minute) to deliver the proper amount of fluid.

The simple genius of AODD pump design means that there are only a few wetted parts that are dynamic: the two diaphragms, which are connected by a common shaft, the two inlet valve balls and the two outlet valve balls. The diaphragms act as a separation membrane between the compressed air supply and the liquid. Driving the diaphragms with compressed air instead of the shaft balances the load on the diaphragm, which removes mechanical stress from the operation and extends diaphragm life. This also allows the valve balls to open and close on the valve seats, which direct liquid flow. This simple design and operation makes it easy for the operator to find the correct pressures and flows to optimize its operation.

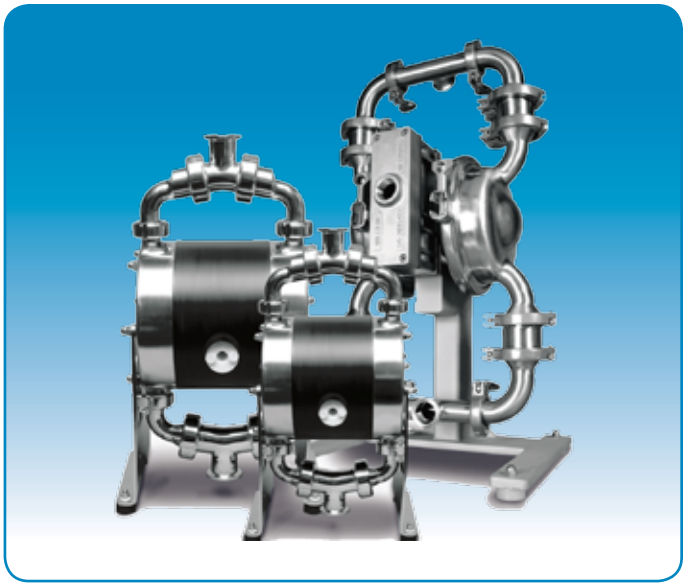


Wilden/Almatec Integral Piston Diaphragm (IPD)

For high purity industries, one of the primary innovations that have made this pump among the most viable selections in the industry has been the Integral Piston Diaphragm (IPD) (see photo above). Unlike traditional pump diaphragms that have an outer plate that supports the diaphragm that is subject more difficult cleaning or be a potential leak point, the IPD is completely laminated with USP Class VI PTFE on the product contact side. This offers the highest degree of containment and cleanability among pumps.

Conclusion

Jim Wilden designed his first AODD pump to handle demanding applications that required a robust design. More than a half-century later, his Wilden® Pump & Engineering Company, LLC, Grand Terrace, CA, USA, and its AODD pumps remain the time-tested standard for a wide range of industries, including pharmaceutical manufacture, that require the efficient, timely, sanitary, cost-effective and maintenance-friendly pumping of a wide variety of liquids and other substances.



Wilden/Almatec Pharmaceutical Pump Solutions

Today, Wilden Pump & Engineering is an operating company within Dover Corporation's Pump Solutions Group (PSG™), Redlands, CA, USA. In all, PSG combines six unique pump manufacturers into one cohesive group. Along with Wilden, Kamp-Lintfort, Germany-based Almatec Maschinenbau GmbH provide cutting-edge air-operated diaphragm pump technologies to the pharmaceutical industry.

While Wilden could have had no idea at the time that the doggedness of will that sprang from that pipe leak would continue to reverberate around the globe in an innumerable of industries all these many years later, he did know that a good idea followed by the proper execution could have far-reaching positive effects. There's no doubt that his air-operated double-diaphragm pumps have certainly met those parameters for innovative excellence—and will continue to do so in the future.

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You can find more information on PSG at www.pumpsg.com.

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