# Sense and actuate

## Use of valve actuators and sensors in pharmaceutical production will enhance safety and maximise production

In 2012, it was reported that weaknesses in the manufacture of sterile injectable drugs resulted in almost one third of the biopharmaceutical industry's manufacturing capacity being taken off-line. A major reason for these shortages has been quality and manufacturing issues[1]. According to US Government Accountability Office's 2014 report, the most frequently cited immediate cause of drug shortage was manufacturing disruption due to quality problems – 40% of shortages between 2011 and 2013 resulted from quality issues or plant maintenance issues[2].

The widespread shortages caused inferior treatment regimens, interruptions in care, higher health care costs, and even premature death. To reverse these alarming trends, it is essential that drug manufacturers maximise product quality to ensure patient safety.

Advancements in valve and sensor technology have enabled manufacturers in the life science industry to improve their manufacturing capabilities through maximising uptime, reducing overall cost of equipment ownership, and lowering maintenance costs. These benefits extend throughout the value chain in the form of financial returns and increased maintenance resources, all of which result in better patient care.

But how can valve actuation and sensor technology improve operational performance in the pharmaceutical manufacturing industry? Technologies and materials exist which are designed to complement and improve existing manufacturing trends while contributing excellent performance to the entire plant architecture.

### Diaphragm valves in pharmaceutical manufacturing

Diaphragm valves form an integral part of the pharma manufacturing process, in that they enable drug manufacturers to safely control different types of media. Diaphragm valve technology has been around the pharmaceutical industry since its invention by PK Saunders in 1928.

In general, the pharmaceutical industry has adopted common practices that incorporate the use of industrial communication networks. Industrial networks not only provide efficient control over one common physical media, but also dedicated diagnostics that contribute to preventive maintenance and reduce costly interruptions. The desire to implement new technologies by pharma manufacturers has pushed the valve industry to create new accessories that, in conjunction with aseptic valves, offer unparalleled control, complete and accurate status of a valve, and in the bigger picture a much more solid and reliable manufacturing process.

**Pair of Saunders S360 actuators**

As the inventor of the diaphragm valve, Saunders' vision for the future aligns with the goals of the pharmaceutical manufacturing industry as a whole. Manufacturers seek new processes and technologies that drive the current offering of materials for valve bodies or diaphragms (valve design and polymers). The company likewise drives innovation of electronic devices that offer new possibilities to end users, engineers, integrators, and OEMs.

Part of the new generation of products specifically designed to increase accuracy and maximise diaphragm life include actuators and sensors. Together, innovations in these two devices can deliver outstanding performance, ultra-reliable valve position indication, and unique diagnostics that can be extracted remotely or locally at the sensor.

Solutions that maximise manufacturing cycles, reduce maintenance time, improve the accuracy of valve position readings, and offer efficient control and robust diagnostics are key differentiators that can reduce the overall cost of ownership of an aseptic valve. The use of this technology can eliminate recurrent issues that are common in the industry, such as:

- False indication of valve position: An unknown valve position could lead to nuisance trips and other associated events (instrumentation failure, batch contamination, etc.)
- Lack of individual cycle counters that monitor diaphragm status: An unknown number of cycles could lead to diaphragm failure and potential batch contamination.
- Long commission time for limit switches during start-ups and factory acceptance tests (FAT), which can lead to higher operating costs
- Overall size and weight of valve assemblies
- Thermal degradation of the

diaphragm during steam in place, which can lead to failure.

### Considerations for actuator and sensor selection

Actuation is often critical to valve operation, not only from a reliability standpoint, but also because the chosen method of actuation can affect the accuracy of the process. In highly-controlled pharmaceutical applications, this consistency and precision is especially important.

Generally, the more mechanical linkages there are in a process, the greater is the potential for error due to wear at the linkage points. Variations in linkages can vary the piston stroke, causing accuracy problems. Therefore, valve users should carefully evaluate methods of actuation to mitigate any accuracy concerns and hysteresis effects[3].

The following list outlines some important considerations in actuator selection, arranged by importance:

- **Closure performance:** Actuator should be able to provide powerful closure performance under wide range of operating conditions. Improper closure can lead to catastrophic failure including loss of a batch
- **Compact design:** A piston actuator with a compact design (versus diaphragm type actuators) is best-suited for the operating conditions found in most biopharmaceutical manufacturing facilities. A compact dimensional envelope will minimise the dead-leg between associated valves and enable a more compact skid design that will optimise system performance
- **Ability to rotate:** An actuator able to fully rotate the actuator head by 360° enables flexible installation and optimises air-port alignment. This in turn reduces installation overall cost for both new and existing projects, and optimises the incorporation of actuators in compact valve arrays or skid arrangements
- **Maintenance free:** Corrosion resistance and easy cleaning ensure conformity with a hygienic environment, thus reducing maintenance costs
- **Material:** Stainless steel housing material delivers a clean OD profile that can withstand the wash-down regimes required in the sterile pharmaceutical manufacturing process

While actuators are critical to a valve's open and close performance, sensors are essential to the accurate determination of overall system status. While not every valve in a pharmaceutical system may have a sensor, those that do are considerably more effective in process control.

Valve sensors are intended to provide positive confirmation of valve position. A lack of confirmation or inaccuracies in valve position indication can result in batch contamination, compromising both the manufacturing process and patients' health. To ensure that cross contamination and harmful chemicals are not inadvertently introduced into drug manufacture, valve users should employ a robust and reliable sensor system.

The following list outlines some important considerations in sensor selection:

- **Mechanical vs. electromagnetic sensors:** Mechanical sensors fail over time and have a tendency to provide erroneous indications, including false open or false close positions. Sensors with ultra-reliable electromagnetic sensing technology provide a high degree of accuracy – potentially less than 0.2mm – reducing the potential for error
- **Compatibility:** Standard switch controls may not be compatible with all process control systems. Sensors that are compatible with existing systems like Point-to-Point (P2P), AS-i, and DeviceNet can offer substantial benefits to ease of integration
- **Solid state continuous sensing technology:** Continuous sensing technology enables diaphragm valve position to be known throughout the range of travel, allowing unsurpassed and accurate monitoring especially in smaller valves
- **Valve size:** It is important to ensure that a sensor can be effective on a comprehensive range of valve sizes
- **Automated valve calibration:** Installation can be simplified by utilising sensors with automated valve calibration. This capability enables a sensor to be incorporated into the system without opening the sensor enclosure, and can drastically reduce set up times


**Saunders I-VUE smart valve sensor**

### Conclusion

Manufacturing practices currently implemented in biopharmaceutical plants have been enhanced through the integration of actuation and sensor technology. Not only does the incorporation of these controls maximise system uptime, but it can reduce overall cost of ownership and enhance safety throughout the production process.

Actuators that deliver superior valve performance and sensors that eliminate false position indication are some of the most important contributions to better performance and maximum safety for the manufacturing industry. Designed to complement existing manufacturing trends while improving entire plant architecture, this equipment will help ensure a more promising future for the pharmaceutical manufacturing industry.

**References:**

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**For more information:**

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