

The Pharmaceutical Industry will Gladly Pay for Improved Valves

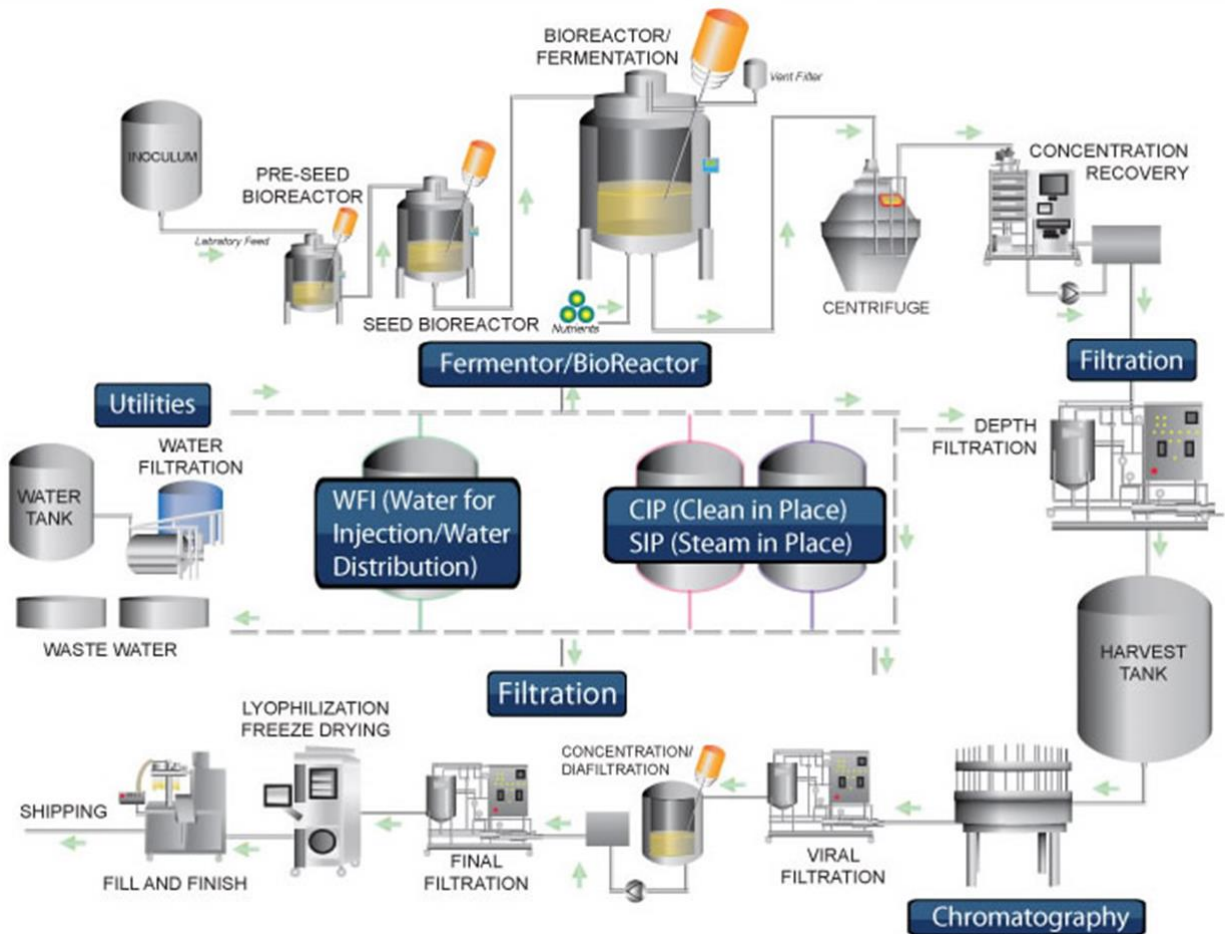
The pharmaceutical industry seeks innovations from valve suppliers. They include

- more accurate control
- less leakage
- lower energy cost for disinfection and actuation
- ability to deal with cryogenic and other severe service conditions
- faster response time
- greater reliability
- less maintenance
- lower contamination potential
- better integration into systems
- faster delivery and maintenance support
- single use design
- sterile transfer
- extended lifetime in service
- lower installation and maintenance costs
- elimination of false alarms / more reliable valve position feedback

The pharmaceutical industry is growing faster than other industry sectors. It is also changing. New drugs can treat diseases such as cancer without harming patients. The challenge is that the drugs utilize the cells from each patient to create a drug which can be used only by that patient.

Manufacturing these single patient drugs has challenged manufacturers. The quantities are small. However, it is very difficult to switch without contamination from the previous batch. The product is both very expensive and vulnerable to damage.

The valve manufacturers are meeting these challenges with new products.⁽¹⁾ The following process diagram supplied by Crane identifies a number of critical applications in addition to the general service valve types needed for water and wastewater.



Here are some of the cost saving features offered by valve manufacturers to meet the critical valve needs.

Alfa Laval: DV-ST UltraPure diaphragm valves are customizable, with slimmer stainless-steel actuators which require less air pressure and therefore result in energy saving. The lightweight cast valve bodies cut installation costs and reduce energy in cleaning cycles due to lower heat input required.

Burkert: The diaphragm valve weir pattern is unique in its ability to control very pure substances where a minimum of wetted materials and dead volumes are absolutely required.

Chargepoint: A unique and integrated solution for sterile product transfer is offered. The AseptiSafe Bio Transfer Valve uses an enhanced decontamination step, exposing the SBV discs to vaporized hydrogen peroxide (VHP) gas within a sealed chamber.

Crane: The innovative self-calibration functionality of the Saunders®-VUE portfolio of valve sensors, allows the sensor to identify open and close valve positions without opening the enclosure. Resultantly, these Sensors require half of the labor and a tenth of the time per calibration, when compared to traditional switchbox technology.

The unique material combination of the Saunders® EX Endurance Diaphragm offers outstanding performance in applications exposed to prolonged sterilization regimes or higher temperature up to 175°C, extending the length of time needed between diaphragm change-out.

DFT: Each vertical or horizontal check valve has a gasket body seal and a quick-release clamp that operators and maintenance staff can use to easily access the valve components for repairs and other maintenance. Lapping the seat and disc ensures tight shut off, which lowers the risk of backflow.

Flowserve: Worcester cryogenic ball valves can handle the rigorous temperature requirements needed in supporting the mass production of the COVID-19 vaccine.

GEA: Ownership advantages of single source coordination for centrifugal separators, fermenters, homogenizers, flow components and aseptic valves are cited.

GEMU: A larger selection of the world's first controllable single-use diaphragm valve is available.

ITT: Sodium Hydroxide is a “slippery” chemical causing leak problems. At a large pharmaceutical company the existing 4-bolt valve shell seal was not capable of remaining leak tight. EnviZion valves have totally eliminated the caustic leaks and batch contaminations.

IDEX: The Sterivalve diaphragm is clamped between the valve body and the actuator. All moving parts in the actuator are completely isolated from the process fluid and tools are not required for disassembly or service for most valve sizes.. Both the valve housing and the process connections are self-draining and have no dead-legs.

IMI: Igenix® valves are available with self-flushing capability and have bi-directional adjustable seating that allows the valve body cavity to be isolated for cleaning with purge ports as well as adjusting for normal seat wear without having to remove the valve from the process line.

KSB: The diaphragm design provides a high operating reliability at high temperatures. The new SISTO actuator has compact dimensions, low weight and sturdy design to achieve very high open/close frequencies and a long service life.

LESER: Safety Valves have low dead space and gap-free internal construction to guarantee a high degree of cleanliness and meet all hygienic and sanitary requirements for the pharmaceutical industry.

Watson Marlow: The new weirless in-line ASEPCO valve allows one minute diaphragm change-over. Flexible installation angles create an unobstructed flow path and operator safety. Composed of a forged body, the weirless in-line valve also eliminates the potential of trapping impurities through the shoulder seal design.

The availability of new valves and materials to meet the new requirements necessitates a new approach to determine which alternative will provide the lowest total cost of ownership.

In the past the leader with many successful installations could use his large market share to validate his equipment. The argument has been if all these users are finding it the best so will a new purchaser.

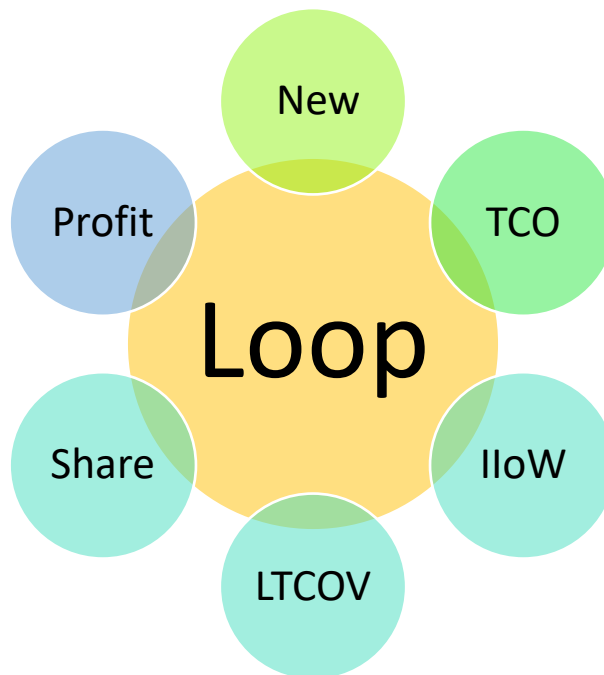
In the new environment purchasers want accurate cost of ownership evaluations for new and better options.

The media, suppliers, and associations are providing instant access to the latest information. In effect this is an Industrial Internet of Wisdom (IIoW) which allows the user to determine which product has the lowest total cost of ownership. This analysis is just one of the IIoW links which should lead to further pursuit of the innovations.

What is being created is an Innovation – TCO- Profitability Causation Loop consisting of

- New design
- Lower total cost of ownership (TCO) due to the innovation
- Industrial Internet of Wisdom (IIoW) communication
- Lowest Total Cost of Ownership Validation (LTCOV)
- Increased market share
- Increased profit margin and total profits
- Funds to invest in R&D for new design

Innovation-TCO-Profitability Causation Loop



The TCO for the innovation can now be validated with ItoW. LTCOV convinces the customer to pay a higher price for the product. In turn the higher price results in higher profits. Funds are then available for more R&D This investment leads to new and better products and the cycle continues.

The pharmaceutical industry is the leader with R&D expenditures averaging 19% of revenues. The valve industry averages 3%. The profit margins for valve companies are far lower than that achieved by pharmaceutical companies.

The large investment in pharma has resulted in remarkable cell and gene therapy treatments and a vaccine for coronavirus.

Valve suppliers need to keep pace with their pharma customers. The Innovation-TCO-Profitability Causation Loop is the recommended route.

(1) *Industrial Valves: World Market* published by the McIlvaine Company