

Reducing the True Cost of Valves in Blood Plasma Fractionation

The market for air, water, and energy products used in blood plasma fractionation, and the development of drugs derived from the plasma, is approaching \$5 billion per year. Alongside this, the global market for valves is approaching \$50 million dollars per year.¹

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Compared to many pharmaceutical processes, plasma fractionation is a large volume application. Nearly 100 million liters of plasma are produced each year, sourced from donors globally.

Due to its complicated processes, fractionation technology is very complex. As a result, plasma donated in developing countries is often discarded and only the red blood is utilized. Man-made recombinant products have been making inroads into the market, though the human-derived plasma product market is still growing at approximately 6% per year.

The technology necessary for fractionation is currently undergoing significant changes. Even the cold ethanol process itself is being challenged by newer technologies. The need to analyze all the technology options in this industry is therefore heightened.

Processes Involved in Blood Fractionation

Fractionation requires that donated blood first be separated into its component parts, namely platelets and plasma. This is usually done by centrifuging the blood, which allows erythrocytes (red blood cells) to settle at the bottom of the centrifuge. When the blood has successfully been treated in fractionation processes, it is then often used in transfusions and other emergency medical procedures. However, the processes for large scale, industrial plasma fractionation processes differ from those used in small scale operations.

How Valves are Used

Valves are critical to minimizing the total cost of ownership for blood plasma fractionation. Purchasers need to know what products have the Lowest Total Cost of Ownership (LTCO) in each niche. Blood plasma fractionation is

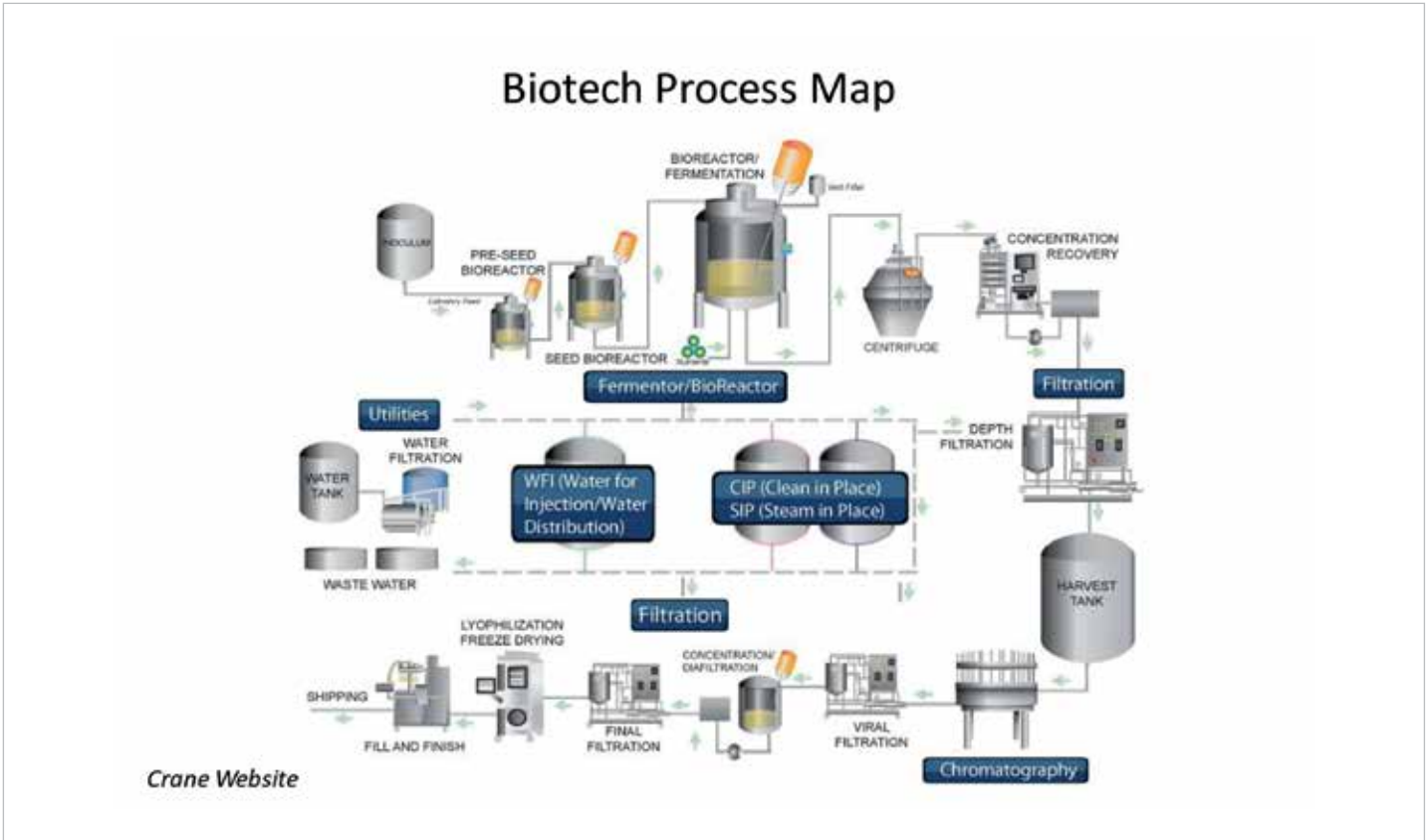
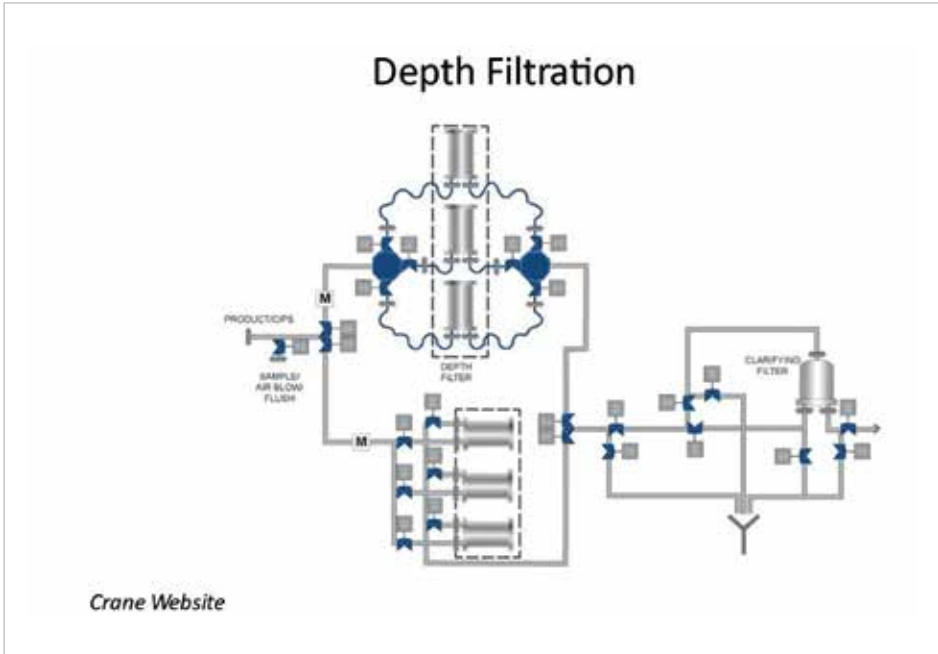


Image 1.

composed of many unique niches which must be analyzed to help determine the LTCO.

Several valves are used in depth filtration, a process which removes a broad range of particles from the medium in fractionation. Single-use can be justified if downtime is avoided or efficiency is improved. However, this is only true if the product price is high, so this would not apply to plasma, but rather would apply to some the plasma products. For example, in developing countries where plasma may otherwise be discarded, single-use could be justified, though single-use is just one more option where total cost of ownership needs to be determined. Companies like ITT make large diaphragm valves and others like GEA focus on smaller ones, making size a factor as well as single-use capabilities.



Ultrapure water is also required for clean, in-place systems. Distillation and membrane filtration are two routes for achieving acceptable water purity. Both of these processes use many valves. Pressure however, is the challenge in the membrane systems, whereas temperature and steam are the challenges in distillation.

Valve Product Examples

There are several companies in the marketplace that manufacture and distribute wide ranges valves that would be suitable for blood fractionation processes. A few of these companies are as follows:

Alfa Laval

Alfa Laval is extending its range of Unique DV-ST UltraPure diaphragm valves. The all-new range comes with slimmer actuators and optimized lightweight cast valve bodies with options for economical operation. The enhanced DV-ST UltraPure range is fully customizable.

Blacoh-Sentinel

Diaphragm back pressure valves are designed to enhance the performance of pumping systems by applying a continuous back pressure to the system pump, while also acting as an anti-syphon valve.

Burkert

Isolation and control valves, including diaphragm valves, are supplied along with a pneumatic valve island for process automation.

Crane

The self-calibration functionality of the Saunders®-VUE portfolio of valve sensors allows the sensor to identify open and closed 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 switch-box 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. This extends the length of time needed between diaphragm change-out. The company's EX diaphragm can also deliver extended diaphragm life on high temperature steam applications and reduce annual maintenance spend significantly. Check valves also meet Sanitary 3A Standard 58-02. This Clean-in-Place Design allows for easy cleaning without disassembly of the system.

Festo

Biotest is using 6000 thousand Festo valves in its new blood fractionation facility. Festo also supplies valves and components for ROTAN's water-based cleaning systems.

GEA

The company says its Vesta valve compares favorably to diaphragm valves. These sterile valves meet the operational requirements for pharmaceutical and biotech processes, comply with the strictest safety regulations, and provide a high-quality product. The most impor-

tant features of the design are hermetic and safe sealing by PTFE bellows with a patented sealing system, actuator systems made of high-grade synthetic material or stainless steel, and easy servicing. These valves offer a cost-effective alternative to diaphragm valves.

The Vesta sterile valve provides the market with a valve series for low volume flow rates, suitable for applications from laboratory up to highly complex process plants. The valves prevent product contamination from the outside, ensure that the process system stays free of change to; germs.

Gemü

GEMÜ claims to have the first controllable single-use diaphragm valve on the market: the GEMÜ SUMONDO. In addition to a pneumatically operated version, the product range now includes a version with a hand wheel for manual operation. With a third diaphragm size now introduced, another high-performance option has been added to the product range: the largest valve of its type to date with up to one inch in process connection size. This means that applications that require a higher medium flow and precise controllability now have a solution.

IMI

IMI PBM Igenix® valves for the Pharmaceutical and Biotech Industry are specifically designed and tested to perform in many types of sanitary and clean steam applications.

ITT

ITT's EnviZion valve technology is an opportunity to increase performance and reduce total cost of ownership by addressing the most common source of diaphragm valve performance issues, thermal swings. The EnviZion active thermal compensation system coupled with a unique PTFE diaphragm provides reliable sealing regardless of process temperature change, assuring valve performance and extending service intervals.

Steriflow

Steriflow offers a variety of sanitary diaphragm valves including manual or air actuated forged 2-way or cast 2-ways, ported and tandem valves, barstock zero static T-block, point of use T-block, divert tank bottom and custom block body valves.

Conclusion

There are many niches, suppliers, and valve types which need to be analyzed in order to achieve the lowest total cost of ownership in the manufacture of fractionation products. Due to the changing technology and market, the need for analysis is continuous. The opportunities for valve suppliers will keep changing.

Valve suppliers have the opportunity to respond to the opportunities to reduce costs and to develop and sell products with higher EBITA. In this manner, both the purchaser and supplier benefit.

Valve Locations in Industrial Plasma Fractionation



REFERENCES

- 1. Industrial Valves World Market published by the McIlvaine Company

ABOUT THE AUTHOR



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