Pharmaceutical Industry Valve Profits through LTCOV

Latest Update July-6-21

Profit Growth Through LTCOV in Pharma Niches

More than half the valves purchased by the pharmaceutical industry are based more on anticipated product performance than on price and delivery. This decision on Lowest Total Cost of Ownership (LTCO) incorporates the following factors and examples.

- Financial: interest rate, evaluation life
- Common: energy, maintenance, product value
- Shared product features: some competitors also have these features
- Unique product features: only offered by one supplier

This analysis provides preliminary information on the market niches and the claimed unique product advantages of some of the suppliers.

The purpose of this presentation is to function as a catalyst for suppliers and the media to help persuade customers to make the best valve choices. This has been categorized as Lowest Total Cost of Ownership Validation (LTCOV).

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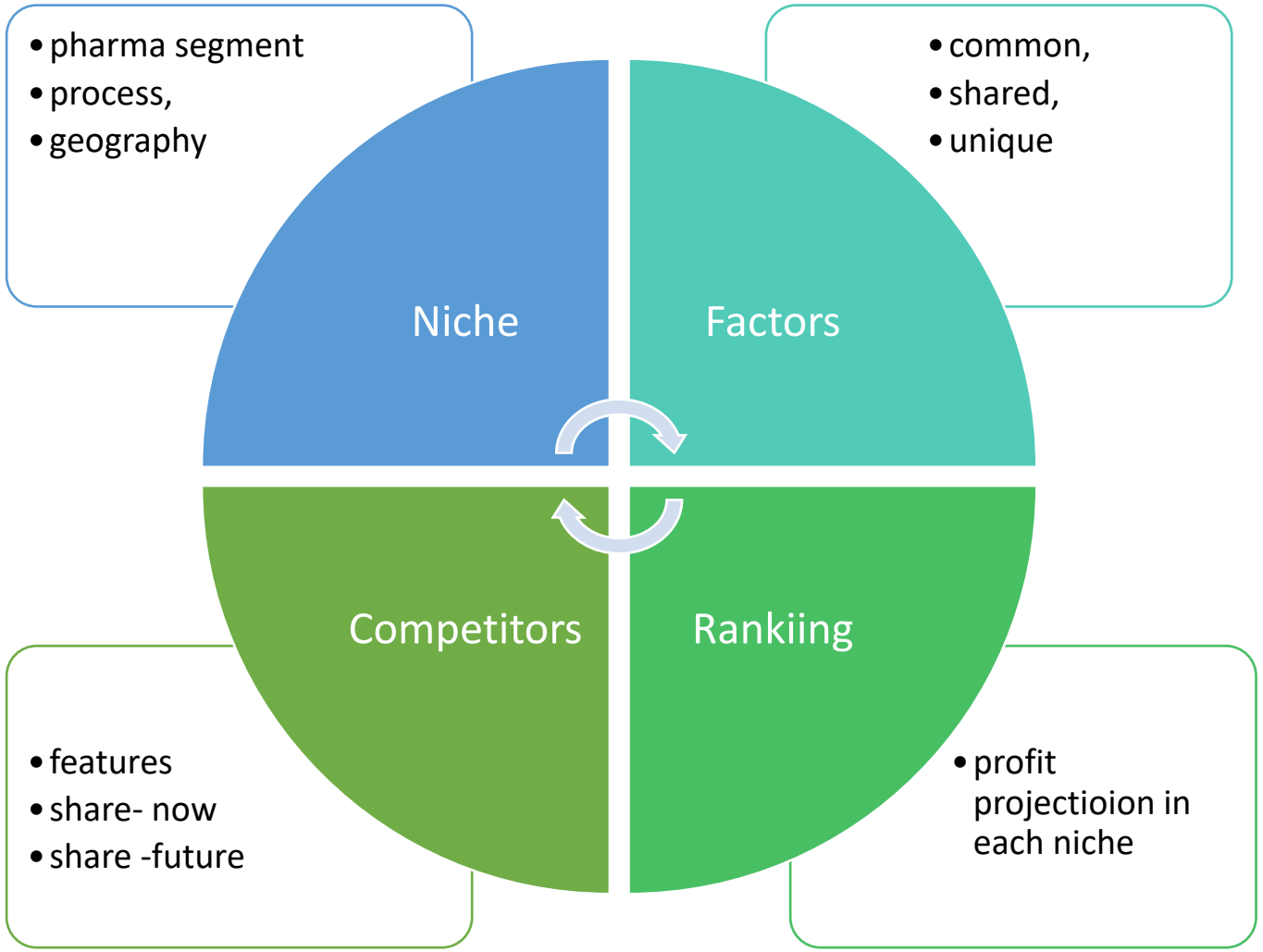
Determining the Best Market Niches Based on LTCO



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Ranking the Opportunities to Pursue

Suppliers wishing to gain market share should approach the pharmaceutical opportunities from the basis of how the supplier could provide products with lower total cost of ownership than that offered by competitors.

With many pharmaceutical segments, many processes, and many geographies it is critical in each niche to

- Determine the present and future size of each niche
- Determine present competitor market shares
- Determine future competitor market shares based on LTCO
- Calculate the potential for the selected product
- Rank opportunities relative to profits which can generated
- Rank the opportunities in each niche against opportunities in each niche in other industries

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Customer Processes Vary Widely

The market can be broadly segmented into biopharmaceuticals and other processes

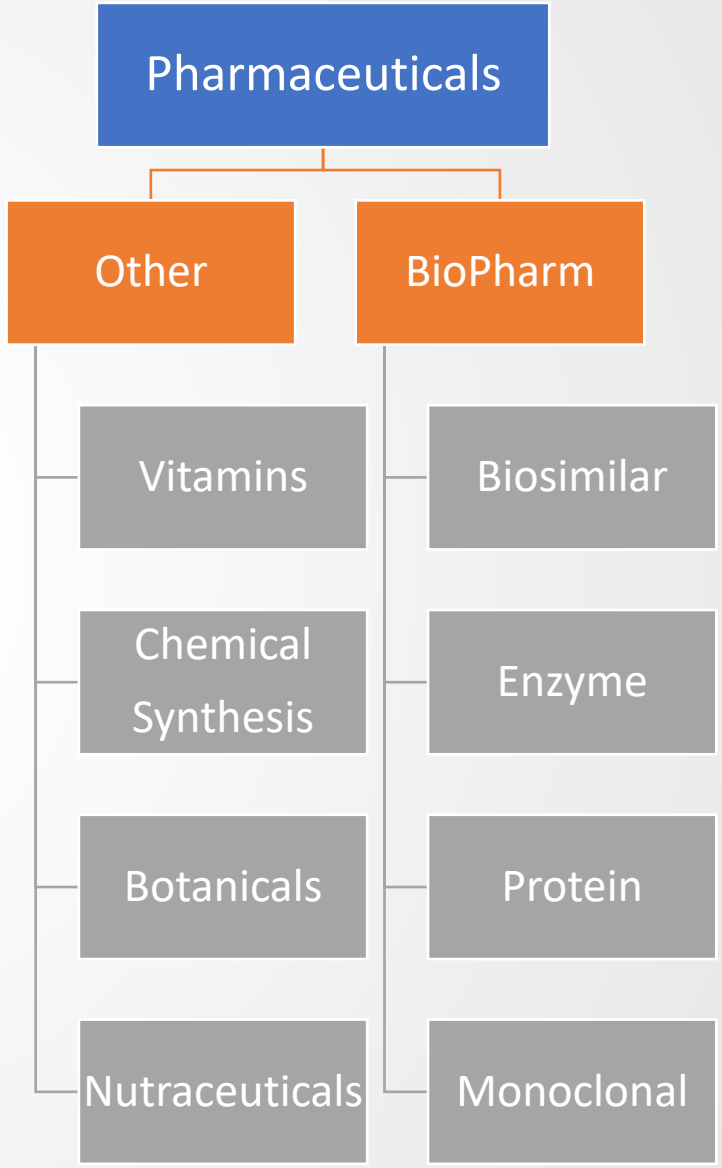
The reason is that biopharmaceuticals are growing faster

Gene therapy (monoclonal) is growing at double digit rates

The market for valves will rise to over $3.4 billion by 2030 or double the size of the present market.

Valve profits in this sector are anticipated to be higher than average.

This does not include single use valves. This segment of the market has grown rapidly but is still only a small percent of the total



Pharmaceutical Valves

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Pharmaceutical Valve Sales Could Double by 2030

Some segments of the pharmaceutical industry will grow by more than 10% per year over the next decade. Others will grow at lesser rates. The average annual growth for valve revenues will be 5-8%.

Profit margins for pharmaceutical valves will be higher than for valves in most applications. As a result, the pharmaceutical industry could account for 3-5 % of valve profits in 2030.

Diaphragm valves are included under globe valves but due to their popularity in pharma applications deserve a separate analysis.

Pharmaceutical Valve Sales $ millions			
Type	2014	2020	2030
Total	1,449.71	1,726.12	TBD
Ball	331.88	395.16	
Butterfly	210.60	250.76	
Check	50.58	60.22	
Gate	225.65	268.68	
Globe	371.64	442.50	
Industrial Plug	129.47	154.16	
Other	107.23	127.67	
Safety Relief	22.65	26.97	

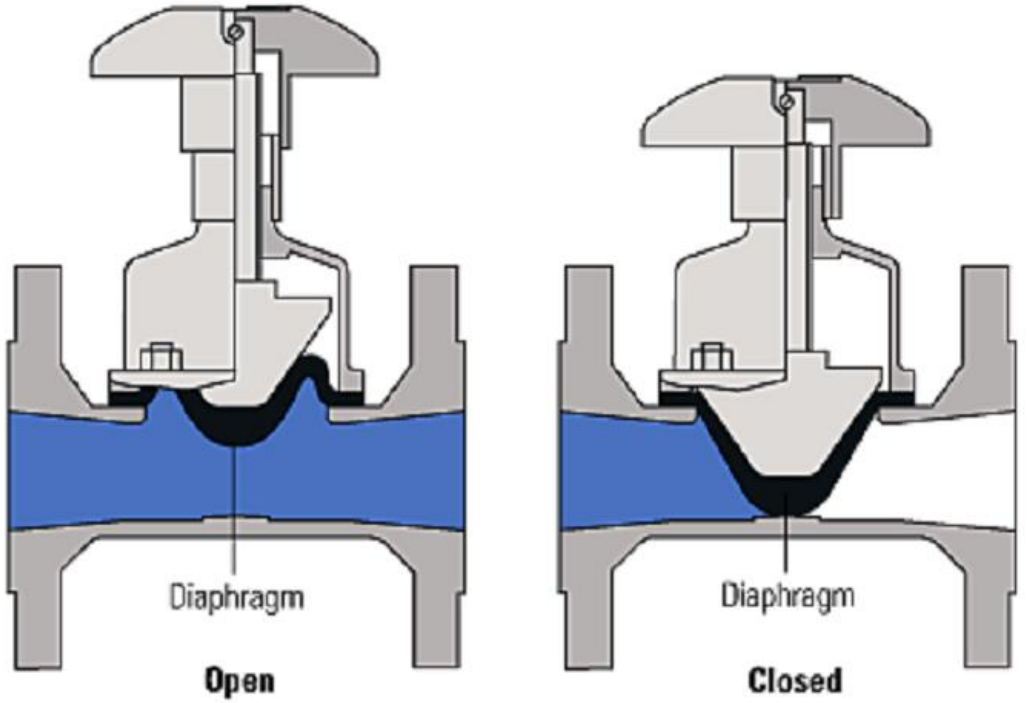
McIlvaine is conducting an in-depth study of valves for the pharmaceutical industry. The revenue and market share forecasting will be in part shaped by the assessment of cost of ownership factors as shown in the following slides.

Diaphragm Valves have a Globe Like Path and are Included in this Category

Diaphragm valves consist of a valve body with two or more ports, a diaphragm, and a “weir or saddle” or seat upon which the diaphragm closes the valve.

The diaphragm valve was initially developed for industrial applications and pipe-organs. Later, the design was adapted for use in the bio-pharmaceutical industry by using compliant materials that can withstand sanitizing and sterilizing methods.

What’s more, sanitary diaphragm valves are specially designed with the highest standard for applications in manufacturing of medicine and food.



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Unique TCO Segments

Category	Explanation
Medium	Water, UPW, process fluids, air, gases, free flowing solids
Products	Split by end product
Intermediates	Final product supported by API and excipient production
Bioprocesses	Shown in subsequent slide with bioreaction, fermentation, filtration, chromatography and fill/finish
Utilities	Air, gases, water, and UPW.
Wastewater	Sedimentation, filtration, RO

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Unique TCO Products, Parameters and Geographies

Category	Explanation
Major valves categories need to be supplemented	Separate TCO factors for diaphragm valves but also for mating flange butterfly valves for closed systems
Geographies	Cost of energy is twice as high in some states as others. Energy in some developing countries is not only expensive but not fully available.
Regulations	Regulations also differ by geography
Product Price	Some cell and gene therapy products are 1000 times more expensive than cough syrup. So, the importance of valve leakage TCO will vary greatly depending on the product.
Life Value	The UK has well defined costs of a life lost or damaged. The U.S. Quality Adjusted Life Years has limitations.
Discounted Future Value	The discount of a future value is greater in unstable countries
Cost Evaluation Variables for Specific Customers	Individual customers will have differing view on the number of years to be included in any cost analysis

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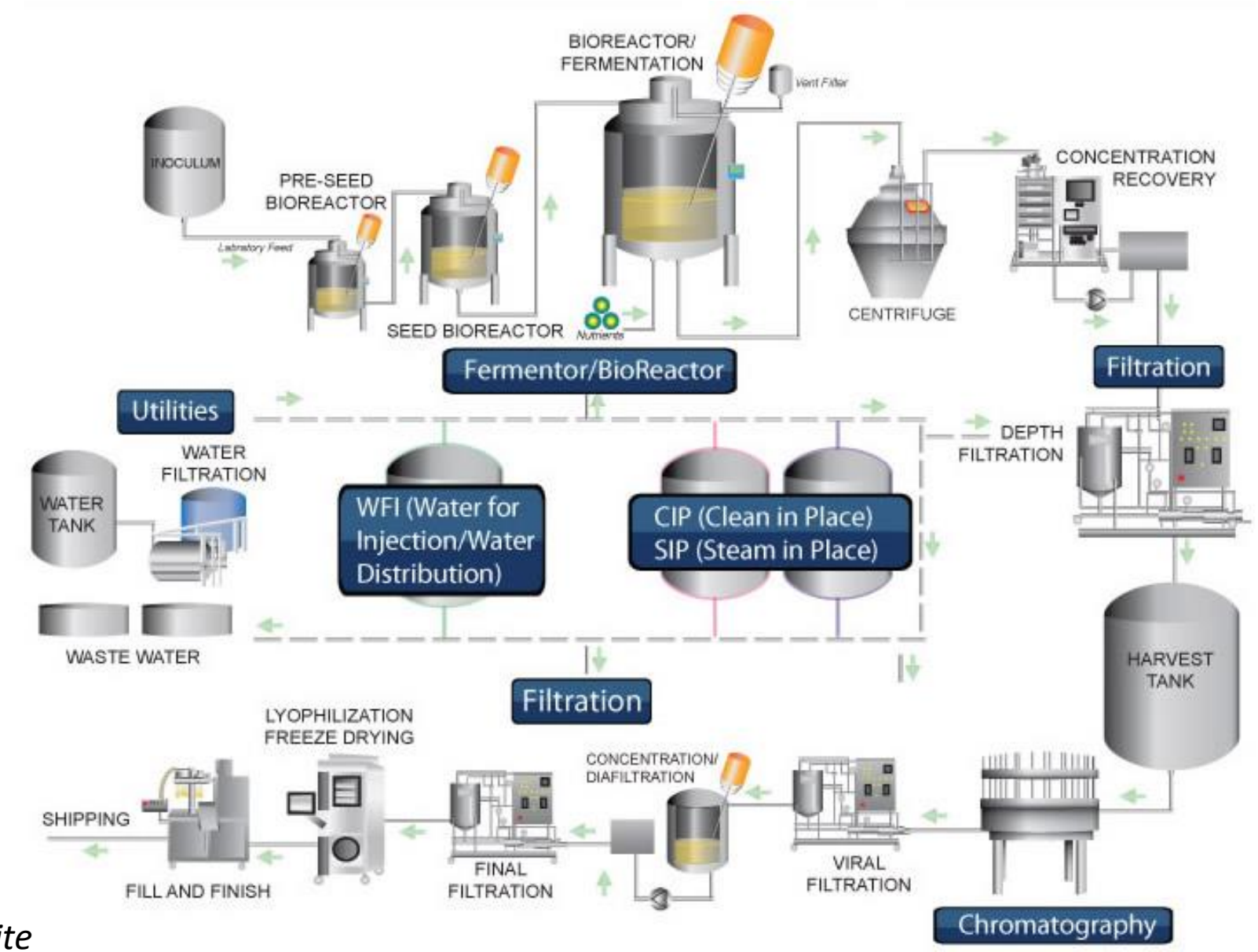
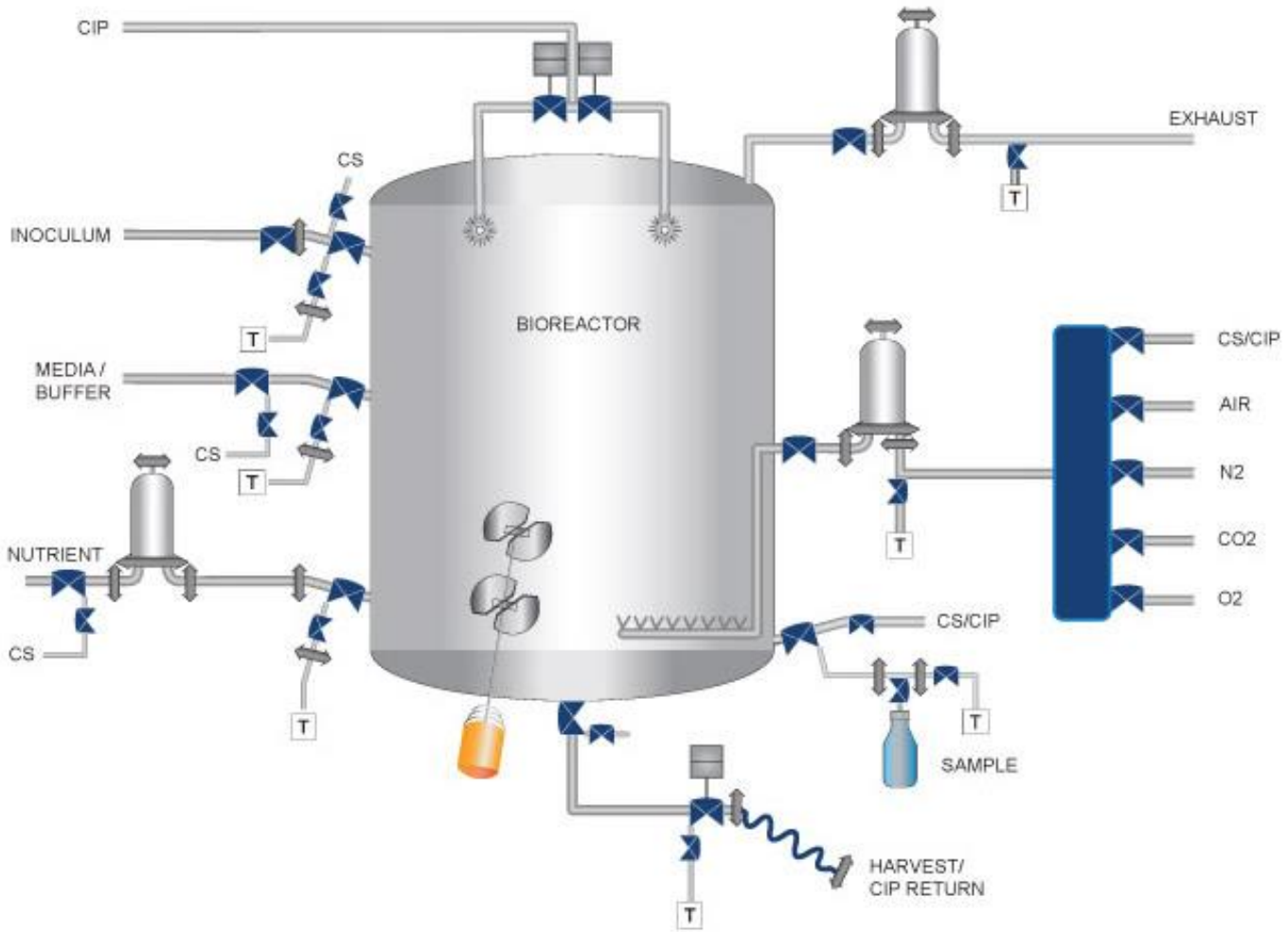
Valve Applications

Biotech Process Map



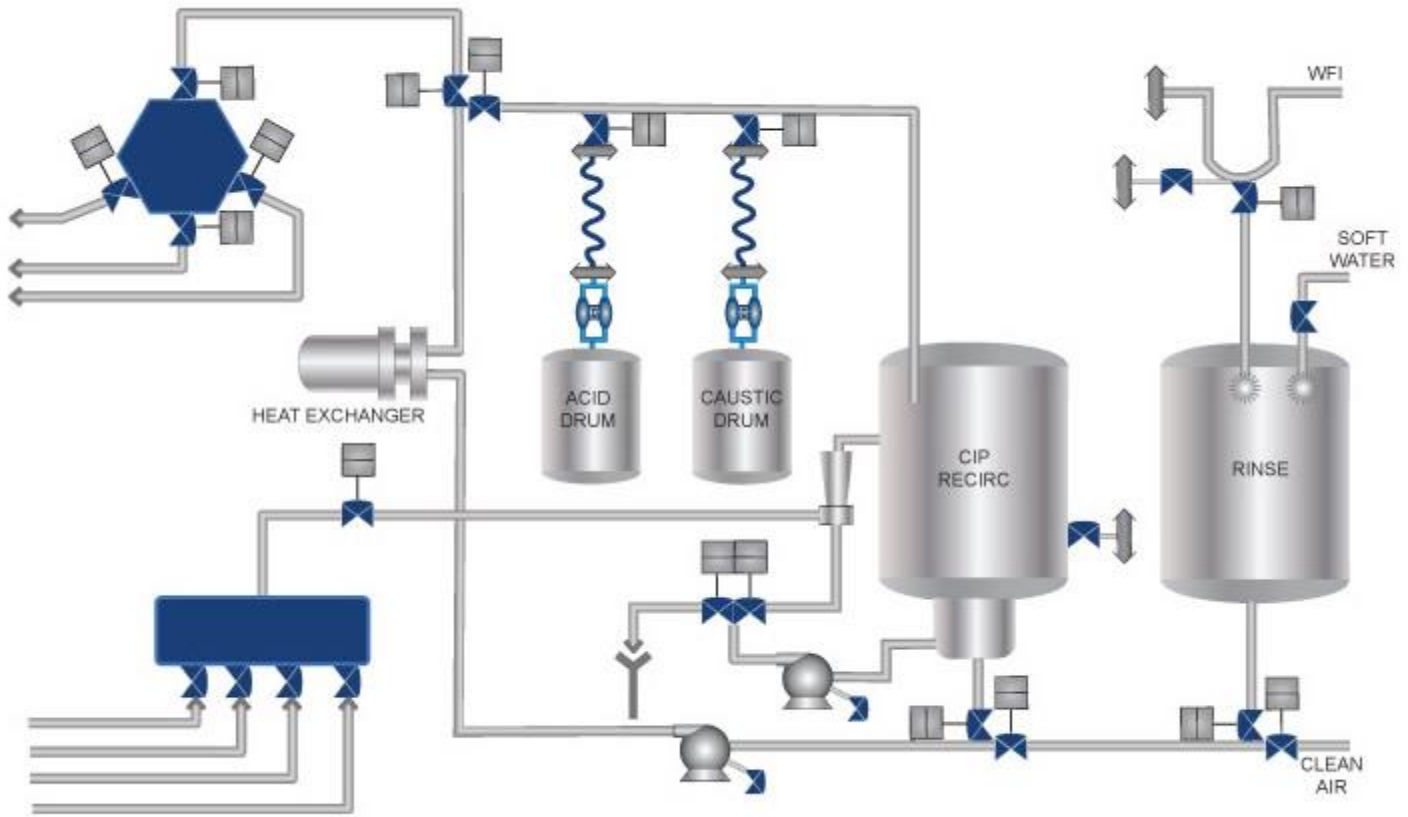
Crane Website

Bioreactor - Fermenter - Mixer



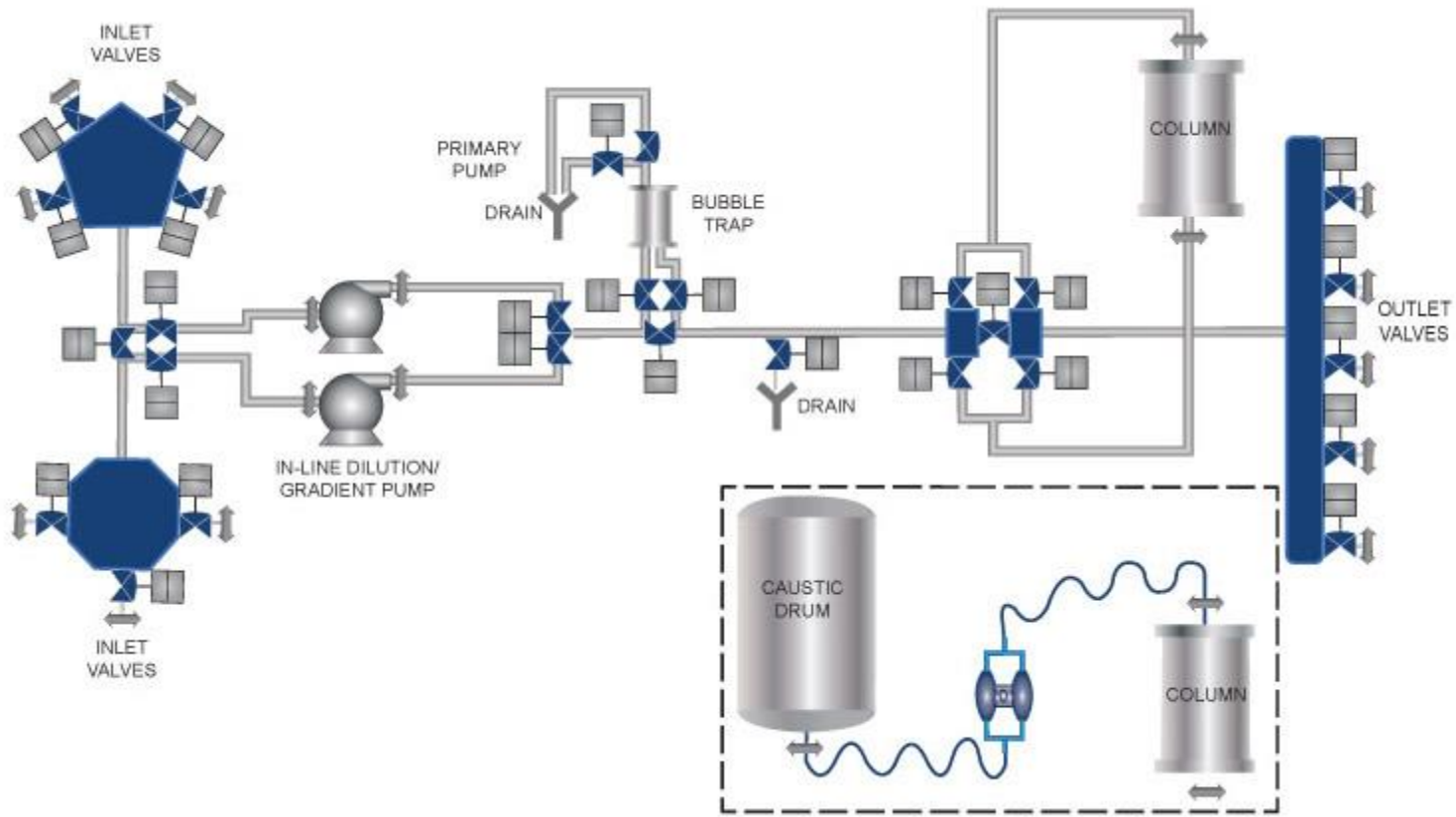
Crane Website

Distribution Loop



Crane Website

Chromatography



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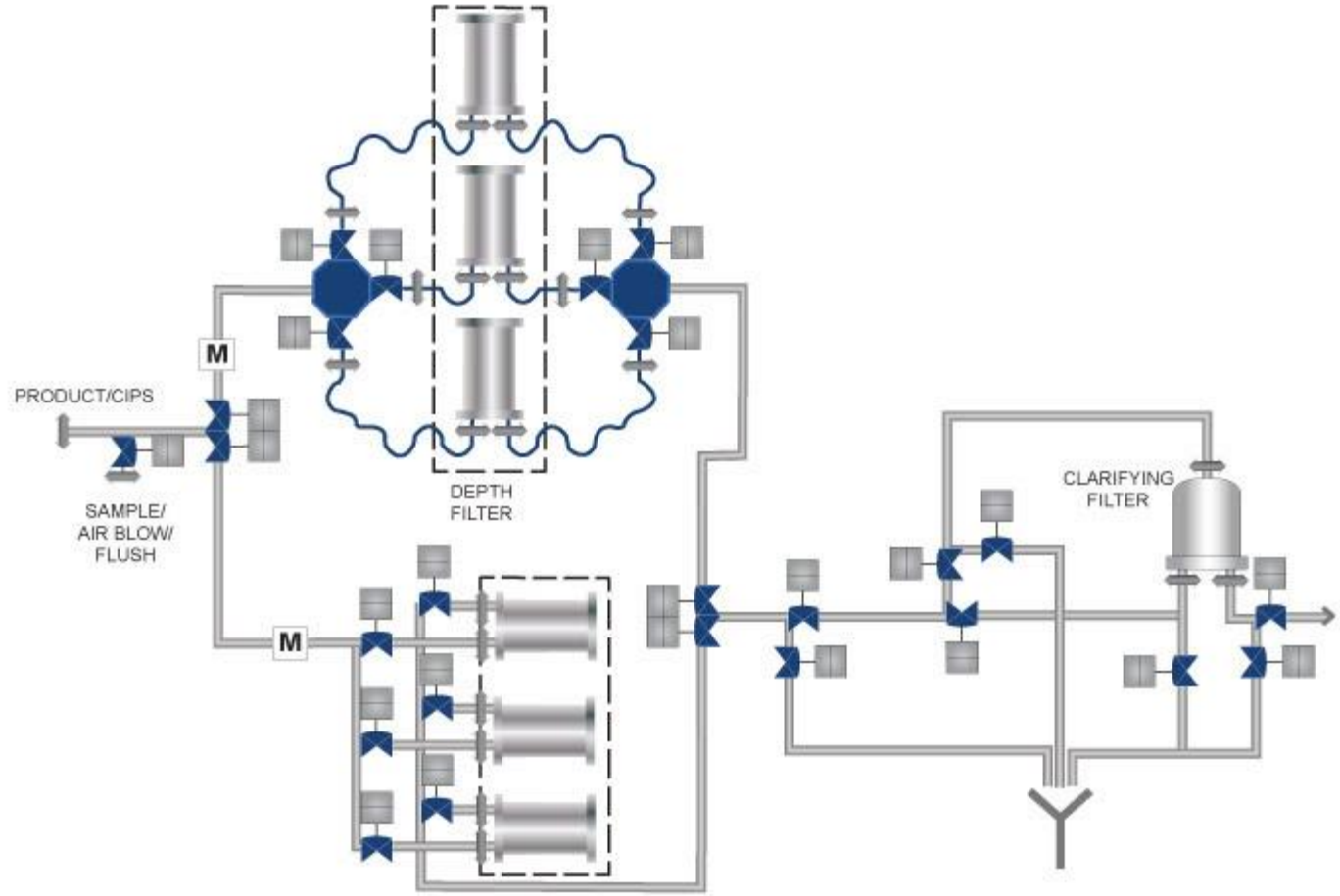
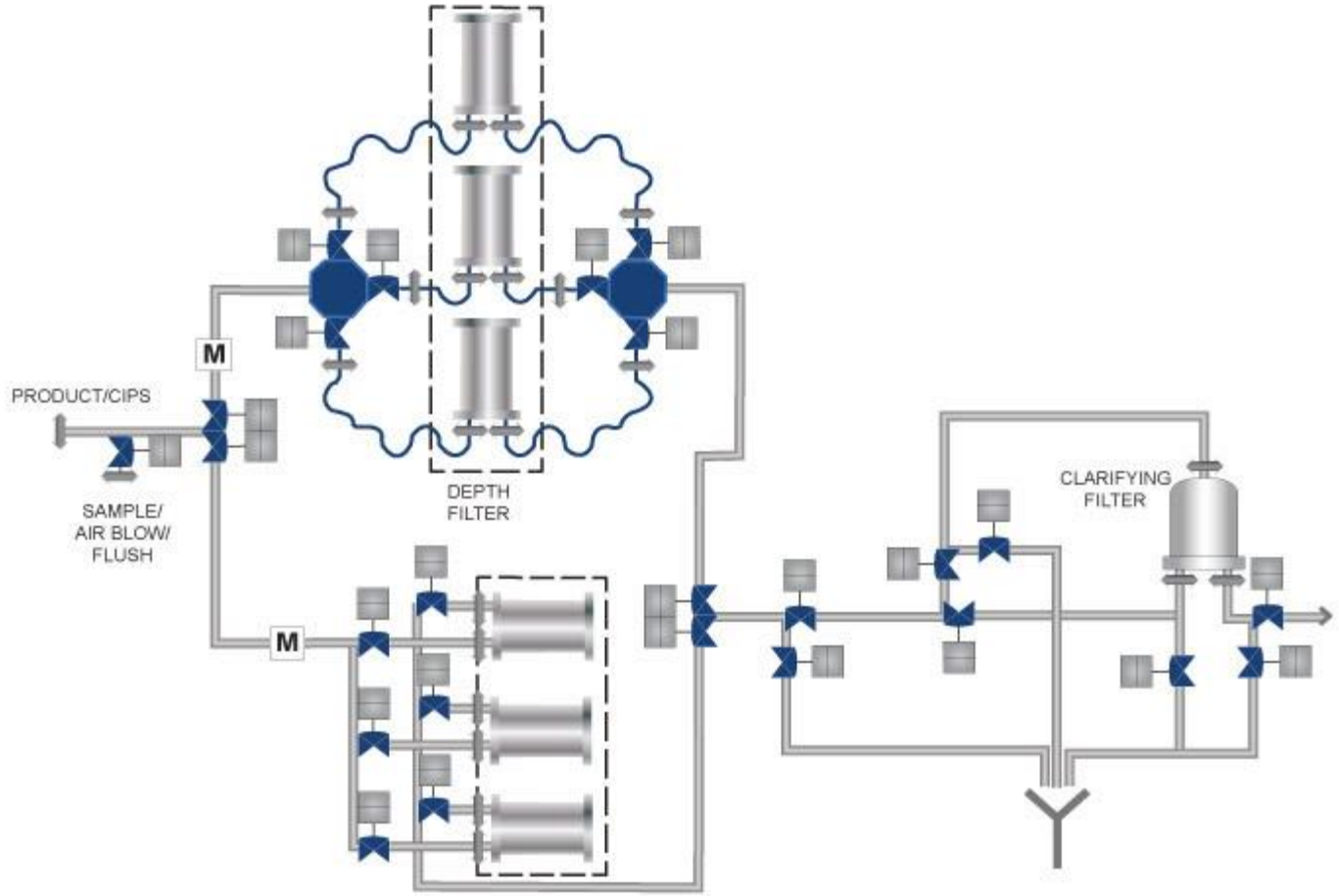
Depth Filtration



Crane Website

Final Filtration



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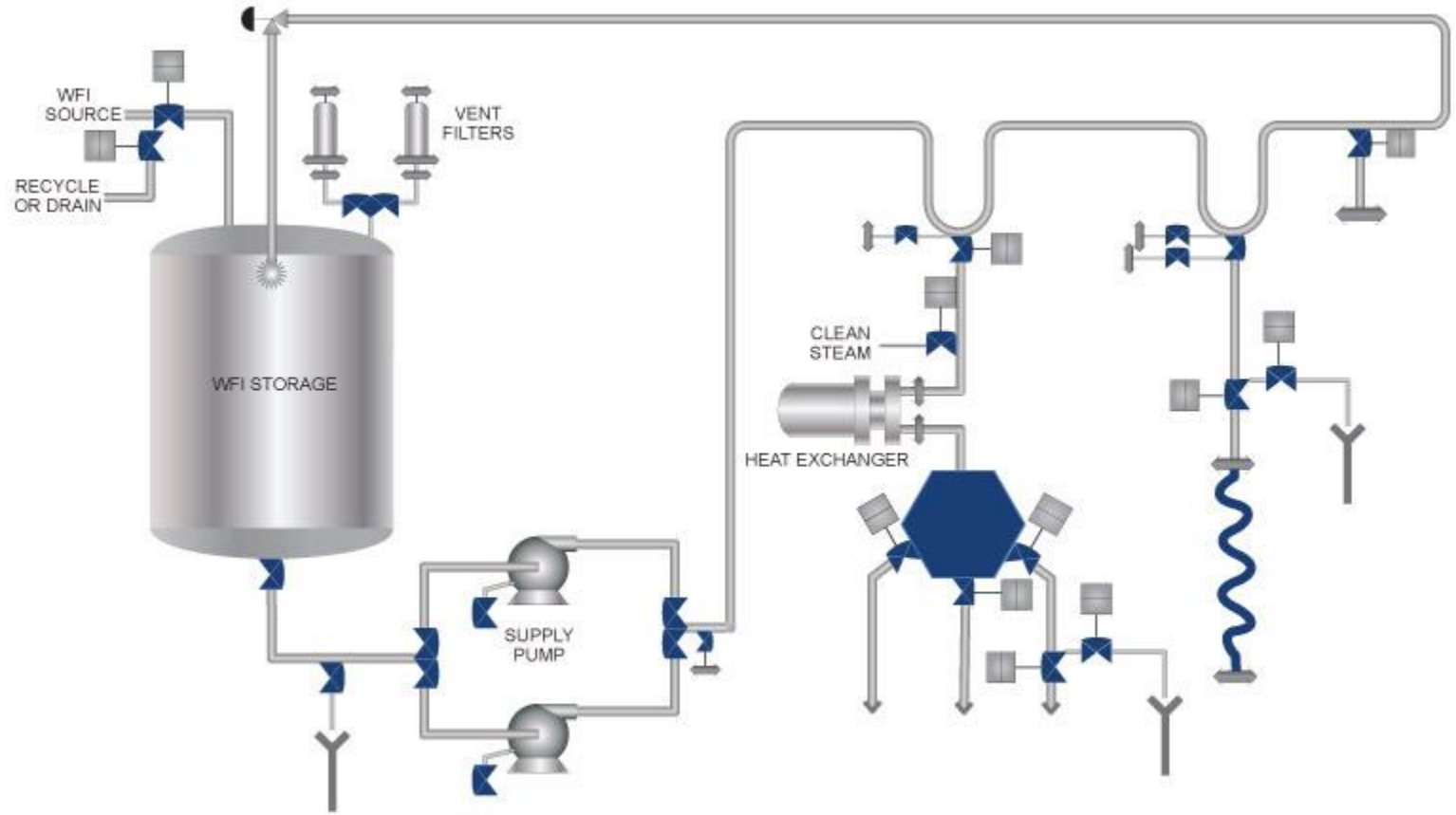
Water Distribution - WFI



Crane Website

Valves Play a Critical Role in Vaccine Manufacture

The pharmaceutical solutions to deal with COVID involve large quantities of valves used in the manufacture of vaccines and therapies.

For large vaccine plants stainless steel components will be used. For small therapy plants single use systems will account for much of the production. A number of single use diaphragm valves are available.

Many of the operations will involve closed systems instead of ball room cleanrooms. Butterfly valves provide aseptic transfer from one closed system to another.

Due to the complex nature of the manufacturing processes used in bioprocessing and the high degree of sterility required, the industry uses hygienic diaphragm valves where stainless-steel systems are employed. A stainless-steel-based bioprocessing plant typically has thousands of diaphragm valves across the entire production process. Processes such as water treatment, media and buffer preparation, harvest, and purification all employ diaphragm valves extensively.

An example of the quick response by the valve industry has been provided by ITT at the time of an earlier pandemic. By 2009, a new flu strain known as H1N1 (swine flu) spread globally and was declared a pandemic. After devising an expedited construction plan, one North Carolina vaccine facility needed to be fully operational in less than a year to ensure preparedness in the event of a national outbreak.

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Vaccine Manufacture, cont.

To comply with government demands, plant personnel decided to advance all installation orders—including a number of bioreactors, fermentation skids and other bioprocessing equipment. The plant contracted several original equipment manufacturers (OEMs) and contractors for the project. In order to construct and complete the skids, the OEMs needed more than 1,000 diaphragm valves before plant construction was complete—a sizable order to be produced in a condensed time frame.

ITT Engineered Valves' quick delivery and attention to detail helped expedite the order without sacrificing quality. Specialists at ITT Engineered Valves were able to customize the unique valve orders to meet the customer's needs and uphold the appropriate hygienic standards. With the accelerated process— and the teamwork provided by all ITT Engineered Valves locations— the plant was able to maintain a steady construction schedule, and the ITT team installed most of the plant's inventory in almost half the time.

Due to the urgency and magnitude of the vaccine requirements, the valve industry will be challenged to meet the demand. It has proven in the past to be up to the task but now is the time to address the coming need.

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Suppliers A-C

Unique or shared advantages are show in red

Alfa Laval Extends Range of Diaphragm Valves

The new, extended range of Alfa Laval Unique DV-ST UltraPure diaphragm valves makes high-performance aseptic processing easier. Fully customizable, the enhanced, ATEX-compliant range comes with slimmer stainless-steel actuators and lightweight cast valve bodies with optimized performance

Slim, space-saving actuators

This versatile, space-saving new range of stainless-steel actuators operates at a wide range of pressures. Options include a stroke limiter, economical valve position indication, and comprehensive automated valve sensing and control. For special application requirements, there's the DV-ST high-pressure actuator.

Lightweight cast valve bodies for optimized performance

Smaller seat sizes on the lightweight, ASME BPE-compliant Cast OP valve bodies optimize flow to ensure the same highly efficient performance.

- Higher process efficiency, smaller footprint
- Lower total cost of ownership
- Safe, simple low-cost maintenance
- Reduced energy consumption
- Faster sterilization in place

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Alfa Laval DV-ST UltraPure Valve Range Boosts Aseptic Processing Efficiency

To meet the rising demand for more efficient aseptic processing, 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 unbeatably economical operation. The enhanced DV-ST UltraPure range is fully customizable to meet virtually any aseptic process requirement across the pharmaceutical industries.

Slimmer, space-saving actuators and lightweight cast valve bodies for optimized performance are the innovations behind the enhanced DV-ST UltraPure range. These smaller aseptic diaphragm valves deliver big – from lower total cost of ownership to tangible sustainability gains. These enhancements make our Unique DV-ST UltraPure diaphragm valves second to none," says Paw Kramer, Portfolio Manager, Valves and Automation, Alfa Laval.

Size matters. The new stainless steel slim (SS/SL) DV-ST UltraPure actuator is 42% lighter, 25% more compact, and 17% shorter in height than most actuators. Another plus: it is more energy efficient due to reduced air consumption. Tested to perform a million strokes without service, these fully welded, maintenance-free actuators handle a wide range of pressures. Options include a stroke limiter, economical valve position indication, and comprehensive automated valve sensing and control.

Joining the DV-ST UltraPure family of valve bodies is the new ASME BPE-compliant Cast OP. Engineered based on computational fluid dynamics analysis, it is 36% lighter in weight, on average, than the standard cast valve body and features a much smaller seat size. This translates into benefits including reduced installation costs due to smaller footprint; faster, more energy-efficient cleaning cycles because there's less steel to heat for sterilization in place; lower total cost of ownership due to smaller diaphragms, handles and/or actuators; and safe, simple, low-cost maintenance.

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Bürkert Process Valve

Bürkert process valve technology has a virtually unlimited scope of application. Wherever the task concerns controlling process valves using process controllers in the food or pharmaceutical industry, biotechnology, water treatment or process engineering sectors, and particularly in the segment of diaphragm valves, our technology is unbeatable.

The complete range, from small dosing valves for food dispensing to large valves for water treatment, meets every technical task with extremely efficient solutions of the highest quality. A modular system allows individual combinations that make every application state-of the- art and geared towards the future.

We partner with you to choose the correct valve for your application. Starting with the body we can choose valves to control slurries, steam, aggressive liquids and materials which must remain pure.

We offer four main methods for controlling fluids from world renowned angle seat pattern to a range of quarter turn solutions.

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Burkert Angle Seat Valve: Robust, Long life, High Flow

•On/Off Valves - The ideal alternative to complex actuated ball valves, the angle seat valve configuration is a real fit and forget solution. Bürkert's quality is evident.
•Control Valves - An uncomplicated control valve with large flows perfectly suited to steam, heat exchange and flow control applications.

Globe Valve - Accurate, Reliable, Light

•On/Off Valves - compact alternative to many pneumatically actuated valves, this globe pattern valve is especially convenient for smaller spaces or for connections requiring flanges.
•Control Valves - These valves exhibit effective valve characteristics for continuous variation of the flow as a function of the parabolic plug position guided by a linear low friction stem.

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Burkert Diaphragm - Media Separated, Hygienic, Resistant

•On/Off Valves - a wide range of plastic and metallic materials, this isolated and media resistant design has an excellent reputation for versatility and reliability in both aseptic and in industrial applications where corrosive, pure or abrasive media are controlled. Relied on to provide leak-tight shut-off to the downstream side of the weir, to atmosphere and to the actuator mechanism.
•Control Valves - The weir pattern is quite unique in its ability to control very pure substances where a minimum of wetted materials and dead volumes are absolutely required although using a diaphragm valve without proper understanding of its inherent flow profile would present difficulties.

Quarter turn - Full Flow, Moderate Duty, High Pressure

•All the quarter turn valves can be actuated manually, electrically or pneumatically and can also employ all the possible feedback and control modules available from one source.

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Crane

BioPharm products include vaccines, blood plasma, injectables, and other therapies. Processes include compendium water (WFI), CIP, SIP, fermentation, separation, filtration, fill, and finish operations.

This industry shares common requirements for regulatory conformance, sterile operation, cleanable design, and high reliability. The primary objective is to reduce risk to patient and risk to product. Crane ChemPharma provides tools to facilitate and optimize product selection for hoses, pumps, and valve solutions

Many of the diagrams in the previous section were prepared by Crane and appear on their website.

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API products include any substance or mixture of substances that are used in the manufacturing of drugs; including aspirin, statins, pain killers, and the like. Processes for these products typically use acids and solvents which require corrosion resistant fluid handling products. CRANE ChemPharma products are designed to minimize risk of contamination to drug and secure environmental emissions and leaks.

•CRANE ChemPharma Flow Solutions offers a wide range of solutions for API applications:

- Air Operated Diaphragm Pumps
- Lined Valves
- ResistoPure® Silicone and PTFE Pharma Hoses
- Tufline/Tuflin Sleeved Plug Valves
- Xomox and Krombach Process Ball Valves
- XOMOX, BUTTERFLY, TOV, HPBV, RESILIENT

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Crane Built an Aseptic Diaphragm Plant in India in 2018

Crane ChemPharma & Energy, Saunders a business of Crane Co and provider of fluid handling solutions worldwide, opened, an aseptic diaphragm valve factory in Satara, India in early 2018.

Built within the same complex as two other Crane factories, one for Saunders Industrial Diaphragm Valves and another for CentreLine Butterfly Valves, the new facility is 100 per cent dedicated to Saunders HC4 aseptic diaphragm valves and actuators.

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Steris and ChargePoint Collaborate on Sterile Transfer of Biopharmaceuticals

Powder containment and sterile transfer solutions experts, ChargePoint Technology, have entered into a collaboration with STERIS, a provider of infection prevention and other procedural products and services, to offer a unique and integrated solution for sterile product transfer.

ChargePoint, Continued

Integrating ChargePoint's AseptiSafe Bio Transfer Valve with the STERIS VHP Biodecontamination Systems, this offering provides users with a fully validated solution for the sterile transfer of drug substances and drug products during biopharmaceutical manufacturing.

As regulations around sterile/aseptic processing continue to expand, many manufacturers are looking for sterile transfer solutions that do not compromise operational efficiency. The ChargePoint split butterfly valve (SBV) technology enables contained transfers into a manufacturing process, providing sterility assurance during aseptic processing.

The technology reduces the need for operator intervention and for cleaning and validating large areas, leading to minimal downtime and improving efficiencies during manufacturing.

Christian Dunne, Head of Sterile Solutions at ChargePoint Technology, said: "This collaboration was a natural step for ChargePoint since we've been working with STERIS on different applications for nearly a decade. Combining expertise from the two teams ensures that we are able to offer customers across the globe a unique and efficient solution to one of today's drug manufacturing challenges."

Edward Markewitz, VHP Product Manager at STERIS, added: "We are thrilled to be working with ChargePoint Technology and its unique aseptic SBV systems in conjunction with STERIS VHP. Collectively we are meeting the technical needs of the industry and using our expertise to provide the ultimate sterile transfer solution for products."

The AseptiSafe Bio Transfer Valve uses an enhanced decontamination step, exposing the SBV discs to vaporized hydrogen peroxide (VHP) gas within a sealed chamber. This provides a validated 6-log reduction in bioburden during the drug substance transfer process and removes the need for high grade clean room environments around the process.

The STERIS VHP Generators provide an all-in-one system unit for bio-decontamination in medical, biological and pharmaceutical facilities. The generators utilize STERIS Vaprox Hydrogen Peroxide Sterilant (EPA Reg. No. 58779-4 and ECHA BPR Registered) as a means of achieving dry, low temperature bio-decontamination within sealed enclosures for maximum bio-decontamination.

STERIS VHP and ChargePoint Collaboration: Ritedose Corporation Case Study

Ritedose is a full-service pharmaceutical company that leverages blow-fill-seal technology. Its capabilities extend well beyond manufacturing, with an in-house development team specializing in all aspects of bringing a product to market - from lab scale batches, regulatory filings, scale-up manufacturing, and distribution. They have over 20 years of experience producing respiratory and ophthalmic products and a 1.7-billion-unit capacity facility utilizing the latest technology in formulation, Blow Fill Seal, and high-speed packaging.

The Ritedose Corporation was looking to solve the issue of charging sterile API into a mixing tank. This is a common problem with all aseptically prepared pharmaceutical products.

Critical to the process was maintaining sterile conditions while docking a container to the vessel and then transferring solid API to form a liquid suspension. With a fully dissolved liquid, the product could be sterile filtered to ensure sterility as it was passed to the filler. Although in this case, the product being passed to the filler was a suspension and so this option was not possible.

This required the whole process to be performed under aseptic conditions and as such would normally mean one of the following upgrades would be required.

1. Upgrade the whole room from a grade C cleanroom to grade A.
2. Upgrade the room to a grade B environment and additionally introduce an over pressurized grade-A area around the point of fill.
3. Upgrade the room to a grade B environment and additionally introduce a RABS system at the point of fill or full vessel.
4. Maintain the grade C cleanroom but introduce isolator technology around the point of fill or full vessel.

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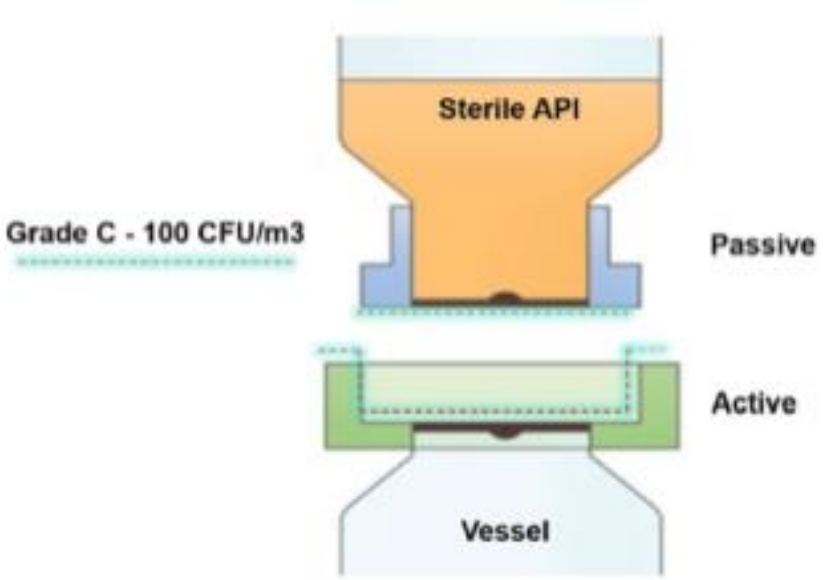
Chargepoint continued

An aseptic bio-valve product was selected as an ideal solution to this problem, providing a sealed powder transfer in a small footprint mounted to the inlet port of the vessel. The valve can be pre-steam sterilized along with the vessel, unlike traditional SBVs or other conventional connections. On final connection, it also removed any room contamination from the mating faces of the transfer in a controlled and validated manner.

The STERIS VHP Unit removes any biological contamination, to a validated 6 log reduction and leaves the space and mating faces decontaminated and ready to fully dock together. Once fully mated the disc can be opened which allows the product to be transferred from transfer container to vessel, free from the risk of contamination. Performing this transfer still within the grade C space provided enormous cost and production benefits, although the process needed to be fully validated to ensure the initial perceived benefits could be achieved.

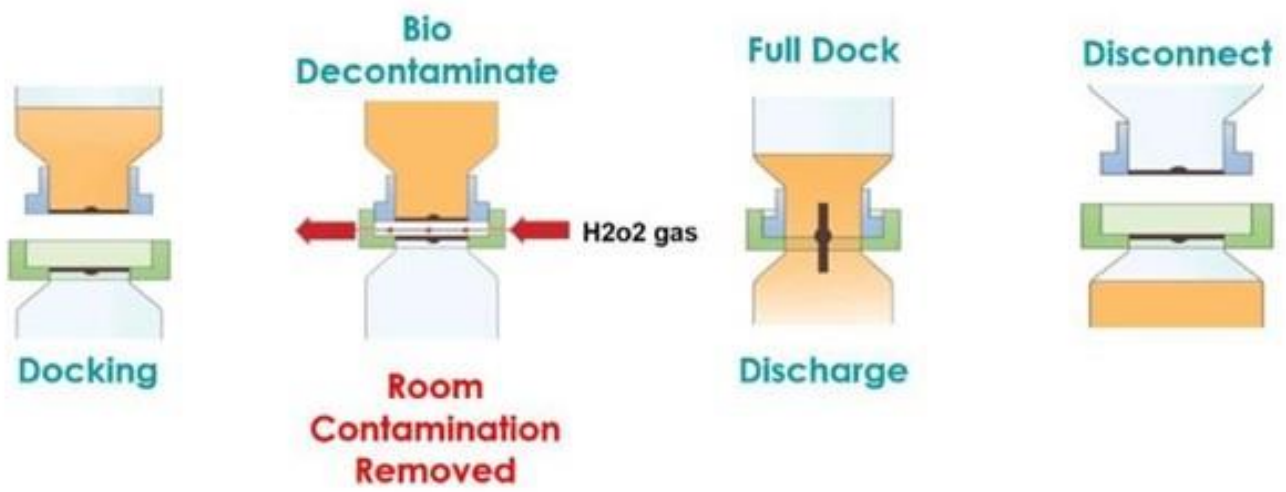


ChargePoint Continued

The installation is now operational and in full production. The original benefits seen at the outset of the project such as low capital equipment cost, smaller footprint and ease of installation, have now been matched by improved sterility assurance, ease of use for operators, and low maintenance. The system is straight forward to use, easy to install / validate and has certainly improved their process.

One learning from this project was at the dispensing stage. At the time of validation, the system installed was a fully rigid reusable solution where pre-sterilized API was supplied to Ritedose in bags. These bags were opened and then subdivided and dispensed within an aseptic isolator to the pre autoclaved transfer container and bio valve passive section. It would have been beneficial to sterilize the product, container and transfer connection in one step (gamma irradiation), although due to the constraints associated with gamma sterilizing stainless steel and elastomeric assemblies as one item this was not possible.

This solution is now available from ChargePoint in the form of a Single Use Passive (SUP) / ChargeBag® and in the future could be adopted to improve and streamline the process. Whereby the whole package (bag and Passive) could be sent away for gamma sterilization, instead of having multiple individual sterilization and aseptic assembly steps.



Suppliers D to I

DFT® Check Valve Products for Pharmaceutical Applications

At DFT®, we provide two main types of pharmaceutical check valves: horizontal valves and vertical valves.

Horizontal Valves

These valves are designed for horizontal piping lines that require a self-draining valve. The forward moving pressurized fluid pushes against the disc and separates it from the valve seat to allow fluid to pass through the gap. One forward flowing pressure is removed, and back flowing pressure is introduced, the disc returns to a closed position stopping fluid flow.

Vertical Valves

Vertical valves are suitable for two main types of locations: vertical pipes and horizontal pipes that don't need self-draining capabilities. Each vertical 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.

Along with our selection of standard horizontal and vertical pharmaceutical check valves, DFT® provides valves suitable for steam and utility systems:

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DFT Sanitary Check Valves

Sanitary manufacturing applications that use fluid systems, such as the pharmaceutical industry, use check valves to regulate fluid flow and pressure. This is crucial for maintaining high product and production quality. DSV® sanitary check valves ensure overall effectiveness and system efficiency by serving as an ideal solution for common issues such as backflow, water hammer, and cleanliness.

Pharmaceutical Check Valve Considerations

•There are many features and design considerations that must be taken into account when choosing a pharmaceutical check valve. To ensure you're choosing the right valve type for your intended application, consider the following features:

Meeting Sanitary 3A Standard 58-02.

•**Clean-in-Place Design.** This design allows for easy cleaning without disassembly of the system. Some design elements include crevice-free construction to reduce material entrapment, high temperature O-rings, a polished surface to reduce the risk of buildup, and stainless-steel construction to prevent corrosion.

•**Non-Slam Spring Assisted Silent Closing.** This closing mechanism prevents the possibility of flow reversal and eliminates water hammer. The spring ensures that only fluid with the proper minimum pressure can pass through the valve.

•**Tight Shut-Off.** Lapping the seat and disc ensures tight shut off, which lowers the risk of backflow.

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Flowserve Supplying Pumps, Valves and Seals to Pfizer

Flowserve Corporation is providing pumps, valves and seals to Pfizer to support production of its COVID-19 vaccine. During the engineering runs of vaccine production Pfizer needed immediate support to replace a mechanical mixer seal on its COVID-19 vaccine production line. Flowserve understood the urgency of the situation and the Flowserve Kalamazoo, Michigan team expedited the rebuild of this critical equipment. “Pfizer has been a Lifecycle Advantage customer since 1997, and now more than ever, we were pleased to be given the opportunity to let the experience and commitment of our associates support Pfizer’s immediate needs as they developed and deployed a COVID-19 vaccine,” said Scott Rowe, Flowserve president and chief executive officer.

Additionally, Flowserve through its channel partner, Corrosion Fluid Products, is providing Pfizer with a cryogenic valve application to support their expanded production capabilities of the COVID-19 vaccine. The Flowserve Cookeville, Tennessee facility will supply Pfizer with more than 200 Worcester cryogenic ball valves that can handle the rigorous temperature requirements needed in supporting the mass production of the COVID-19 vaccine.
And finally, Flowserve’s Chesapeake, Virginia and Itzehoe, Germany pump manufacturing facilities are providing pumps to Pfizer for both their North American and European vaccine production.

“We are extremely pleased to support Pfizer with our full portfolio of products and services during this critical time in the global fight against the COVID-19 virus,” said Rowe. “As with all of our customers, we strive to be a trusted partner, one they can turn to for critical product expertise, engineering and design support in their time of need. This is a true example of that type of partnership and one that will have a significant impact across the globe.

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GEA Valves and Separators Supplied to Hanni Pharmaceuticals in 2017

GEA was chosen by Hanmi Pharmaceutical, one of the largest drug manufacturers in Korea, to supply manufacturing equipment for a new plant that was under construction in the city of Pyeongtaek-si in the Gyeonggi province of South Korea.

GEA provided two production lines for insulin, including centrifugal separators, fermenters, homogenizers, flow components and a significant number of aseptic valves.

The multimillion-euro order, received and booked as order intake in 2016, was scheduled for completion during 2017 and further reinforced the cooperative business relationship between the two companies. The project represented a successful interdisciplinary collaboration within GEA itself, and with Yujin Hitec, GEA's long-term distribution partner in the region.

"Being able to offer the customer different types of equipment from a single source helped to seal the deal," said Hoon Seo, Head of Sales at GEA in Korea.

McILVAINE

GEA continued

The order from Hanmi included equipment for two identical fermentation and media preparation lines, fully equipped with GEA VESTA valves, for the production of a fragment of human immunoglobulin type G.

“As this order is the first of its kind for GEA’s liquid pharma and biopharma groups, incorporating a large number of VESTA type valves, this marks an historical win,” said Dr Marcus Michel, Head of APC Pharma.

Hoon Seo said: “The tight delivery schedule was challenging, but GEA’s technical know-how and advanced state-of-the-art equipment – particularly our centrifugal separators – is well established in the pharmaceutical industry. This, combined with our extensive experience, helped to create a strong bond with the customer.”

Additional orders for an antibiotic plant in Pyeongtaek-si were expected for this year. “We are currently negotiating further equipment orders with Hanmi Pharmaceutical, which again include a large number of VESTA valves,” says Hoon Seo.

“We’re dealing with the largest order for aseptic pharma equipment in GEA’s history. It’s a breakthrough for the company in terms of supplying superior valve technology to the biopharmaceutical sector,” Dr Marcus Michel added.

McILVAINE

GEMU Supplying Larger Single Use Diaphragm Valves

There is now a larger selection of the world's first controllable single-use diaphragm valve: GEMÜ SUMONDO.

GEMÜ, a leading manufacturer of valve designs for the pharmaceutical industry, has established 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. And because of increased customer demand globally, the product range has been expanded in the area of associated valve bodies.

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, up to one inch in process connection size. That means that applications that require a higher medium flow and precise controllability now have a solution.

McILVAINE

ITT Delivers Diaphragm Valves to North Carolina Vaccine Plant to Meet Expedited Schedule

After devising an expedited construction plan, one North Carolina vaccine facility needed to be fully operational in less than a year to ensure preparedness in the event of a national outbreak. To comply with government demands, plant personnel decided to advance all installation orders—including a number of bioreactors, fermentation skids and other bioprocessing equipment. The plant contracted several original equipment manufacturers (OEMs) and contractors for the project. In order to construct and complete the skids, the OEMs needed more than 1,000 diaphragm valves before plant construction was complete—a sizable order to be produced in a condensed time frame. In searching for a global valve manufacturer with the bandwidth to complete the project and the expertise in hygienic valve design, plant operators selected ITT Engineered Valves to fulfill the order.

In addition to the valves supplied for the skid, ITT Engineered Valves manufactured installations for the facility's bulk building, fill finish and central utilities building. To meet the substantial demand, ITT Engineered Valves solicited the help of its European and North American locations, hosting daily meetings between sales and operations to keep the process running smoothly.

Managers and engineers from all locations worked tirelessly day and night to make sure the entire order was accurately filled. Due to the high volume of shipments, ITT Engineered Valves also sent a project manager to assist the plant with maintenance and logistical operations through the duration of the project. Local ITT Engineered Valves sales representatives were also on site at all times to train the plant's personnel

Because of ITT's performance in North Carolina, the ITT Engineered Valves team was asked to help open and stock the company's newest Meningitis B vaccine plant in Brazil. Although the project required a specialized approach and involved working with a new set of OEMs and distributors, the company was confident in ITT Engineered Valves' ability to display the same level of expertise exhibited in North Carolina at an international level. Over the course of the project in Brazil, ITT Engineered Valves used its already proven project approach to support the design, manufacturing, and documentation requirements of the OEMs. Employing a modular construction method to accommodate the shipment overseas, ITT has provided additional support to the firm responsible for building the modules. ITT's support has also included the creation of custom installation and operation manuals written in Portuguese to assist the commissioning, operation and maintenance of the plant.

Irish High Volume Injectables Manufacturer Buys ITT Diaphragm Valves to Stop Caustic Leaks

A multinational pharmaceutical company manufactures a high-volume injectable at a facility in Ireland. Every 2½ days a batch is produced that is worth millions of euros. For this reason, any downtime imposed on the operation is extremely undesirable. In fact, 36 diaphragm valves on a process line located above the operation's six bioreactors had been causing issues for years., the original fasteners and valve diaphragms had become damaged and worn. And so, within three to six months of a diaphragm replacement, the seal would usually fail. The process liquid was sodium hydroxide, which presented a significant health and safety issue. Whenever personnel entered the area, it was necessary for them to wear hazmat suits and breathing equipment. Drip pans to catch the contents were installed by the company as a temporary solution, but replacement was clearly overdue and highly warranted.

The decision was made to buy valves from ITT for the following reasons. First, the EnviZion valve design provides a reliable seal. PTFE suffers from cold flow, so under high pressure and temperature it wants to become flat again. In conventional four-bolt valve designs, the clamping force of the bolts combats this tendency. But over time this force decreases because of wear to the parts, which means that leaks can occur, particularly during changing thermal cycles. EnviZion, on the other hand, contains an integrated thermal compensation system that exerts a constant force around the edge of the diaphragm that is totally independent of whether the valve is heating or cooling down—thereby reducing the possibility of leaks and batch contamination essentially to zero.

Second, with EnviZion valves, diaphragm replacement can be accomplished much more quickly. With its exclusive mount and turn design, diaphragms can be changed in three minutes or less—whereas conventional designs on average require 23 minutes. No tools or torquing are needed, and installations can't be done wrong. The EnviZion valves quoted higher than the in-kind replacements, but analysis indicated that, owing to the faster diaphragm replacement times, the company would earn back the difference after just one scheduled maintenance. What's more, this cost advantage would continue to grow over the life of the valves. Not surprisingly, the decision was made to move forward with EnviZion valves.

https://www.engvalves.com/core/medialibrary/engvalves/website/Tools-Resources/White%20Papers%20and%20Case%20Studies/Major-pharmaceutical-company-undergoes-critical-valve-upgrade.pdf?ext=.pdf

McILVAINE

IMI PBM Igenix® Valves

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.

IMI PBM's Igenix® line of valves include low ferrite cast or forged True-Bore® 2 and 3-way ball valves, fire-rated sanitary 2-way valves, spring-less poppet check valves, Rising stem sampling valves, flush bottom tank valves, and 3, 4 and 5-way Multi-port valves, available in 316L stainless, Hastelloy™, AL6XN, and many other alloys.

IMI PBM's Igenix sanitary valves minimize contamination, comply with sanitary regulations (BPE-2014 compliant, USP Class VI elastomers), solve clogging problems, are piggable, available with self-flushing capability, and have bi-directional adjustable seating (Adjust-o-seal®) 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 process line.

IMI PBM offers valves in "True-Bore® port diameters for US gauge, DIN, and ISO port diameters. IMI PBM's engineering and manufacturing teams will work with you to design specific valve configurations to meet your process requirements.

McILVAINE

Suppliers J-Z

KSB SISTO Diaphragm Valves for Large Swiss Pharmaceutical Plant

In October 2018, the KSB Group's SISTO Armaturen S.A. in Luxembourg started manufacturing several thousand diaphragm valves for a new production facility in Switzerland.

Hydraulically optimized SISTO-C valves with the compact Lap.520 pneumatic actuator for highly-purified water (HPW) applications. (KSB SE & Co. KGaA, Frankenthal)

The valves of the SISTO-C type series have been ordered for the construction of Lonza AG's Ibex biopark in Visp (Valais).

The new facilities will produce therapeutic substances of very high quality on a biotechnological basis. The valves will be delivered to Lonza AG as well as to various engineering contractors from Europe and China.

McILVAINE

KSB continued

All valves, including the multi-port valves, are manufactured in Echternach of quality forged steel 1.4435 (316L) and 1.4539 (AISI 904L). To meet the tough requirements of biopharmaceutical production processes, the diaphragms are made of EPDM or TFM with an EPDM backing diaphragm.

The nominal sizes needed range from DN 8 to DN 200. Thanks to a metal spiral supporting the rear of the diaphragm, the installed SISTO-C valves, including large nominal sizes, are approved for a maximum operating pressure of 16 bar. This design provides a high operating reliability over a long period of time, also at high temperatures.

More than 95 percent of the valves are fitted with pneumatic piston actuators, using the new SISTO actuator generation, which is characterized especially by its compact dimensions and low weight. With their sturdy design these actuators achieve very high open/close frequencies and a long service life.

One of the reasons for the Luxembourg-based manufacturer to be awarded the contract was that the Swiss customer had made good experiences in similar production facilities with the quality and long service life of the sealing system with an enclosed diaphragm and support spiral.

McILVAINE

Leser Safety Valves

With the Clean Service series, LESER offers safety valves that meet all requirements of the pharmaceutical industry.

The low dead space and the gap-free internal construction guarantee a high degree of cleanliness.

The valves can be opened automatically during the cleaning process with the existing pneumatic lift.

Surface packages according to ASME BPE and DIN 11866 with high surface quality and FDA-compliant elastomers, for example, enable sterile processes.

McILVAINE

Sterivalves Butterfly Valves

In the pharmaceutical industry, butterfly valves are a key system component as they can be combined with the most performing equipment to manage delicate products.
They are used to guarantee the transfer of bulk solid products according to the strict health and safety international standards.
From the design to the choice of materials, everything contributes to developing a valve able to handle dedicate products and to inhibit at most some typical problem that may occur in the process:
Shedding: contamination of the pharmaceutical product with elastomer or polymer particles resulting from valve wear.
Oxidation of metals: when metals are not chosen according to the standard or properly worked (welding).
Product contamination: bacterial charges due to surfaces not perfectly done (surface roughness).
In this regard Sterivalves srl uses exclusively:

- Elastomers with compound compliant FDA 177§2600.
- Stainless steel according to EN 1.4404 in contact with the product
- Roughness of surfaces such as to prevent the formation of bacterial charges. (Internal surface Ra <0.5µm; External surface Ra <1.2µm).

In terms of costs, the valve is one of the items that less affects within a plant, nevertheless, it is one of the most critical parts, both in terms of function and in terms of safety.
Choosing the right valve is fundamental to the success of the entire process. SteriValves butterfly valves are subject to strict controls, and they all carry with them the certification that guarantees the quality of each production step.

McILVAINE

Watson Marlow Diaphragm Valve is Easier to Install and Less Prone to Leaks and Contamination

Watson Marlow (division of Spirax Sarco) has a unique diaphragm valve with claims of lower cost of ownership due to easier installation and the ability to better prevent leaks than conventional designs. Since leaks can lead to product loss and contamination this is a significant cost avoidance.

The design of the basic weir-style diaphragm valve seal presents a number of issues for process engineers working in the biotechnology and pharmaceutical industry. In typical configurations, a weir in the valve body rises in a fluid path and when the valve is closed, the diaphragm meets the weir to shut off the flow. While a simple technology intended to reduce turbulence and shear, weir-style valves present a number of issues, for example in upstream processing applications they can be difficult to install, prone to leaks, and increase the potential of product contamination.

In traditional weir valves, a seal is made by placing a diaphragm between the mating faces of the valve body and actuator. This assembly is then held together with a set of nuts and bolts. The valve bodies are made from stainless steel due to its outstanding chemical compatibility outstanding corrosion resistance when exposed to repeated clean-in-place (CIP) and steam-in-place (SIP) cycles.

In the Watson Marlow design the diaphragm seal moves independently of the shoulder seal (the seal between the inside and outside of the valve). Using a manual or pneumatic actuator, you can easily open and close the seal. The cylindrical shape of the diaphragm, when squeezed into the sealing position, holds the seal—tested to an internal water pressure of up to 20 bar (varies depending on diaphragm material and actuator type) without leakage.

When the valve is closed, the unique CIP/SIP “behind-the-seat flow path” can be created if you add a CIP or SIP port. This flow path makes it easy to steam or clean the valve while the valve is closed. This allows for validated aseptic and sterile system connections and transfers to be performed. Combined these features save time and money by reducing maintenance time, improving performance with a less restrictive flow path.

https://www.wmftg.com/en-us/biotech-pharmaceutical/asepco/?ppc_keyword=diap

McILVAINE

ASEPCO Weirless Radial Diaphragm™ In-line Valve

With accelerated diaphragm change over and easy maintenance, the new weirless in-line valve series from ASEPCO valves has been developed with time and cost savings in mind.

- One minute diaphragm change-over
- Compatible with EPDM and Silicone diaphragm options
- Flexible installation angles for unobstructed flow path and operator safety
- Defined shoulder seal minimizes contaminant entrapment

Composed of a forged body, the in-line valve is designed to provide a less restrictive fluid path over traditional weir style valves. The weirless in-line valve also eliminates the potential of trapping impurities through our innovative shoulder seal design.

Every surface material that touches your process fluid is manufactured to comply with multiple global industry standards, safeguarding you and your process.

McILVAINE

Watson Marlow, cont.

Features and benefits

- Radial diaphragm - eliminates entrapment for easy cleaning
- Fully drainable within a 180-degree range of installation angles
- Simple, Tri-Clamp assembly makes maintenance 80 % faster compared to a weir type valve
- Integrated travel stops
- No readjustment or retightening

Technical Summary

• Mounting type	Clamp, Weld-in
• Max. operating pressure	10 bar
• Max. operating pressure	150 psi
Compatible actuators	Fail closed, Manual, Pneumatic
• Compatible diaphragms	• EPDM, EPDM plus, Silicone
• Surface finish options	• Electropolished, Inner: Max. 15 µin Ra (0.38 µm), Outer: Max. 32 µin Ra (0.8 µm)
• Certification	• ISO 9001
• Standards	• ASME BPE, ASME BPVC, CE-PED