Pure-Flo® Integrated Block Valves

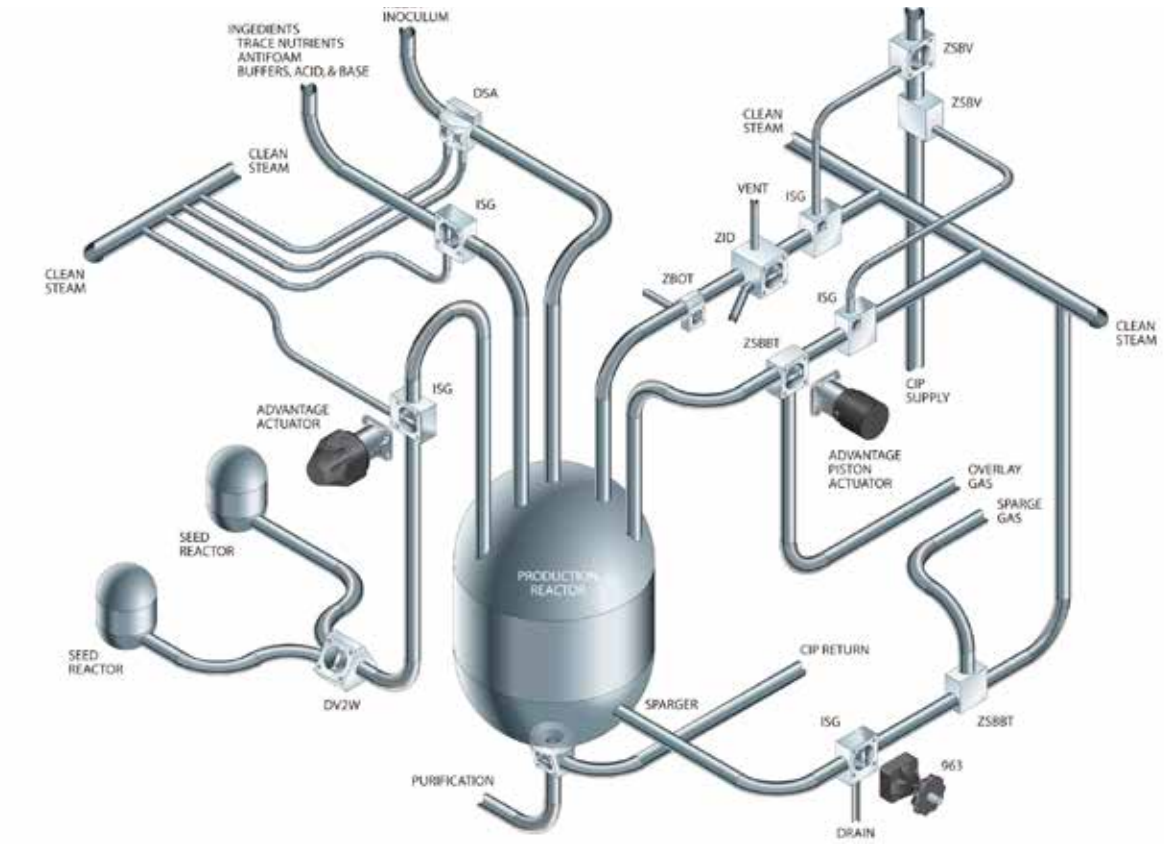
The Pure-Flo IBV - Integrated Block Valve product line is constantly changing to meet the rigorous demands of the Biopharmaceutical processing industry. An extensive array of innovative integrated block valves specifically designed to achieve the utmost in process efficiency. Pure-Flo developed the first integrated block body diaphragm valves over 30 years ago. We have a history of listening to customers and industry needs to develop valve solutions for the toughest applications.

Biopharm processes are complex and sensitive to system and environmental factors. Drug purity and process yield is greatly affected by system design. Integrated block valves can play a substantial role in developing a robust high yield process. Many valve solutions can produce acceptable results, but Pure-Flo integrated block valve technology can make a marginal process better and a good process great.

Integrated block technology is a cost effective means of reducing total cost of ownership. By optimizing drainability, hold-up volume, deadlegs and cleanability, block technology can decrease cleaning cycle times and increase process efficiency. Combining multiple valves into a single valve body can substantially reduce total installation and validation costs. Efficient designs pay for themselves over and over again.

Utilizing powerful 3D modeling software we can create almost any valve configuration imaginable. Working hand in hand our engineers will develop the valve configuration that fit your needs to a "T".

Integrated Block Valves in a Typical Bioreactor Process



Drainability and Hold Up Volume

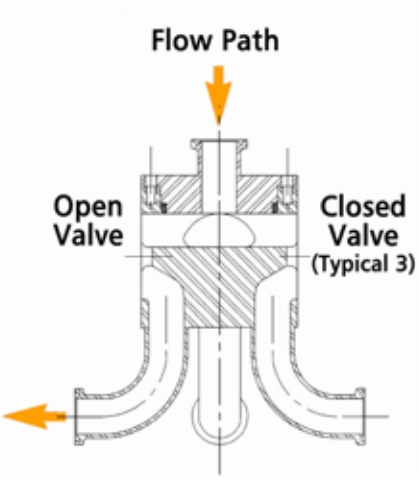
ITT Pure-Flo hygienic weir style diaphragm valves have become the most important control element of process piping systems utilized in the Pharmaceutical and Bio-processing industries. The weir style diaphragm valve has become the standard due to its unique ability to provide maximum drainability and minimized product hold up volumes.

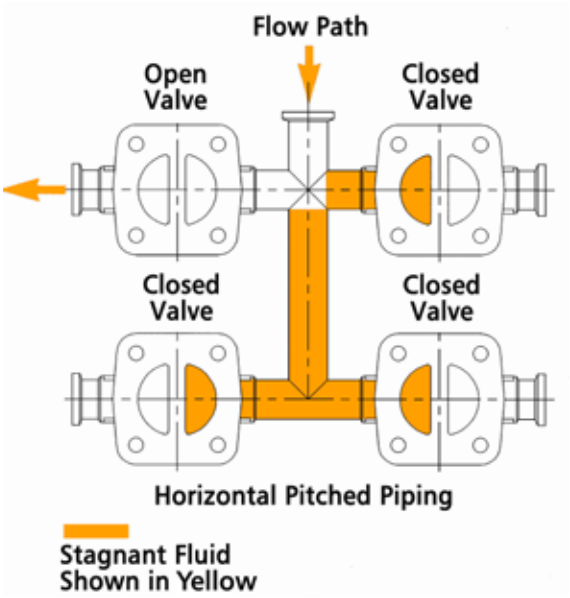
Integral Block technology further improves drainability and minimizes hold up volumes by reducing the process pipe volume between control elements.

Utilizing the unique characteristics of the weir style diaphragm valve, valve manufacturers have helped develop many process fabrications that have reduced product contact surfaces, reduced hold up volumes, and minimized piping dead-legs. The theory is that as contact surfaces are minimized, and hold-up volume are reduced in a process piping system, product yields and product purity will be improved.

In the not so distant past, typical process fabrications were produced by welding of standard forged valve bodies in configurations designed specifically for certain applications and orientations. This fabrication has served the industry well, but has limitations. In many instances the dead leg between the two can fall outside FDA expectations.

4-Way Divert Valve vs. Conventional Divert Valve Assembly





Deadlegs

The FDA Guidelines for High Purity Water Systems has "defined dead legs as not having an unused portion greater in length than six diameters of the unused pipe, measured from the axis of the pipe in use. It should be pointed out that this was developed for hot (75-80° C) circulating systems. With colder systems (68-75° C) any drop or unused portion of any length of piping should be eliminated if possible, or have special sanitizing procedures".

In case where process piping falls outside of FDA expectations, as noted from the High Purity Water Guide reference above, the owner of the system is expected to have special sanitizing procedures. These special sanitizing procedures can be costly in production time and processing cost and should be avoided whenever possible.

Current Good Manufacturing Practice (cGMP)

The cGMP regulation is a total quality concept applicable to processes and associated operations that assure the desired quality product. cGMP compliance, like quality, is fundamental and must be designed and built in from the earliest stages of a drug production project.

Drug manufacturers are required to maintain current Good Manufacturing Practices. This means that manufacturers must stay current with:

- New Technology
- New Methodology
- New Thinking
- New Requirements
- New Trends

One of the most critical factors in the production of drugs is the ability to clean and validate the drug production process. cGMPs require that processing equipment be designed to be cleaned and sterilized to minimize the potential for contamination, assuring the purity of the end drug product.

Hygienic weir style diaphragm valves have become the most important control element of process piping systems utilized in the Pharmaceutical and Bioprocessing industries, due to their unique ability to provide drainability with minimized product entrapment areas. Integrated block valve designs take these characteristics to an even higher level.

Block Valves: Total Cost of Ownership

Total cost of ownership for a process system can not be calculated by material costs alone. Installation and ongoing operational costs should be taken into account when making any component purchasing decision. In many cases the cost of integrated block valves are greatly offset by reductions in installation costs, space requirements and improvements in operational efficiency.

Integrated Block Valves can improve production efficiencies by:

- Minimizing internal valve volume
- Minimizing hold up
- Minimizing dead-legs
- Reducing CIP cycle times
- Increasing product purity
- Reducing qualification and validation efforts

Integrated Block Valves also reduce:

- Installation time and cost
- Expensive field welds
- Process piping footprint

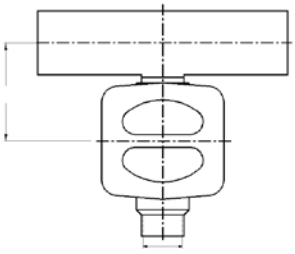
6D Rule vs. ASME BPE L/D

Dead-legs - What ever happened to 6D?

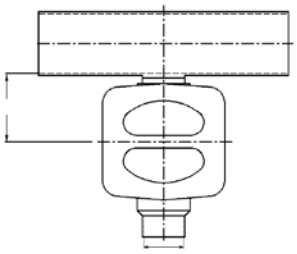
Basically, a "dead-leg" is defined as a one-way water system. Dead-legs result in process systems that are difficult to clean. The FDA reference document "Guide to Inspections of High Purity Water Systems" indicates that dead-legs for hot (75-80° C) circulating water systems (self sanitizing) shall be no greater than 6 diameters of the unused pipe, measured from the axis of the pipe in use. Colder water systems (65-75° C) are not self sanitizing and therefore should eliminate dead-legs, if possible, or have special sanitizing procedures in place.

This 6D requirement has been the basic standard for many years when designing high purity water systems. Due to the method of measurement however, 6D as defined was not truly representative of what dead-leg characteristics are critical to designing a cleanable process piping system. Defining a dead-leg from the axis of the main pipe simply does not address the characteristics that affect the ability to clean and sanitize the dead-leg in question.

6D Rule



L/D = 2:1 Rule



ASME BPE L/D = 2:1

The Bioprocessing industry has found that 6D piping standards are not sufficient to assure optimal cleanable and sterilizeable process systems. The sensitive nature of the production processes and the substantial value of the end product have required the industry to develop even more stringent requirements in critical systems. In 1997 the American Society of Mechanical Engineers (ASME) addressed this need by creating the ASME Bioprocessing Equipment Standard. The ASME BPE standard suggests that high purity water, clean steam systems and bioprocessing systems such as fermentation, purification and filtration systems can be designed to meet an L/D ratio of 2:1. L is defined as the Length of the dead-leg extension measured from the ID wall normal to the flow pattern. D is the nominal size dimension of the extension of a valve or instrument.

The ASME BPE standard states that the L/D ratio of 2:1 should be considered a target, not an absolute requirement, but the system designer/manufacturer should make every attempt to eliminate system dead-legs, and identify where exceptions exist.

Since the L/D ratio of 2:1 is a target, the system designer must make the determination of what L/D ratio is warranted for a particular system or project. In many cases L/D ratios of 2:1, 3:1 or sometimes 4:1 are utilized.

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