The butterfly **effect**

Split butterfly valves offer effective containment solutions when transferring powders, particularly potent drug ingredients. **Ben Wylie**, sales & marketing executive for ChargePoint Technology, looks at key criteria for correct valve selection

Correct split valve selection can be crucial to containment performance and ease of operation

Pharmaceutical industry legislation continues to enforce more stringent health, safety and environmental requirements as a result of the potent nature of pharmaceutical compounds and today's 'green' issues. Companies that address these concerns with a forward-thinking containment strategy now strive towards 'shirt sleeve' manufacturing operations – i.e. eliminating the requirement for Personal Protective Equipment (PPE) in a safer, greener and more ergonomic working environment.

Although conforming to the same principle of operation (see figure 1), a variety of different Split Butterfly Valve (SBV) designs exist to suit a variety of applications. Correct selection of a split valve system for a particular process is crucial if drug and API manufacturers are to achieve the optimal operability and containment performance on time and on budget.

The factors affecting SBV selection typically fall into two categories:
1) factors on the client/application side; and
2) vendor/valve-based considerations.

On the client/application side, such factors include the following:

- Current facility design
- Process specifics
- Product characteristics
- Production/project requirements
- Operator considerations
- Environmental objectives

When considering current facility design, the space that exists around the current, installed process equipment may dictate the size of valve and, where lifting/docking systems are required, the height available. Ergonomic requirements should be evaluated at this point with regard to what access there is for manual operation. The class or zone category of the room prescribes the need for a particular containment performance from a valve and, in some cases, requires sterile powder transfers.

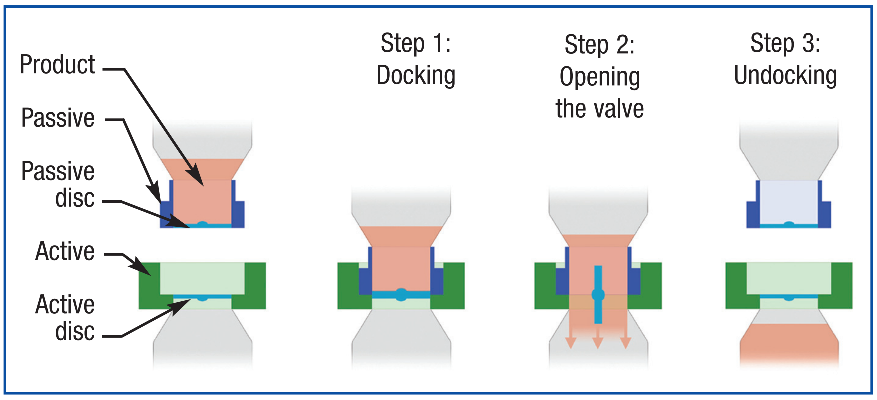

Figure 1: The generic split butterfly valve operation principle

Choice of materials

Process specifics include the batch size, which dictates container size (e.g. IBC) and influences in turn the size of the valve and the need for automation and docking systems. Frequency of operation may result in selection of more wear-resistant materials of construction (MOC) but is more of a precursor to spare parts and maintenance requirements.

Clearly, a robust valve design will withstand a higher frequency of operation before major maintenance and part replacement is necessary. The operating temperature and solvents used during cleaning and normal processing are the major determinants of MOC selection.

Fundamentally the Operator Exposure Level (OEL) required for the product prescribes the type of SBV needed. The level of product sterility that must be maintained during processing will also affect the choice of SBV. Other product characteristics (bulk density, flowability, cohesiveness and percentage wetness) all determine how easily material will pass through the valve and, importantly, to and from the charging or receiving container or vessel.

Low bulk density products or cohesive materials will present difficulties during the transfer process and could result in a reduced transfer yield. An ideal solution may include ancillary vibratory equipment to aid the charging sequence.

Project requirements include the time and budget resource of the client. Being able to deliver a solution on time, to budget, that satisfies the production schedule with the necessary operation, containment performance and health and safety requirements, is a primary project management function.

Operator considerations are another important set of considerations. Operator buy-in to any SBV solution is key, and this is more likely if the operator is involved in equipment selection from the initial stages through to post-installation training.

During the initial project stages an operator should be confident with the operability and ergonomics of the valve. The containment level of a valve is only as good as its operation, therefore operatives should be fully trained in operation, cleaning and maintenance procedures to understand fully how the solution works and how to obtain optimum equipment performance.

Environmental responsibility

Pharma manufacturing sites are increasingly faced with targets for reducing their carbon footprint as a result of corporate environmental policy and objectives. To meet these targets all elements should be reviewed – including containment. By their nature, SBVs provide an extremely 'green' process solution compared with alternative methods such as gloveboxes, which have high energy and utility consumption levels.

The second category of vendor/valve-based factors falls into the following areas:

- Vendor experience
- Types of valve
- Valve design characteristics
- Cleaning & maintenance
- Materials of construction
- Valve versatility
- Financial/time resource
- Valve size
- Other vendor competencies

Vendor experience or the ability to really understand the process application and advise the client of the most appropriate containment solution should not be overlooked.

Valve design characteristics, in particular the disc sealing methods, form a basis for the overall containment performance of a split valve. Typically, there are four methods of sealing seen in the marketplace. Some solutions include an O-Ring or inflatable seal between the two mating disc halves of the valve. In the event of a seal failure, it is possible for powder particles to migrate onto the disc faces and be exposed to the operator environment once undocked.

Alternative methods involve a direct metal-to-metal seal. In this design, a precision-engineered disk is critical for maintaining containment and negates the need for elastomeric disc seals. A final method is a hybrid form that couples two independent butterfly valves with a void that is cleaned prior to the undocking sequence. This method ultimately involves more equipment and utility resource.

Another important sealing interface occurs between the disc and the main body of the valve via a component such as a seat or inflatable seal. Precision tolerance here will optimise the balance between ease of operation and containment integrity.

Some solutions overplay tolerance to ensure containment. However, this can

Figure 3: SBV with integrated automated docking system

cause unnecessary extra friction between the disc and seat and make manual operation difficult, especially on larger valves sizes which then require an increase in torque to operate the valve. The knock on effect is the need for automated operation, which brings an increased cost for the necessary control systems and services.

During bulk powder transfer processes, for example when discharging IBCs where manual handling is impossible and repeatability of docking accuracy is vital, it will be necessary to use automated valves and docking systems. For these more demanding operations, the robustness of

Figure 2: A vibratory collar to aid charging of cohesive product through a SBV to a mill

the valve should come into focus.

Employing either of the two techniques below generally ensures that a valve can maintain pressure and thus containment during processing.

1. Use of the Active disc to achieve a pressure rated seal
2. Use of a pressure rated component inserted into the Active.

When the process demands that the valve must be used for charging under pressure (i.e. be open), the first method cannot be used, as when the discs are open there is nothing to maintain the pressure seal. This design raises further issues during operation in atmospheric conditions: an increase in disc thickness (in comparison with option two) means a greater friction due to the increase in surface area in contact with the seat, in turn creating more difficult manual operation. The increase in disc surface area also creates more resistance to powder flow, raising the risk of bridging.

Alternative systems

There are alternative systems that can accommodate charging under pressure. A pressure rated Passive device that does not adopt a pressure seal against the disc edge can be used. With the cross-sectional thickness of the Active and Passive discs remaining the same as in a non-pressure rated version, the risk of bridging and powder flow restriction is reduced.

Generic split butterfly valve designs generally contain to an OEL of <10μg/m^3. There are, however, further enhancements to this principle available that enable OELs to be reduced to nanogram levels. These systems typically involve a means of safely extracting contaminated air from in and around the valve to a filtration unit.

Contained valve cleaning is another consideration. This can be done in place via specially modified CIP mechanisms — manual or automated. Options include ▶

devices to clean the valve or valve and vessel attached. Simple valve design and minimal use of components are desirable for efficient disassembly and effective cleaning procedures.

The most common material used for SBV bodies is stainless steel and this is suitable for the majority of applications. Where process solvents present corrosion issues with stainless steel, alternative materials such as Alloy 22 or 276 can be used. This is a more costly but often unavoidable option.

In some applications a plastic alternative can be used for the Passive MOC. This is more cost-effective and is lighter – ideal for manual handling of the valve operation. Sealing components also require important MOC decisions depending on product and solvent compatibility and can vary in cost.

Cost considerations

Valve versatility can be important, as a versatile SBV solution is a cost-effective one. Some split valves can be used for purposes other than simply powder transfer: for example, contained Clean In Place (CIP) procedures; contained sampling; in vacuum conveying applications; and in a pressure rated sightglass assembly.

It goes without saying that larger, more complex valve systems with automation and docking extras are more expensive. Simpler, standard systems that do not require any application-specific customisation will be easier and quicker deliver to site, validate and install.

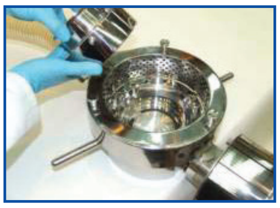

Figure 4: An extraction system adjoined to the Active half of an SBV

Valve size is nominally quantified as the diameter of the discs, i.e. the cross-section area through which material can pass through the valve. Typically SBVs are available in 50, 100, 150, 200, 250 and 300mm sizes, with smaller valves for simple manual additions and large fully automated systems for bulk powder transfer.

Vendor competencies, such as the capability of a vendor to provide suitable ancillary equipment to enhance SBV operability and containment performance, should not be ignored. Items such as compatible containers, control systems and docking systems to enhance material handling are often vital to solve specific or unusual process difficulties.

Additionally, the competence of the vendor in supplying validation services, training, maintenance provision and reliable technical and onsite support is important.

Selecting the ideal SBV solution requires careful integration of all these factors. The SBV comes into its own as an industry standard for high containment powder transfer, and is becoming recognised globally as a simple, cost-effective and versatile containment solution in preference to alternative methods. They are equally useful, where applications dictate the need for SBVs to be used in conjunction with other containment systems. ■

CONTACT
Ben Wylie,
Sales & Marketing Executive,
ChargePoint Technology, part of
Powder Systems Limited
Estuary Business Park
Liverpool L24 8RG, UK
T +44 151 448 7700
F +44 151 448 7703
ben.wylie@thechargepoint.com
www.thechargepoint.com