B BRAUN
SHARING EXPERTISE

BROADENING THE SCOPE OF USER REQUIREMENTS WHEN SELECTING VALVES FOR MEDICAL DEVICES.

Consider the process of purchasing a car. You go to the dealership with a set of criteria: four doors, American made, at least 30 miles per gallon highway. Perhaps you have a preference for a leather interior and a price limit of $30,000. These are your "specifications."

A good salesperson will ask you a series of questions that will help you narrow your selection, such as:

- How big are the people who need to fit in the car?
- Do you expect to fit four people or five people?
- Do you have kids? How old are they?
- Do you expect to do more city or highway driving?
- Do you expect to use it for commuting to work or transporting kids around town?
- How important is acceleration?
- How do you listen to music: CDs or MP3 or satellite radio?

If you are willing to answer the questions fully and honestly, the salesperson will be able to direct you to a car that likely meets all your needs, including requirements you may not have realized when you entered the dealership. If you don't or won't share information, you may be disappointed with the recommendation or your eventual purchase.

And so it is with valves for medical devices. These small, seemingly simple components are actually quite sophisticated. Engineers have many valve designs from which to choose. Selection usually starts with the Broadening the scope of user requirements when selecting valves for medical devices. specifications: connection port types, flow rate, opening pressure and back pressure are among the most common. These specifications outline the required function of the valve. They do not address the intended use.

It is paramount to move beyond the specifications when identifying the best valve for a device. By broadening the scope of user requirements, one can ensure that a valve will function as expected over the device's entire life cycle - from manufacturing through clinical use. Below are several requirements worthy of consideration. Although they are important, they often are unshared unless the valve supplier and device engineer engage in open communication early in the purchasing cycle.

MATERIAL COMPATIBILITY

Material compatibility is often viewed as a functional issue, not a manufacturing issue. Discussions between a device engineer and a valve supplier often focus on performance criteria and how the fluid passing through the valve will impart stress to the valve – or how the valve may impart stress to the fluid. After all, some drugs and fluids are corrosive: lipids, chemotherapy agents and other caustic substances could compel the use of one material over another. Similarly, some bodily fluids (blood, for example) can actually be damaged by certain valve designs, so a compatible option must be used.

Material compatibility assessment needs to extend beyond the functional requirements and into the manufacturing process. It is important to understand how the valve will be integrated into the final product. Will tubing be bonded to the valve? Will other components be attached? Forces from the bonding of tubing to a valve can create both hoop and tensile stresses. Solvent used to bond the tubing can degrade the material at the connection port. Depending on the plasticizer and valve materials, plasticizers in the tubing can leach out over time, causing chemical stresses on the valve. Attaching a component to a valve can impart similar as well as additional stresses and compatibility issues. For instance, the torque used to attach a valve to another rigid component on the device could impact stress. What torque limits can a material sustain? Informing the supplier what the valve will be assembled to and how it will be assembled will lower the chance of incompatibility.

Further, stresses on valves are cumulative. One must add up all potential mechanical stresses and chemical stresses on the valve. Under a low mechanical stress, a certain level of chemical stress could be acceptable. But combine a high mechanical stress with multiple chemical stresses and a malfunction could result.

STERILIZATION METHOD

Sterilization methods are critical to any medical device. Full understanding of how the valve will be incorporated into the final device and intended sterilization method can help expose potential risks early in the design cycle. Mitigation strategies can then be identified. For example, consider normally closed valves which are used in many medical applications.

By their nature they are sealed until a specific amount of pressure is applied. When both ends of a valve are open, the entire component can be ethylene oxide sterilized. However, a closed attachment on either end of the valve could act as a barrier to the flow of EtO. The device may have to be designed to incorporate a venting mechanism so EtO can reach the entire valve. Other options could be pre-conditioning of the valve before assembly or gamma sterilization.

CRITICALITY OF FUNCTION

The risk assessment of the final device needs to evaluate valve criticality. If the valve failed, what impact would it have on the proper function of the device? How would it affect the patient? Many stocked valves are designed for a specific application. While the specifications for a new application might be very similar to the original application, the criticality of certain specifications may be higher than the initial design intent. Like any product, valves can be designed and tested to meet extremely rigorous demands. The criticality of the valve will influence its design as well as manufacturing methods and test protocols to ensure it meets the requirements of desired application. Ultimately, both supplier and customer specifications should match.

COUNTRY OF USE

It's vital to know in what countries the medical device will be used. Countries may prohibit the use of particular compounds, for example DEHP, or require the manufacturer to note the presence of the compound on the packaging, which could be viewed negatively by a purchaser or clinician. Additionally, there are often clinical preferences from country to country. Some valves in the United States feature a Luer lock connection whereas the Luer slip is common in most European countries. Knowing where the device will be distributed may bring resolvable issues to light early on.

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LENGTH OF USE AND SHELF LIFE

Understanding the intended use of the valve is critical. Will the lifespan of the disposable device be measured in hours or days? And how many open-close cycles will the valve complete during its use? Both are crucial questions. Valve manufacturers test their valves to a specific number of cycles based on patient contact and duration of use. Anything beyond the existing test limit will require additional testing and validation. Shelf life is another important factor. Many valves have a five-year shelf life, but some have shorter ones. If the device will be stored for an extended period of time, additional age testing may be required to extend the labeled shelf life and ensure proper function.

QUANTITY OVER TIME

Sharing how many valves you may need over three years is as helpful as telling the supplier how many you need in three months. Accurate projections of long-term volumes can impact decisions about tooling and assembly that could lower costs, improve efficiency and ensure capacity over time.

While specifications are a great place to start a discussion with a valve vendor, they should be just that: the beginning. A host of additional variables should be considered before a valve is selected. Communicating openly and fully with the valve supplier can help overcome unexpected problems and ensure selection of a valve that functions as required. Of course, many of the discussions deal with sensitive and sometimes strategic information. A well-written NDA is essential.

Working over time with an established supplier can provide another element of success: trust. A valve supplier that is willing to listen to customers and share its expertise becomes a valuable partner in the design and manufacturing process.

How B. Braun OEM Division can be a resource

As a major medical device manufacturer, B. Braun has extensive resources throughout the organization – experts in engineering, materials, project management, packaging, quality systems, regulatory support and more. The B. Braun OEM Division can apply the organization's wide-ranging expertise to your contract manufacturing projects.

B. Braun is also a recognized leader in the design and production of standard and custom valves. Hundreds of valve designs and configurations have resulted from decades of innovation and adaptation to market needs. We can help you optimize the performance of your medical device through proper valve selection.

Because we're a full-service outsourcing partner, B. Braun OEM Division approaches projects with the same standards and quality that we apply to endproducts that carry the B. Braun logo.

Contact us at (610) 691-6785 or visit bbraunoem.com to learn more about our capabilities and schedule an introductory discussion about an upcoming project.

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