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Four Questions to Ask Your Beta Bag Supplier

By Jim Peterson

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INTRODUCTION

The race to create a COVID-19 vaccine captured the collective attention of the world in 2020. With the global pandemic raging, pharmaceutical companies kicked their research-and-development departments into hyperspeed, with the resultant three vaccines going from drawing board to patients' arms in less than a year, which was one-third to one-fifth the time it usually takes to get a new vaccine to market.

While the speed of these vaccines' creation set them apart, the development of the COVID-19 vaccines shared a commonality with traditional drug R&D in that they needed to be done in a highly sterile, aseptic manufacturing atmosphere. This means that, among other things, beta bags were used in the COVID-19 vaccine-manufacturing process – as they are in the development of all Life Science products like pharmaceuticals, biologics and biosimilars that feature Active Pharmaceutical Ingredients (API).

If you use beta bags, you know how important they are. But do you know the right questions to ask your beta bag supplier before settling on a certain brand, style or model? Here are four questions you should ask beta bags suppliers before selecting this oftentimes incredibly important component:

1. How Do Single-Use Beta Bags Differ From Traditional Multi-Use Systems?

For many years, multi-use systems and components were used in the storage and handling of sterilized components in aseptic-processing applications. While effective, these multi-use systems have a few drawbacks, such as the initial cost for equipment and installation, and a lack of flexibility in product development. The most significant drawback, however, is the need for complex, costly and time-consuming validated cleaning systems that are required during product changeovers within manufacturing runs.

Single-use systems that see sterilized components changed out after they have completed their service can eliminate the need for expensive and time-consuming cleaning regimes while still helping the processing operation meet all relevant regulatory-compliance considerations. Realizing the importance of maintaining a sterile working environment in an isolator or clean room, single-use beta bags are subjected to a strict, highly engineered construction process.

Typically, sheets of Tyvek® – which is a high-density polyethylene fiber that is difficult to tear – and a high-density polyethylene (HDPE) plastic – which has a high strength-to-density ratio – are welded together in a controlled environment to form a contaminant-free, strong and tear/leak-free bond. The single-use beta bags are then welded to an HDPE weld ring connected to a polycarbonate flange to complete the beta bag system. When used, the polycarbonate flange mates the bag assembly to the Alpha port on an isolator; these flanges may be compatible with numerous Alpha port designs. This can be a differentiator for sterile-product manufacturers who would like to have more beta bag options available.

2. What Types of Sterilization Processes Can Be Performed on Your Beta Bags?

Beta bags can be sterilized in two ways (Note here that they can only be sterilized once and should be disposed of after use):

Autoclave Sterilization: An autoclaving process uses heat in the form of pressurized steam to produce a sterilized beta bag. Specifically, an unsterilized beta bag, which has been manufactured in a clean room environment free of contaminants, is placed in a chamber that is pressurized and filled with steam that has been heated to a temperature between 250ºF and 273ºF (121ºC-134ºC). The beta bag is left in this sterilizing atmosphere for a prescribed period of time to ensure that any outside contaminants that may have come in contact with it are killed.

Gamma Sterilization: This process uses gamma rays, which are a form of high-energy electromagnetic radiation. What differentiates gamma sterilization from its autoclave cousin is that it is a controlled process that requires no heat or steam; instead, the gamma rays are passed over and through the beta bag to kill any present contaminants. A benefit of gamma sterilization is the convenience it offers through its ability to be used on pre-packaged materials, i.e., whole cartons of beta bags can be sent through a gamma-ray processor for sterilization. In comparison, while autoclave sterilization is just as effective in killing contaminants, the autoclaving process must be performed in a stainless-steel chamber.

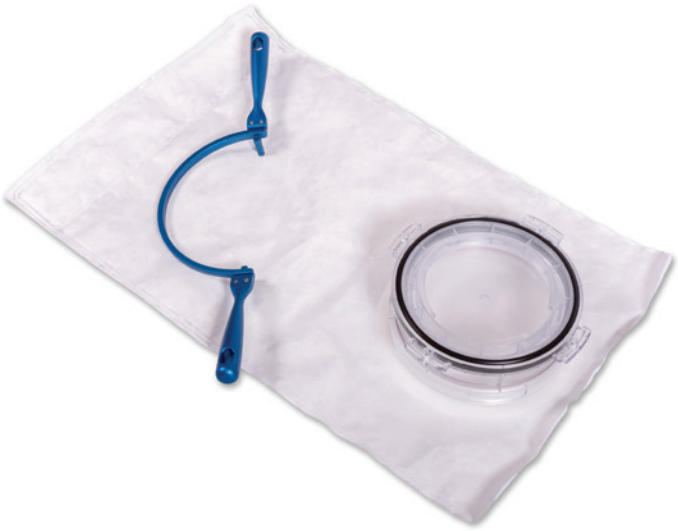
In the end, both methods achieve the same outcome: a completely sterilized beta bag that can be used in the most pharmaceutical aseptic-production processes.

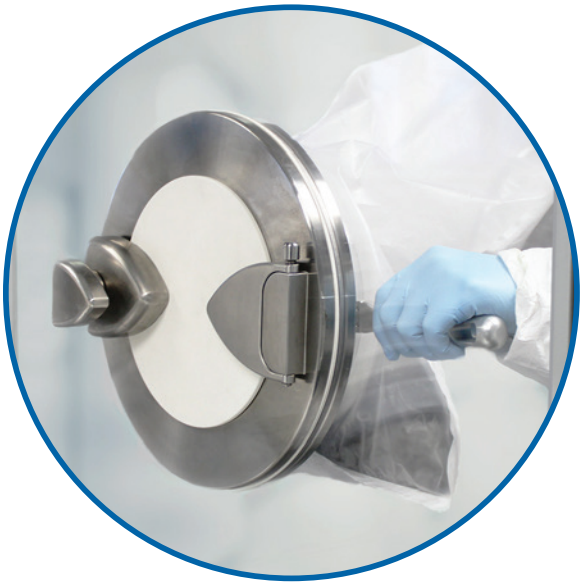
3. Are Your Beta Bags Ready-to-Sterilize or Ready-to-Use?

Beta bags can be delivered in one of two conditions, depending on the preferences of the end user: ready-to-sterilize or ready-to-use. Ready-to-sterilize beta bags are built in an aseptic, clean room environment then individually packaged and shipped to the customer. They are stored until the user needs a bag, which is then filled and sterilized according to the parameters of the user's production process. In some cases, the beta bags can be delivered to the user ready-to-use, meaning the supplier fills the bags with whatever the user requests – vial stoppers, syringes, hand wipes, sponges, cable ties, pens/markers, etc. – and sterilizes them before shipping. Once received, the user only has to attach the pre-sterilized beta bag to the isolator's Alpha port, which is a quick and easy way to introduce the bag's sterilized contents into the manufacturing process.

4. How Is Your Beta Bag Docked And Undocked?

A recent advance in beta bag capability is the ability to incorporate a removable handle into its operation, which saves the user space, waste, packaging and cost while making the docking/undocking process easier and more ergonomically friendly with added support for the bag. The removable handle has teeth that mount to the flange on the beta bag's exterior at any of eight rib locations. To dock, the single-use beta bag, the user just lines up the outer bayonets with the isolator door and rotates clockwise to the fully locked position. To undock the beta bag, the handle is placed back on the flange and rotated counterclockwise. The doors on the isolator can be opened only if the placement of the removable handle is performed successfully during the docking process. If the bag is docked improperly, the doors won't open. This creates an added level of safety and security for the production process.





Single-Use Beta Bag docked to
Clean Rapid Transfer Port (CRTP)

Building on its 75-year history of overall innovation, and being well aware of the needs of operators in the Life Science market, Central Research Laboratories® (CRL), Red Wing, MN, USA, has created its own Single-Use Beta Bag product line for use in aseptic-production processes. CRL Single-Use Beta Bags are available in a 190-mm (7.5-inch) size with a capacity of 25 liters (6.6 gallons) and are autoclavable and gamma-sterilizable.

CONCLUSION

The prominence of vaccine production became front-of-mind in 2020 – and CRL beta bags were used in some COVID-19 vaccine-production processes – but the development of new vaccines and drugs used to battle the world's diseases has always been a critical undertaking for the world's pharmaceutical companies. In that realm, beta bags have always been a critical partner in a new vaccine or drug's R&D and production processes. Single-use beta bags are continuing to be a bold new player in this market and their benefits include notable improvements in cost, efficiency, contamination prevention and compatibility with different styles of Alpha ports. The result is a new option for beta bag users, as long as they receive the proper answers to several important questions before making a supply decision.

ABOUT THE AUTHOR

Jim Peterson is a Sales Manager for Central Research Laboratories® (CRL), Red Wing, MN, USA. He can be reached at jpeterson@destaco.com. CRL possesses more than 75 years of innovation experience in the development of remote-handling systems, including Telemanipulators, Transfer Systems, Glove Ports and Waste Drum Transfer Systems. CRL's industry-leading technology helps its customers safely and efficiently handle hazardous and sterile materials in nuclear and life science applications around the world.

Destaco, a Dover company, is a global leader in the design and manufacture of high-performance automation, workholding and remote-handling solutions. The company serves customers in a variety of end-markets, including the automotive, life science, consumer packaged goods, aerospace, industrial and nuclear sectors. Destaco is based in Auburn Hills, Michigan, U.S.A. The company has more than 800 employees with 13 locations, in 9 countries, across the Americas, Europe and Asia.

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