



Facing The Challenges: Single-Use Approaches To Powder Transfer

Media and buffer preparation is a key part of the biopharmaceutical manufacturing process, and while it doesn't have to be carried out in sterile conditions, improving the powder transfer process makes this step cleaner, safer, and more efficient, protects personnel and could cut time and costs as well.

The Issues Of Powder Handling

Because sterility is not vital at this early stage of manufacturing, powder ingredients for media and buffers have historically been transferred from stock containers using scoops, and weighed and mixed in buckets or open top bags. This process has often been carried out in a separate room from the production line to contain any airborne contaminants. Many companies are starting to move to single use systems as a simpler, cleaner, and safer way to handle ingredients, but this still means that the dry ingredients for buffers and other media need to be transferred into single use bags in pre-weighed amounts from large-scale storage drums or bags. There are challenges to face in this process, including the generation of airborne particulates, and the overall aim for powder transfer management is to meet these through the optimized handling of raw materials.

Handling any powders creates levels of fine particles in the air. While the ingredients used in media and buffer preparation are typically benign and stable, long-term exposure to any airborne particles is not ideal for employees' health. Even with the most stable of compounds, a fine powder 'haze' in the air also comes with a slight risk of ignition, particularly when there is a chance of static build-up.

Because airborne particles eventually settle out onto surfaces, these could contaminate the next batches of media and buffer to be prepared, so the preparation area has to be cleaned between batches. This lengthens the time needed for changeover, and increases staff costs, or takes people away from more vital jobs.

Biopharmaceutical manufacturing is an expensive process, and waste, even of relatively low-cost ingredients has an impact on the overall costs. Potential sources of waste include single use bags that are difficult to fill quickly and accurately without spillage, are made of polymers that become charged with static and so are 'sticky', or that have dispensing lines that trap powder, or are difficult to control precisely. These issues can also make it harder for users to stick to recipes accurately, which can have an impact on reproducibility all the way through the manufacturing chain.



Finding The Solution

To provide a practical solution, single use bags should:

- Be robust and purpose-designed
- Be easy to fill and seal
- Have an ergonomic design
- Discharge easily, quickly, and completely

Robust And Designed For Purpose

Many companies have developed powder-handling systems, but these are derived from existing liquid containment systems. While powders and liquids do behave in a similar way, their flow and handling characteristics are not the same. Powders also may need to be dispensed in different volumes to liquids, or need different flow rates, meaning that a liquid-type system just doesn't quite meet the right criteria.

ILC Dover has been working in flexible films since its inception in 1947, from NASA spacesuits to drug manufacturing. ILC Dover's DoverPac® Containment Systems division specializes in powder containment systems and has purpose-designed EZ BioPac™ from scratch specifically for powder handling in the biopharmaceutical industry, with a focus on getting the usability of the system just right for its customers. Furthermore, the EZ BioPac™ is a true 3D design allowing for enhanced flow and control of the powder, unlike its 2 dimensional competitors.

Easy To Fill And Seal

Packs with narrow openings are harder and slower to fill, and increase the risk of spillage, leading to contamination of the pack surfaces and wasted raw materials. DoverPac® has designed its EZ BioPac™ with an open funnel-like top for easier and quicker filling, and it fits into a light, non-metallic frame that holds the top open. Because of this, no separate funnel is required, and so there is one less piece of equipment needing cleaning in the filling area. The large target opening also reduces the chance of overfilling, and makes it easier to fine-tune the weight of product, leading to a more accurate fill.

By reducing uncontrolled powder handling, the EZ BioPac™ system lessens the amount of powder that disperses into the air, thereby lowering the risk of cross-contamination and the need for as frequent cleaning. This also serves to protect the staff from long-term exposure to inhaled particulates. By lowering the amount of powder in the air, the packaging system also reduces ignition risk.



*The
EZ BioPac™
system lessens
the amount of powder
that disperses into the
air, thereby lowering
the risk of cross-
contamination*

It is easy for traditional style single use bags to become contaminated on the outside as product is spilled or overflows, or simply settles from the surrounding air. DoverPac's® EZ BioPac™ has a protective outer skirt that covers the outside of the bag during filling, reducing surface contamination and making sealing and handling a cleaner process.

The EZ BioPac™ is simple to seal, just requiring a fold in the bag's upper neck, which is then clamped tightly closed with cable ties.

Ergonomic Design

Some manufacturing processes require large quantities of buffer and media, needing ready supplies of raw materials in various locations. The filled EZ BioPac™ is self-supporting, making it easier to move around and store before use. This allows the packs to be filled centrally and stored where they are needed, saving time and resources, and ensuring that supplies are always available. The variety of sizes available off-the-shelf (1-100 liters) or as custom orders means that the right volume of bagged raw materials is always available, making media and buffer preparation simpler and cutting the waste of time and product caused by using bags that are too large or too small.

Bags filled with raw materials need to be robust, to avoid damage during handling, and need to be ergonomically designed to protect staff from injury while lifting. DoverPac's® EZ BioPac™ has been designed to be easier to handle, with built in handles or lifting loops, depending on the size.

Discharge Easily, Quickly, And Completely

All media and buffers used in biopharmaceutical manufacturing must be made up accurately to ensure that the entire manufacturing process is as reliable and reproducible as possible. As well as ensuring that the single use bags of raw materials are filled as accurately as possible, they also need to be discharged fully into the mixing vessels.

In contrast with many of its competitors, the EZ BioPac™ has a separate filling inlet and discharge outlet, keeping the flow path for discharge clean until the contents are required. One of the sources of incomplete emptying and wastage for single use bags is the static that builds up on the film, causing particles to cling to the inside of the bag. The EZ BioPacs™ are made from ArmorFlex® 114 antistatic film, which meets FDA, USP, and EU regulatory compliance standards.

What's In The Future

As the needs of the biopharma companies, regulatory authorities, doctors, and patients continue to change, biopharma manufacturing approaches must rapidly adapt. For example, the industry is moving towards open suite processing, as a way to lower facility costs. Such facilities demand closed processing to prevent cross contamination, which was formerly avoided by the use of segregated rooms and processing suites. While media and buffer preparation have been notorious contributors to airborne particulates and contamination, improved powder transfer management allows the process to be closed and contained easily to avoid these risks. Companies supplying single use disposables will have to ensure that their products are compatible and competitive within this new manufacturing paradigm.

*The EZ
BioPacs™ are made
from ArmorFlex® 114
antistatic film, which
meets FDA, USP, and EU
regulatory compliance
standards*

About DoverPac® Containment Systems

DoverPac® Containment Systems, an ILC Dover brand, is the global pioneer of disposable process and powder containment systems. Launched from a partnership with multi-national pharmaceutical companies to develop high containment for API production and oral solid dosage processing, DoverPac® is the global standard for containment, reliability, and service. We've been providing proven Flexible Containment solutions since 1997 and have over 300,000 installed to date. ILC Dover has state-of-the-art manufacturing facilities dedicated to the production of the DoverPac® line including custom designed sealing equipment capable of producing reliable 3D and 2D heat seals, and an ISO Class 7 Clean Room. A staff of experienced design engineers permits us to customize products and create systems to fit your needs while optimizing worker ergonomics and productivity. Decades of work with NASA gives us the experience to provide the detailed documentation packages, critical quality data, and certifications required.



ILC Dover
www.doverpac.com
customer_service@ilcdover.com

To correspond directly with the author contact:
Chris Rombach
Biopharm Product Manager
302-335-3911 x792
rombac@ilcdover.com