EZ BioPac® Powder Transfer Gets Your Biologic to Market Faster, with Less Risk

This white paper quantifies how one simple change can drastically reduce the time it takes to get biologics manufactured. Getting media and buffer into large-scale, continuous bioprocessing has been burdensome, time consuming and messy. Upgrading to modern single-use powder handling in your process gets your product to market without time wasted on complicated weigh and dispense steps, cleaning validations, or worries about powder in the air and in the room.

INTRODUCTION

Currently, biopharmaceutical companies are striving to produce biologics more efficiently, with a lower cost point and fewer people. Most small-scale media and buffer operations are carried out with small bottles of liquid media, but as processes are scaled up to manufacturing levels, that is no longer a viable option. Costs of shipping liquid are simply prohibitive, so the industry has migrated to using media and buffer in a powder form. In fact, 90% of cell culture media and buffer for sale is now in a powder form that needs to be hydrated, mixed and packaged to be used in the process. This "just in time" hydration allows for increased compliance and process efficiency.

One of the biggest concerns with this process is that it could become an entryway for contaminants to enter the process. Everyone remembers the story of a high-profile biologics company that had a facilitywide animal virus contamination, and how it resulted in shortages of vital medicines and a long shutdown to determine the root cause. To reduce the chances of such contamination, the entire system must be closed.

Making biologics safely also means designing the process to reduce contamination risk at every step, even those that may not seem obvious. One of those often overlooked steps is mixing media and buffer powder during the process. It is still common to see people pouring open buckets of powdered media into a mixing tank, with powder flying into the air and around the room. This leads to a dirty environment that is hard to clean and validate. We have found a way to make this process seamless, easy and safe, using a system that is the state-of-the-art solution in single-use facilities.

THE ILC DOVER EZ BIOPAC SOLUTION

The EZ BioPac powder transfer system has been designed to reduce operating time with every deployment. This single-use system makes transfer, charging and discharging of biopharmaceutical powders fast and easy. One-person operation reduces manpower requirements, and high levels of containment performance help to ensure operator safety. In this white paper, we examine the accumulated savings when the EZ BioPac system is deployed throughout a typical biopharmaceutical process. But first, a short recap:

HOW EZ BIOPAC POWDER TRANSFER SAVES TIME, EACH TIME

The most efficient powder containment and transfer equipment, like the EZ BioPac powder transfer system, exhibits a number of specific characteristics, including:

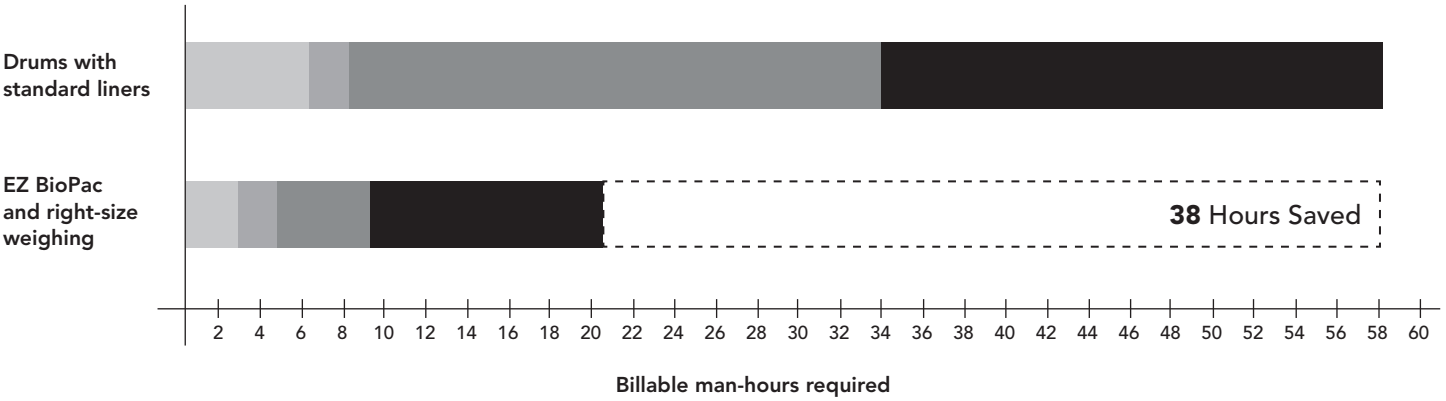
- A design developed specifically to handle powders
- Fast filling
- Easy, complete sealing
- Fast, clean dispensing
- Complete product recovery (i.e., virtually no powder left in the container)
- Self-supporting containers to promote easy handling and distribution

When combined, these characteristics provide fast and efficient powder handling.

BULK POWDER TRANSFER BAGS: HOW EZ BIOPAC® SAVES TIME AND MONEY

Key

Receipt/Sample Process | Warehousing Process | Dispensing Process | Hydration Process



Receipt/Sample Process

STANDARD LINERS	EZ BIOPAC
6 Hours	**2.5** Hours

Releasing warehouse materials takes the EZ BioPac only half the time, and sampling takes only a quarter.

Warehousing Process

STANDARD LINERS	EZ BIOPAC
2 Hours	**2** Hours

The overall warehousing phase takes both bags about an hour per person to complete.

Dispensing Process

STANDARD LINERS	EZ BIOPAC
26 Hours	**4.5** Hours

EZ BioPac bags save a lot of time in this phase because they eliminate the need to scoop, weigh and measure product in intermediate containers.

Hydration Process

STANDARD LINERS	EZ BIOPAC
24.5 Hours	**11.5** Hours

The need to meter powdered raw materials into WFI from intermediate containers is eliminated with the EZ BioPac, saving 6.5 hours per person in the hydration process.

Numbers reflect the number of man-hours saved when two employees are carrying out the task.

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FILLING

In trials designed to test the filling efficiency of ILC Dover's EZ BioPac system, the larger size and design of the fill opening and skirt proved to offer filling performance superior to other designs with narrower openings.

For instance, to measure its specific performance, ILC Dover tested its EZ BioPac system against a typical competitive 2D transfer bag. The test procedure required filling each bag to approximately 5.25 kg, and then adjusting the final weight consistently to an endpoint value of 5.0 kg. The EZ BioPac system yielded a 71.1% faster total fill time, averaged over three independent trials.

SEALING SPEED AND SIMPLICITY

The EZ BioPac is also simple to seal, by either of two methods. The first requires making only a Z-fold in the bag's upper neck and then clamping the fold tightly closed with attached cable ties. The second uses ILC Dover's proprietary, robust CrimpLoc™ crimping system, which allows quick, one-person sealing under virtually any conditions.

Competitive bags require placing a cap over the opening, and then holding it in place while putting a split-ring clamp in position over the cap and tightening it in place. The cap can easily slip out of position during this process, requiring repeated attempts to properly align the cap and clamp before the clamp can be tightened to seal the bag.

DISCHARGING

ILC Dover has also tested its EZ BioPac bag versus a competitive 2D transfer bag in head-to-head time trials to measure discharge efficiency.

The test procedure consisted of removing the clamp (if required), installing the bag, opening its closure, discharging the contents and fastening the closure. The test results showed the EZ BioPac system yielded an 18.6% faster total discharge time, with 33.3% less product retention, averaged over three independent trials.

Some manufacturing processes require large quantities of buffer and media, readily available in a number of locations. Because the filled EZ BioPac 3D containment pack is self-supporting, it can be filled in a central location, and then moved easily and staged in appropriate locations, as required by the process.

GETTING TO MARKET FASTER

Our comparisons were based on just one transfer and filling operation. In a typical biopharm process, all of those steps (and, therefore, the savings) can be multiplied by a factor of 10 or 12, when each deployment in the process is considered.

For instance, media prep/cell production — where the EZ BioPac system can help considerably — is followed by as many as 11 buffering operations. In each of those, an EZ BioPac system can reduce total production time significantly. But processing operations are not the only place where single-use EZ BioPac bags can save time, manpower and, consequently, operating costs.

INCOMING GOODS

The design of the EZ BioPac bags also makes it faster and easier to take samples at the product receiving station. In fact, using EZ BioPac bags instead of drums with standard liners can reduce typical raw material intake time — from receipt at the loading dock to warehouse placement — by as much as 1.5 hours or more. In most plants, this is also a two-person operation, so total savings reaches three man-hours per product received.

At the same time, the EZ BioPac unit's design helps reduce employee safety risk and contamination risk during sampling and transfer.

DISPENSING

It's in the dispensing stage that EZ BioPac powder transfer systems can really separate themselves from the alternatives. Not only does their use reduce the amount of time required to retrieve raw materials and verify quality before release to production, but it can also completely eliminate a two-person, five-hour process step — scooping, weighing and measuring powder into intermediate containers. That's another 10 man-hours saved, just in that step alone. When all of the savings are accounted for, across all dispensing steps, the total reduction is more in the range of 20-plus man-hours.

Again, in several dispensing steps, the design of the EZ BioPac bags and crimp sealing system helps to reduce worker safety risk and contamination risk.

HYDRATION

Finally, during hydration operations, using EZ BioPac bags can eliminate another manufacturing step — namely, scooping, weighing and measuring powder into intermediate containers. Like the step eliminated in the dispensing stage above, this one cuts 5.5 hours off the total time, for each of two individuals — for a total savings of 11 man-hours. When savings in the other hydration steps are included, the total saved by EZ BioPac rises to 13-plus man-hours.

CONCLUSION

By adding the savings across all three categories, we find the total to be in the range of 38 man-hours — nearly a full workweek, not including the potential for additional cleaning validation in case something were to go wrong. While every manufacturer would have to apply its own logistics and cost factors to determine its real potential savings, all our testing and field experience indicate the savings is substantial. We would welcome the opportunity to work with you to calculate just how much the use of EZ BioPac powder transfer systems could contribute to your success.

ARMORFLEX® 114 — THE PREMIER FILM FOR POWDER HANDLING AND CONTAINMENT

Already validated for use at most major pharma and biopharma companies, our regulatory-compliant film offers integral static-dissipative properties, very high tensile and tear strength, high visual clarity and a five-year shelf life. Moreover, it is gamma-irradiation compatible and designed from the ground up for modern powder handling applications.

ILC Dover has been containing drug manufacturing since starting in the '90s with Eli Lilly.

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ABOUT US

Since 1947, ILC Dover has built a global reputation for out-of-the-box thinking that makes the seemingly impossible possible. Our engineered solutions solve our customers' most complex challenges through the creative and efficient application of flexible materials often integrated with advanced equipment and hardware.

We look beyond the boundaries of convention to help customers see what could be, and discover the extraordinary possibilities within everyday things. We are a diverse company serving many markets. We are dreamers, engineers, scientists and pragmatists — all dedicated to outperforming tradition to better mankind.

We apply our vast knowledge of materials, soft goods, film-based solutions and design to move the world forward, from advancing spacesuits for astronauts to developing solutions for NASA Mars missions to engineering lighter-than-air vehicles here on Earth. We continue to pioneer the use of flexible containment solutions to support advanced pharmaceutical and biopharmaceutical manufacturing, and we're revolutionizing the packaging and extraction of bulk liquids to enhance customer profitability and sustainability.

Additionally, we create quick-deploy systems that protect cities and critical infrastructure from floods, and design and manufacture advanced respirators to protect against a range of chemical and biological threats.

Every day, everything we do brings new solutions to light. Are you ready to take your vision beyond boundaries? Let's talk.

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