



ARE YOU FORGETTING SOMETHING IN YOUR SINGLE-USE STRATEGY?

A Q&A eBook with ILC Dover



Table of Contents

1. How can manufacturers enable cost-efficient manufacturing to support the demand for more affordable biologics?
2. Why are single-use technologies becoming the cost-efficient option?
3. What are best practices manufacturers should be aware of when implementing a single-use strategy?
4. What are some misconceptions surrounding single-use technologies?
5. In your experience, what has the outcome been like when an organization has taken the time to improve its' single-use strategy?
6. American Biomanufacturing Summit 2017

How can manufacturers enable cost-efficient manufacturing to support the demand for more affordable biologics?

Eliminating contamination is increasingly becoming a driver in the manufacturing of biologics. One of the main problems that is overlooked is the initial charging of powdered media and buffer into mixers. There are two problems at this point. The first is that this is a major source for potential contamination. Media is specifically designed to grow things. Do want it all over your manufacturing suite?

This process is often done in open air and due to the clumpy nature of the powders mallets are often used to break up the powder and get it into the mixer. These lumps that are left can break the mixing system.

Critical questions to consider include:

- Will the system help to eliminate productivity bottlenecks, decrease material waste and the cost of raw materials, and simplify the changeover of the line to new products?
- Is it robust enough to provide reliable transfer throughout the production run? And has it been designed from the ground up specifically to contain and release powders?

Why are single-use technologies becoming the cost-efficient option?

The cost of extra cleanings and the validation that that entails when there is powder containment is a clear risk that is expensive to mitigate with present strategies. A properly designed solution will provide superior fill adjustment and speed when adding the powders. More importantly it should close the system and reduce contamination. In addition, it will enable rapid discharge and simplicity in sealing. Having all of these characteristics in one place removes time and risk from your process.



What are best practices manufacturers should be aware of when implementing a single-use strategy?

Make sure the products you are using actually fit your process and won't add extra time and effort. Using bags designed for liquids means they aren't designed to be accurately filled with powders which leads to additional time being spent on getting the right amount of powder into a small opening and then pulling some out when too much is put in. With bags designed for this work you can easily adjust powder amounts to get the measurement right the first time. In addition, our bag is designed so if there is any spillage it is caught by the skirt so clean up is simple and contained. Finally, when it becomes time to use the powder in your process our anti-static film means there is no residual powder in the bag so there are no concerns about lost product.

The most efficient powder containment and transfer equipment will exhibit 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., no powder left in the container)
- Self-supporting containers to promote easy handling and distribution

What are some misconceptions surrounding single-use technologies?

Misconception: All films and designs work well with powder applications.

This is absolutely not the case. Bags designed for liquids are hard to stand up, fill with powder accurately, and due to 2-D construction often make it hard to get the powder out. A bag with engineered for purpose openings and an anti-static film can make all the difference.

While powders and liquids do behave similarly under some conditions, their flow and handling characteristics are not the same. Differences arise in required dispensing volumes, flow rates, and the most efficient cross-sectional area of the filling and dispensing openings, among others.

Static build-up in the containment material also plays a different role in powder handling than in liquid handling. ILC Dover's EZ BioPac® system, for instance, was designed by its DoverPac® Containment Systems engineers from scratch, specifically for powder handling in the biopharmaceutical industry. Their focus, from the beginning, was to get the usability of the system just right. Furthermore, the EZ BioPac® system is a true 3-dimensional design, allowing for enhanced flow and control of the powder, unlike its 2-dimensional competitors.

In your experience, what has the outcome been like when an organization has taken the time to improve its' single-use strategy?

The first thing people sigh in relief about is that there is no danger of breathing in particles and that they are dispersing all over the manufacturing facility.

Once the system is closed, there is no longer so much time spent on cleaning and validation. In addition, it helps speed up the process making it so there is one less bottleneck on the road to continuous manufacturing.





American Biomanufacturing Summit 2017

ILC Dover attended Generis' American Biomanufacturing Summit May 23-24th, 2017 in San Diego and discussed the topic "Are You Forgetting Something in Your Single-Use Strategy?" in a Lunch & Learn Roundtable Discussion.

To learn more about this topic and ILC Dover, please check out the website below!

Published by the Generis Group.

[VISIT THE WEBSITE](#)

