SEXTON
BIOTECHNOLOGIES

The Challenge

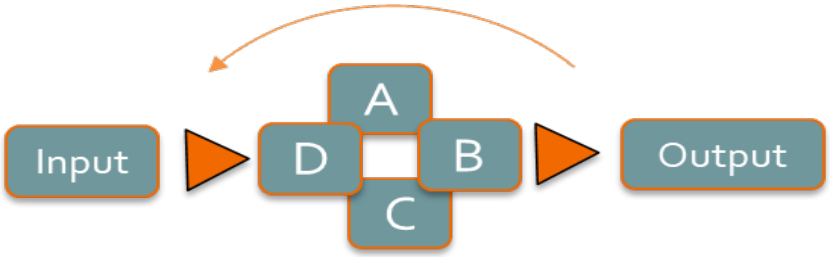
As with any manufacturing process, cell therapy manufacturing can be boiled down to a sequence of unit operations. The process starts with an input, runs through operations A, B, C, D, etc., and it ends with an output, generally using separate systems that do not interact with each other. While the specific operations may be unique to cell therapy, the goal of standardizing the process flow is not different to other manufacturing processes and should be incorporated early in translational stages.

In cell and gene therapy, many of these unit operations involve moving fluid from one place to another. Over the last year, we've been considering how a cell and gene therapy manufacturing platform, that was *really good* at moving fluids from one place to another, could positively impact the industry. To be really good, our customers tell us that there are the important aspects to consider…

The unifying need across various therapy types is the integration between unit operations in a way that meets early and late stage GMP manufacturing needs. Today, most of these fluid handling operations are either performed manually, each with its own dedicated instrument, or with an all-in-one instrument. Process specific instruments require the user to purchase individual systems for each operation, while all-in-one systems are very expensive and limit utilization by tying up the instrument for whole manufacturing process. Either way, scaling and automating the processes is a clear need in the industry and poses significant logistical and financial challenges. Often scale and phase of development dictate pushing off industrial-level automation until later in development, inherently leading to costly, and difficult re-validation of processes. Ideally, a user-focused system would support processes at early phases as well as through later clinical trial or commercialization stages.

Our Goal

At Sexton, we are developing a new system intended to help integrate unit operations of cell and gene therapy manufacturers with the flexibility that you need. The motivation for our solution is to provide a fluid handling platform with the capability to run multiple processing operations using a single base instrument with versatility, reproducibility, and control. The system provides the power and fluid handling capabilities with the ability to integrate across unit operations using single-use consumables and closed, aseptic connections. This type of platform fundamentally alters the process diagram in a way that consolidates multiple operations onto a single instrument, while still providing the user with operational and logistical flexibility at a low cost. The solution runs process operation A, B, C, or D, etc. and turns it into an output, then that output is used as an input on the next process operation. Now each operation requires only the processing consumable instead of a unique operating system.



To realize this goal of flexibility for the end user, the instrument will provide the ability to run custom routines which can be optimized for the user's process, or to run previously optimized, locked-down, GMP compliant routines. The fluid handling system will also have hardware and software interfaces that are accessible and fully programmable to allow the user to develop custom processing operations if needed.

Our first-generation release of the instrument is focused on what we currently do well; product formulation and final fill/finish. Currently, most manufacturers either perform this process manually or develop custom, dedicated systems. Our platform will offer the ability to perform automated formulations from up to three sources and up to 1.5 L volumes, followed by final/fill finish into a variety of output containers. Ready-to-use consumable kits with CellSeal vials or cryostorage bags will be offered, as well as the ability to attach user-supplied output containers.

Future product releases are planned to continually realize the full potential as a modular manufacturing platform. These include additional processing modules as well as consumable kits with expanded functionality and throughput. At Sexton, we believe this solution is a simple idea that can have a paradigm-changing reach as a manufacturing platform.

Your Voice

We have some ideas about how to use the platform, but the accessibility and programmable functionality are intended to let the users gain the functionality and flexibility they need to be successful. We're looking to hear from you about your needs in fill-finish as well as integrating other unit operations. As we move forward with this project, we are looking for interested parties to evaluate and help refine the functionality of the system. Look for us at Phacilitate this year in Miami to learn more.