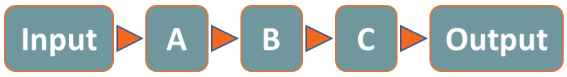
Signata CT-5™

The challenge

As with any manufacturing process, cell therapy manufacturing can be boiled down to a sequence of independent and dependent unit operations. The process starts with an input, runs through operations A, B, C, D, E, etc., and it ends with an output.



In cell therapy manufacturing, this is usually accomplished using separate systems that do not interact with each other. The result is that multiple tedious and high-risk manual processes are commonplace in the industry. As in any manufacturing environment, standardization and automation of the process flow will increase quality, decrease risk and improve manufacturing costs, if it can be implemented. When incorporated early, automation and standardization limit the need for expensive and complicated late-stage re-validation of processes. However, typically cell therapy manufacturing undergoes a substantial amount of process development late in the path to market limiting the ability to "lock-in" automation steps. Perhaps more importantly to many early stage companies, automation of processes is capital intensive and inherently inflexible.

Our goal

In cell and gene therapy, many of the manual operations involve moving fluid from one place to another using traditional laboratory methods such as pipetting or the use of syringes. While adequate for early development and small-scale manufacturing, these techniques carry inherent limitations (for example, process variability, lack of records and control, etc.)for translation to cGMP practices.

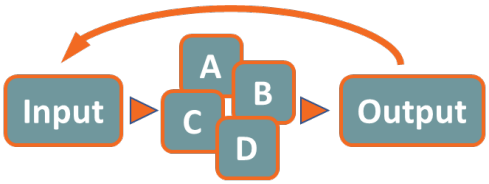
At Sexton, we are developing a new fluid handling system, the Signata CT-5™, intended to help integrate unit operations of cell and gene therapy manufacturers with automation of some of these processes while retaining the flexibility needed during early process development. The motivation for our solution is to provide a fluid handling platform with the capability to run multiple processing operations using a single base instrument. The intent is to eliminate the paradigm of typical trade-offs: Signata CT-5™ allows for cost-effective, early implementation of semi-automated processes with control and electronic records while maintaining a customizable degree of flexibility that can support users in research, development, or commercial stage manufacturing.

Reason to implement automated solution	Reduce manufacturing burden (process time, changeover, contamination control, etc.) Simplify GMP controls with compliant processes (process repeatability, record keeping, control)
Ideal Features	Compatible with current processes Adjustable controls Maintenance of critical parameters (volumes, temperature, etc.) Small footprint Closed System Operation Flexible and multi-use Cost effective

Signata CT-5™

To realize this goal of flexibility for the end user, the system provides the ability to run custom routines through multiple pumps and control valves 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.

The 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 controls at a lower capital costs. Now, transferring outputs from separate operation processes requires only the unique processing consumables instead of separate operating equipment.



Our first-generation release of the instrument is focused on an element of cell therapy manufacturing that is underserved; Formulation and Final Fill. 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 Sexton CellSeal vials or cryostorage bags will be offered, as well as sets that support the ability to attach user-supplied output containers. Self-assembled consumables will be provided with connectors to support use in a BSC, with weldable tubing to allow use in lower grade background environments downstream. The platform supports fill volumes from as low as 1 mL and fluid flow rates up to 400ml/min.

The Sexton Signata CT-5™ processing capabilites:

1. **Fill into final container:** Transfer contents into multiple CellSeal cryovials, cryostorage bags, or user specified containers using connectors or weldable tubing.

2. **Product formulation and fill:** Reduce time in cryoprotectant by formulating and filling using the same system.

3. **Media preparation:** Mix media from up to three sources and aliquot into multiple containers for use during manufacturing.

4. **Cell washing/Media Exchange:** Connect to 2D or 3D growth vessels and exchange media.

5. **Fluid filtering (with wash):** Fluid is pumped from up to two source vessels through a filter, positioned off the system, into an output vessel. Optionally, fluid from a third source vessel may be used to "wash" the product from the filter into a final output vessel.

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.

Contact us for more information at:

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