

VIABLE MANUFACTURE OF CELL THERAPIES THROUGH THE INTEGRATION OF MULTIPLE UNIT PROCESSES ONTO A COUNTER-FLOW CENTRIFUGATION DEVICE

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With growing proof of efficacy in varied indications, regenerative medicine has reached a positive inflection point in the investment of time and money by established industry leaders and disruptive startups. With rapid growth comes the need to devote resources to the engineering challenges that currently prevent the quick and cost-effective manufacture of therapies that maintain a consistent, high-level of quality and, in turn, can support commercial manufacturing. This is especially true when looking at patient specific cell therapies that require rapid change over of equipment and benefit little from traditional sterile barriers (i.e. filters and heat inactivation). Counter-flow centrifugation (CFC) presents an intriguing technology that, when implemented using closed and automated system, provides a platform for upstream and downstream processing of cellular therapies by incorporating multiple unit processes and mitigating the risk imposed with manual equipment transfers.

The CFC technology under development by a partnership Hitachi Chemical Advanced Therapeutic Solutions (HCATS) and Invetech compounds the benefits of a fully integrated, closed processing kit with easily customizable procedures to integrate multiple unit processes onto a singular device. Increased integration of unit processes will be integral to addressing the dynamic challenges of commercial cell therapy manufacturing in a scaled-out model. This CFC device has shown the capability to perform platelet wash steps with 99% efficiency and retain 100% of the mononuclear cells. The platform can then harvest a concentrated volume of cells or shift directly into an elutriation protocol to separate hematopoietic cell populations. Further development work is being done to create a CAR-T manufacturing protocol using the device and to establish fill/finish capabilities. By incorporating multiple unit processes onto a device that also meets the need for rapid change-over between lots this device offers a unique solution to the emergent challenges of cell therapy manufacturing.



Figure 1. Image of performing a platelet wash on an incoming apheresis collection using counter-flow centrifugation.