

CREATING COMMERCIAL MANUFACTURING OPPORTUNITIES FOR REGENERATIVE MEDICINE BY INTRODUCING CLOSED, AUTOMATED SOLUTIONS WITH SINGLE-USE PRINCIPLES

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Cell and gene therapy, with growing proof of efficacy in varied indications, has reached an inflection point resulting in a steep increase in the investment of time and money by established companies and disruptive startups. With rapid growth comes the need to quickly and economically manufacture 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) or economies of scale. Counter-flow centrifugation (CFC) presents an intriguing technology that, when implemented onto a closed and automated system, provides a platform for upstream processing of cell therapies by incorporating multiple unit processes and mitigating the risk imposed with frequent equipment changes.

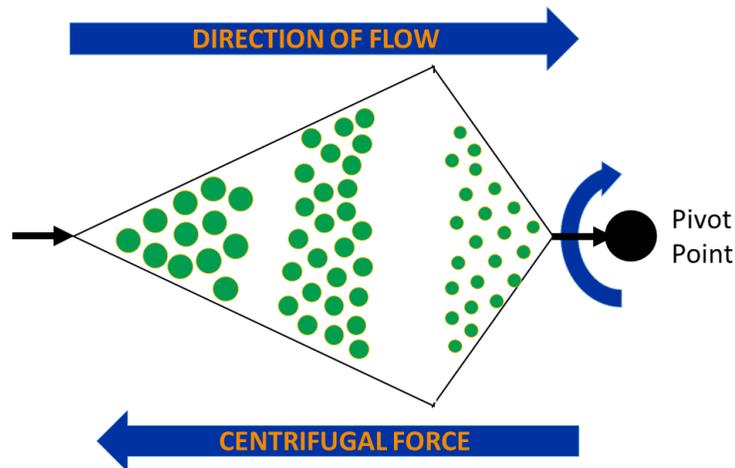


Figure 1. Illustration of counter-flow centrifugation and how it separates objects on a basis of size and density.

The CFC technology under development through a partnership by Hitachi Chemical Advanced Therapeutic Solutions (HCATS) and Invetech uses single-use processing kits with dynamic fluid paths to address the challenges of commercial cell therapy manufacturing. 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. By utilizing single-use disposables, this platform sees a large cost and time reduction from the large lot number of patient specific therapies. The CFC device provides an effective process solution that exploits single-use technology to meet the commercial manufacturing needs of regenerative medicine.

This work will highlight the benefits of moving to closed, automated solutions for reduction in cost, increase in robustness, increase in scale potential, increase in efficiencies across the therapy lifecycle will highlight important factors in considering a move to automated, closed solutions for individual therapies, utilizing the CFC technology as an in-depth case study.