ACOUSTIC CELL PROCESSING (ACP) AN INNOVATION IN CELL THERAPY MANUFACTURING

Nina Bauer, FloDesign Sonics
n.bauer@fdsonics.com

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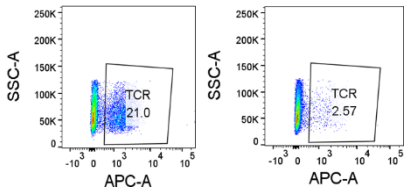
With a significant portion of cell therapy manufacturing costs being attributed to consumables and inefficient processes, there is an enormous industry-wide focus on the industrialization and overall improvement of cost of goods. To date, the focus has been to develop closed, integrated systems with automation. Therapeutic innovators are sometimes creating these systems on their own or through collaboration with equipment vendors. Although incremental improvements have been made through this approach, there is concern that these ad-hoc solutions will not meet the demands of production for large patient populations. This is due to the inherent technologies for each unit operation and their technical limitations.

Acoustic waves have long been known to have the capability to manipulate particles of all sizes in suspension in a closed, continuous manner. Now this technology, now called Acoustic Cell Processing (ACP), is being applied to key steps in the cell therapy manufacturing process as discrete unit operations such as cell selection, transduction, and concentrate/wash.

This presentation will highlight data generated by FloDesign Sonics in collaboration with several clients showing the capability of ACP. It will specifically focus on marked improvements in yield, shear force reduction and reduction in processing time. These improvements all lead to a reduction in the cost of goods, which will ultimately lead to increased access to life-saving therapies. Case study data for both Acoustic Concentrate / Wash (ACW) and Acoustic Affinity Cell Selection (AACS) with be provided (sample data below). Will be supplemented this process data with cost of goods analysis to highlight the real world impact of ACP in the production of therapeutics.

Representative AACS Data

Cell Surface Marker	Cell Conc. (x10^6/mL)	Feed Vol. (mL)	Initial % TCR-cells	Final % TCR-cells	Recovery % TCR-cells
TCR	10	100	79	96	89
TCR	30	100	79	94	95



Representative ACW Data

Process Inputs	Low Cell Density						High Cell Density
Kit Used	FDS-1LE	FDS-1LH	FDS-1LH	FDS-1LH	FDS-1LH	FDS-1LH	FDS-1LH
Volume (mL)	1105	750	1000	1000	1000	1250	950
Viable Cell Density (million/mL)	1.86	40.0	5	7	9	20	35.3
Process Outputs							
Volume (mL)	6.9	100	12	30	100	100	48.9
Cell viability Δ (%)	-1.2	-3.2	-0.2	+0.2	+0.4	-0.2	-0.8
Process Performance							
Viable Cell Recovery (%)	84	83	80	89	93	84	86
Volume Reduction Factor	160-fold	7.5-fold	83-fold	33-fold	10-fold	160-fold	19-fold
Process Time (minutes)	51	60	90	90	90	90	33