

Cell line development for biopharmaceutical production: The simplicity and cost-efficiency advantages of the Namocell Single Cell Dispenser



"The introduction of Namocell Single Cell Dispenser has brought significant reduction in sorting time and cost of goods. The device is small, quick to set up and easy-to-use with high probability of monoclonality and clonal outgrowth."

Lina Chakrabarti, PhD
Associate Director R&D
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Building the framework for successful cell line development

Biotherapeutics represent a powerful and promising modality of treatment for a multitude of conditions, including cancer, autoimmune diseases, hematological disorders and more. Cell lines are the bedrock of the manufacturing of most of today's biotherapeutics. Developing cell lines that produce the therapeutic molecules with high productivity, in a safe and time- and cost-effective way is at the core of cell-based biopharmaceutical industry.

Dr. Lina Chakrabarti leads a team at AstraZeneca that tackles such core capability. Her work focuses on continuous improvement of the efficiency, predictability, and robustness of the cell line development process to produce biotherapeutic

proteins. Dr. Chakrabarti's experience spans the entirety of the biomanufacturing cell line development process, from transfection to cell banking, and includes flow cytometry assay development for target cell isolation, phenotype and genotype characterization, feeding strategies and process development.

Dr. Chakrabarti has led development of several novel methodologies¹ as well as applications of new and conventional technologies to continue pushing for more efficient and streamlined cell line development processes.

Ensuring reproducible product quality

A regulatory emphasis in biopharmaceutical manufacturing is that a production cell line must be derived from a single cell progenitor,

to ensure consistent product quality throughout the production process and within a defined cell age beyond the production process. It is paramount in Dr. Chakrabarti's work to ensure her cell lines are monoclonal, stable, with consistent product quantity and quality that are thoroughly characterized.

It is also critical to ensure sterility and minimize cross contamination from other cells. The ultimate goal of biopharmaceutical production is patient safety and drug efficacy.

Namocell Single Cell Dispenser - an effective single cell sorting solution

Dr. Chakrabarti, along with other veteran scientists in the cell line development space, had experienced the transition from using the manual,

low efficiency limiting dilution method to higher throughput fluorescence-activated cell sorting (FACS) for plating single cells for clonal growth.

While FACS sorting technologies boosted the efficiency in isolating target single cells, they are expensive and resource-heavy devices, with large footprints and requiring highly skilled operators. On a day-to-day basis, they often take hours for setup, and the cost of consumables and large volumes of sheath fluid that is required can be cost-prohibitive for many labs that are facing budget constraints.

In addition, for Good Manufacturing Practice/ Good Clinical Practice (GMP/GCP) it's important to maintain sterility and eliminate cross contamination. However, most current FACS sorters do not have disposable fluidics. With the few that offer such an option, the cost of disposable components presents a major hurdle.

As a well-recognized expert in the International Society for Advancement of Cytometry (ISAC), Dr. Chakrabarti has an informed view on the pros and cons of various cell sorting technologies³. With its small footprint, budget-friendly price point, rapid setup, fast single cell dispensing and disposable microfluidic cartridge, the **Namocell** Single Cell Dispenser presented Dr. Chakrabarti with an attractive multi-parametric solution for single cell sorting for biopharmaceutical cell line development.

The introduction of the Namocell Single Cell Dispenser has brought a significant reduction in sorting time and cost of goods to Dr. Chakrabarti's team, while the flow cytometry capability allows selection of clones using markers predictive of high productivity, which helps reduce the clone screen size. The simple operation not only saves staff time, but also makes the device accessible to more end users to operate on their own without

special training. The advantages of the Namocell Single Cell Dispenser make it a compelling single cell sorting solution for biopharmaceutical cell line development.

Reference:

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3. Czechowska *et al.*, Current and Future Challenges in Cytometry: Reports of the CYTO 2018 Conference Workshops. *Cytometry A.* 2019 Jun; 95(6): 598-644. doi:10.1002/cyto.a.23777. PMID: 31207046.



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