



# Development of chemistry, manufacturing and control (CMC) framework for bioengineered extracellular vesicles for phase I clinical trial in oncology

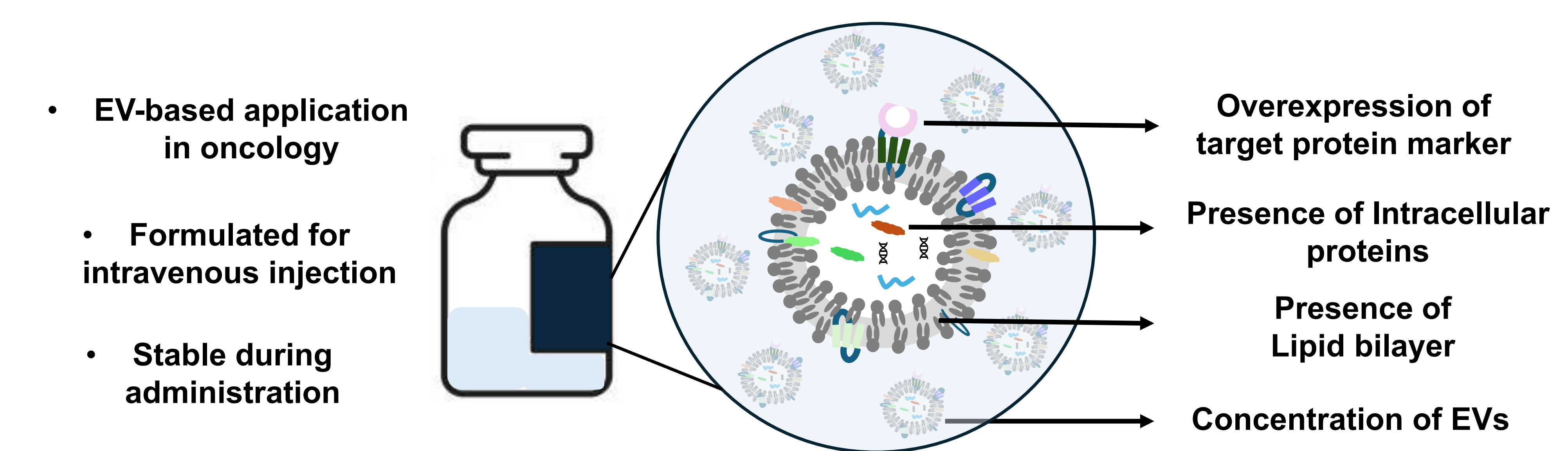
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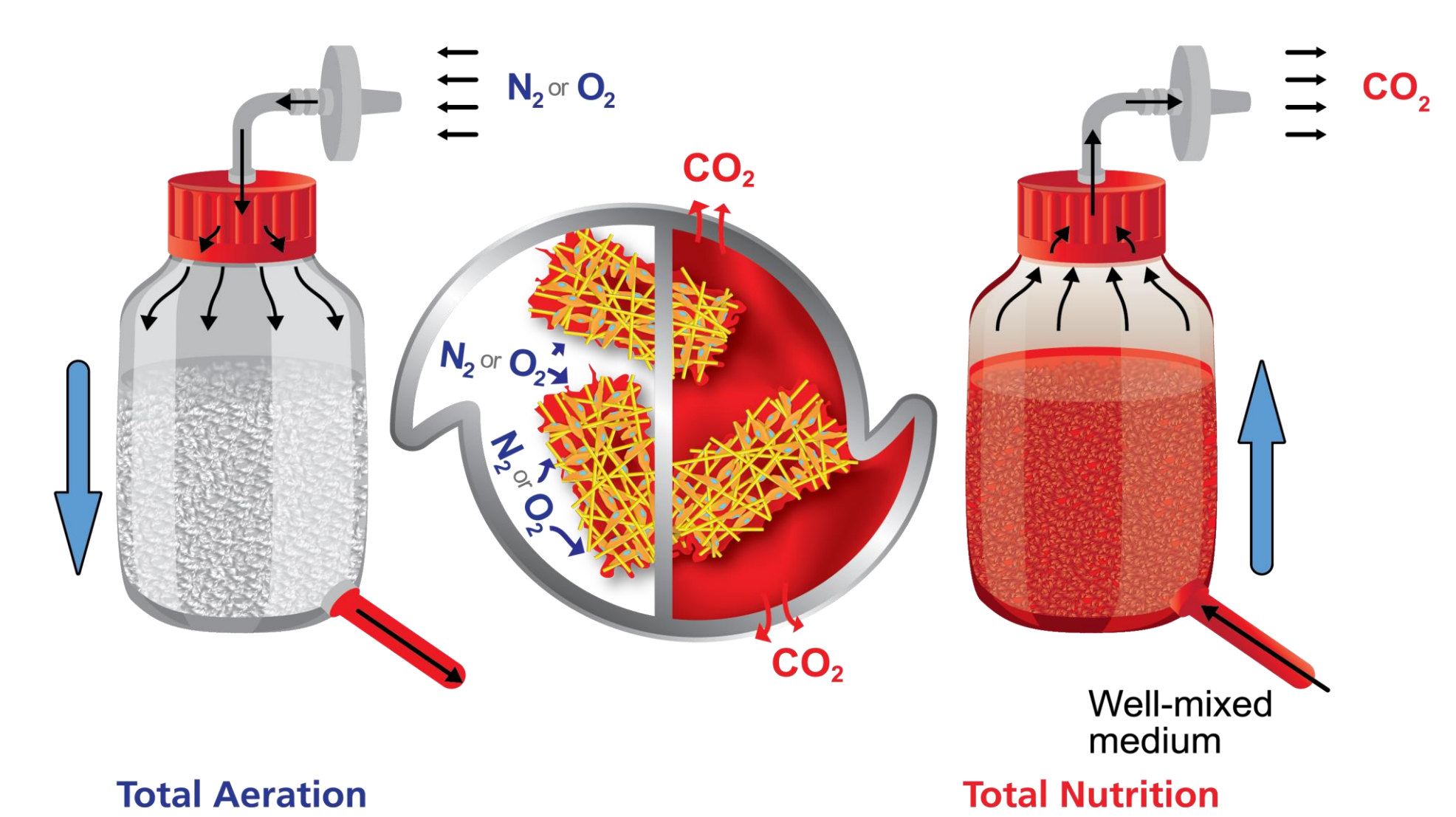
Summary

Extracellular vesicles (EVs) exhibit structural and molecular heterogeneity due to their diverse origins. Their production conditions may influence the characteristics of EVs. A CMC framework is required to support consistent and scalable manufacturing, complement with analytical characterization of EVs, that meet regulatory quality standards for clinical applications. This framework focus on three key aspects, mainly the design, manufacturing and analytical characterization methodology of the bioengineered EVs.

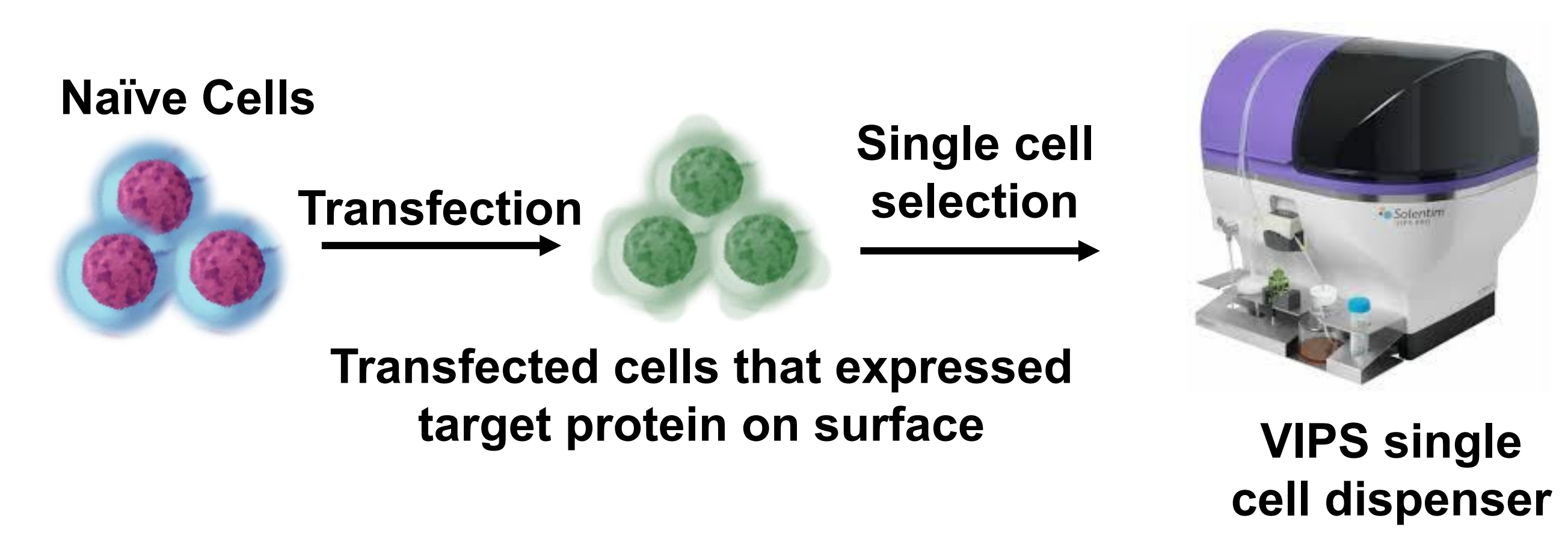
Quality Attributes of EV Product



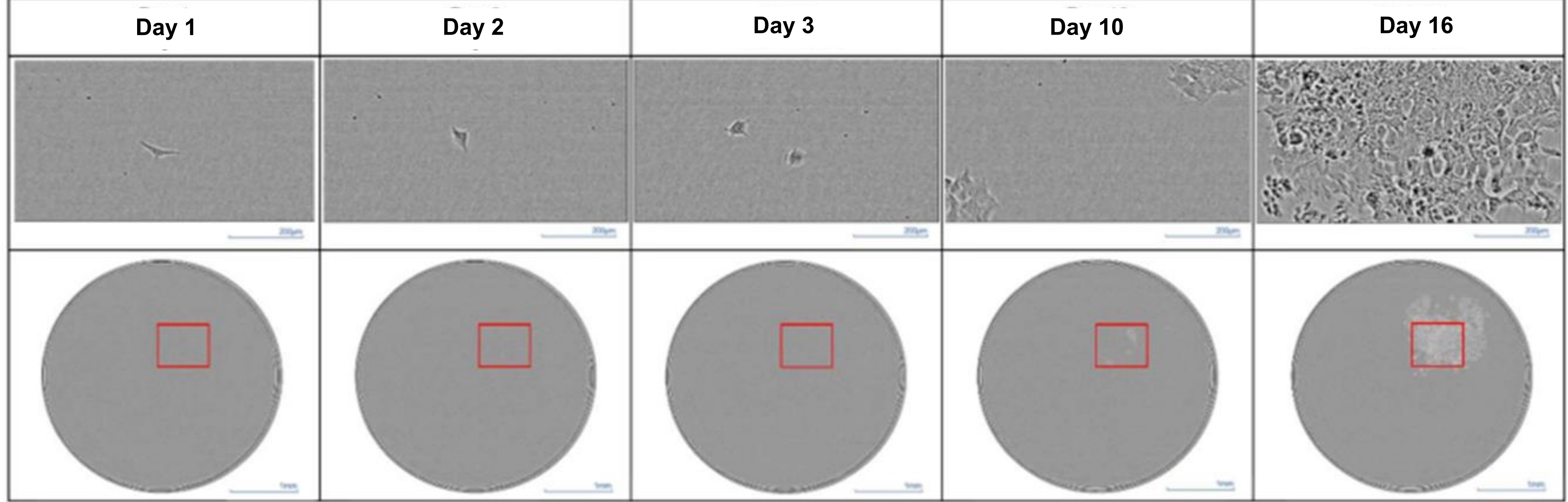
Tide Motion Platform for Cell Cultivation



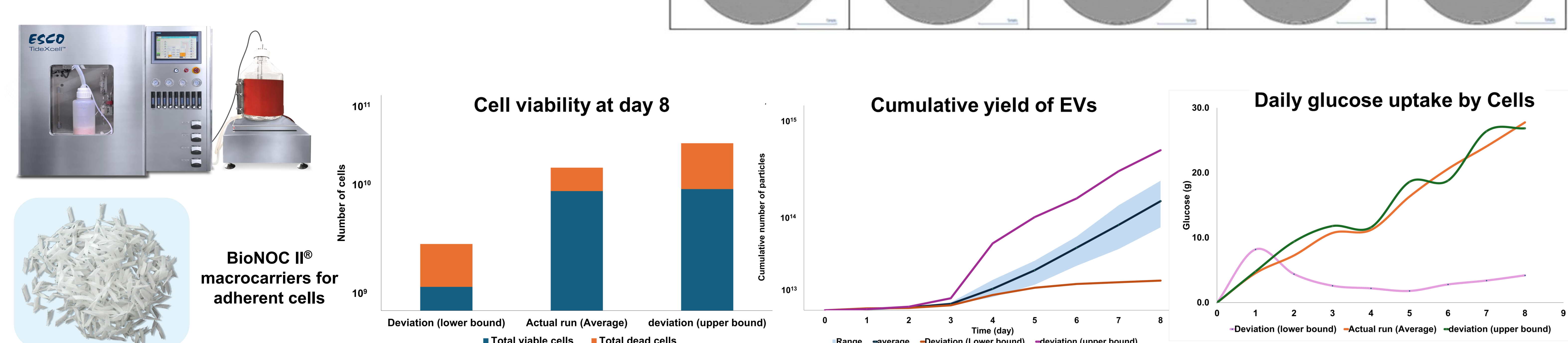
Cell Line Creation



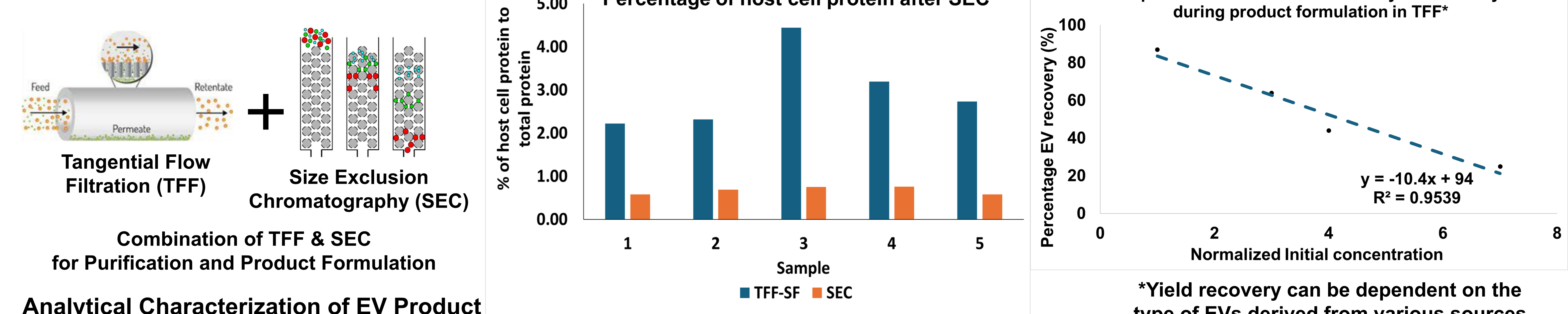
Single Cell Selection Image



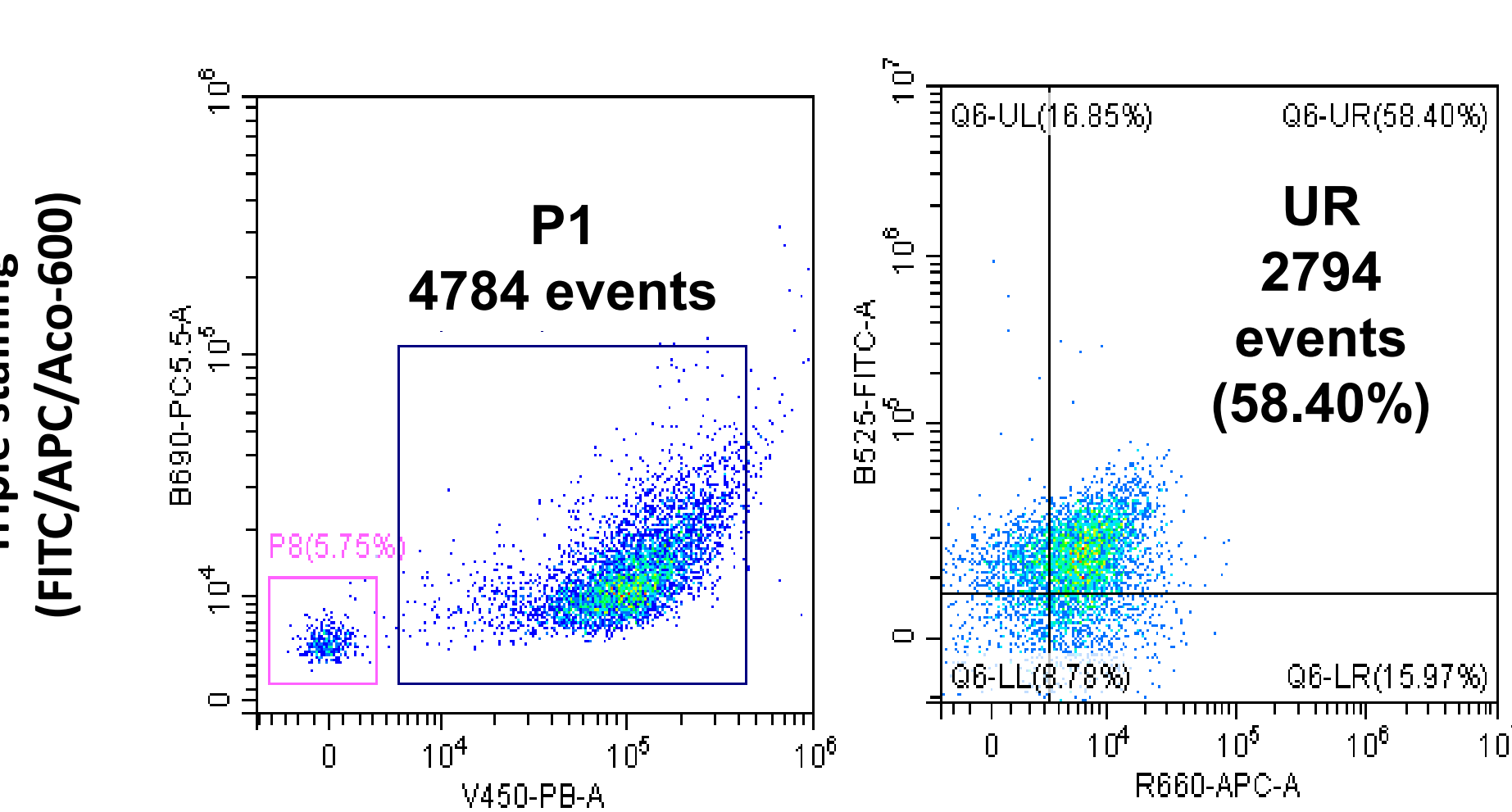
Cultivation condition of cells in TideXcell®



Downstream Process Development



Analytical Characterization of EV Product

Characterization of EVs Using Flow Cytometry		Analytical characterization		Results	Analytical characterization		Results
	<ul style="list-style-type: none"><li>EVs are positive for lipid bilayer by staining with water-soluble lipid membrane dye (Acoerela A600)</li><li>Sample stained with EV-specific markers</li></ul>	Visual Inspection		Pass	Concentration of Intracellular Protein (pg/mL)		100-150
		Turbidity		Pass	Host Cell Protein Concentration (µg/mL)		As per requirement
		Particle Size (nm)		80-150	Endotoxin		Pass
		Particle Concentration (Particles/mL)		As per requirement	Mycoplasma		Negative
		Concentration of Target Protein Marker (ng/mL)		As per requirement	Sterility		Pass

Funding: This project is kindly sponsored by China Medical University Hospital and Shine-On Biomedical Co. Audience may refer to the scientific work presented by China Medical University Hospital titled “ Genetically engineered HLA-G targeted exosomes and safety study” during the ISEV2025 conference. The poster number is 848 and is held in Poster session 2 on Friday, 25<sup>th</sup> April 2025 at 1630 -1730 CET.

About Esco Aster: A CDMO organization focuses on cGMP compliant end to end manufacturing process. We focus on offering vaccine-, bio-, cell- and gene-therapy development manufacturing services using primarily its proprietary Adherent Tide Motion Platform supplemented by single-use suspension, downstream bioprocessing, and custom bioengineering equipment for client specific therapeutics.