RAPID PRODUCT CHARACTERIZATION FOR RELEASE USING MEMBRANE MICROSCOPY

Bernardo Cordovez, PhD, Halo Labs, USA
bernardo.cordovez@halolabs.com

Key Words: CAR-T, rapid particle analysis, lentivirus, lot release, Dynabeads

Cell, protein, and viral aggregates are critical quality attributes for all biological products. Subvisible biotherapeutic product aggregates indicate low product stability and low shelf life. In addition, these attributes are a crucial indicator of potential immunogenicity for a given biological drug. The FDA suggests that “strategies to minimize aggregate formation should be developed as early as feasible in product development.” Cell therapies present a unique challenge in that cells themselves are subvisible in nature, and distinguishing cells vs. large cellular aggregates and other product impurities remains a challenge, until now. Aura™ is the first system specifically designed to count, characterize, and ID particles in a rapid and low-volume assay by combining membrane microscopy with labeled fluorescence.

Here, we demonstrate how to the Aura quickly and accurately finds trace amounts of subvisible and visible particle contaminants in cell and gene therapy materials. Some examples include residual Dynabeads in CAR-T cell products, identifying the presence of extraneous fibers, and lentiviral aggregates. Aura enables the ability to characterize, size and identify every particle in across every cell and gene therapy experiment.