

Confirming Instrument to Instrument Equivalence with Slingshot Biosciences ScatterBridge™ Controls

CATEGORY Flow Cytometry

PRODUCT ScatterBridge™ Scatter Controls

Overview

As cell therapy manufacturing expands across distributed facilities at multiple sites and even on multiple continents, analytical comparability becomes a prerequisite for scale.

Flow cytometry is a foundational QC method for cell therapy characterization, yet the industry continues to rely on variable donor-derived PBMCs as reference controls. Biological variability makes it difficult to distinguish donor-driven noise

from differences in methods or instrument performance. This variance complicates site-to-site comparisons, extends validation timelines, and increases operator dependency during method transfer.

Filling the Missing Gap in Flow Cytometry QC

As a development and manufacturing organization expanded from single-state/single-site operations to a global network of manufacturing facilities, their analytical methods were required to transfer rapidly and reproducibly across sites.

This growth required QC reference materials that:

- ▶ Are independent of donor availability and biology
- ▶ Enable direct site-to-site comparison
- ▶ Support regulatory expectations for analytical consistency

Without standardized controls, QC became a bottleneck that limited the speed and reliability of global manufacturing expansion.

One Control Offered the Perfect Fit

Slingshot flow cytometry controls are designed to eliminate biological heterogeneity, allowing QC workflows to focus on what truly matters: instrument performance, method robustness, and operator consistency.

The manufacturer deployed ScatterBridge Scatter Controls across its laboratories, operators, and instruments. ScatterBridge delivers single-digit CVs and consistent accuracy to certified specifications, across lots and over time. By removing biological

variability as a confounding factor, synthetic controls enabled operator-, instrument-, and site-independent performance to directly support technology transfer and the comparability needs of regulatory agencies.

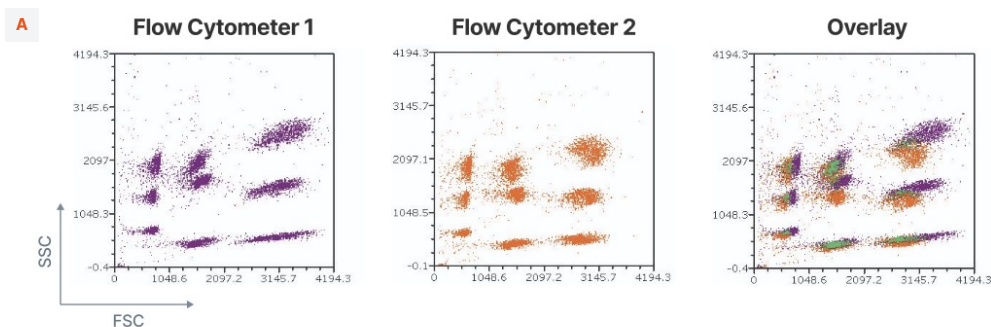
A Paradigm Shift in Quality Control Standardization

This work validates a fundamental shift from variable biological controls to standardized synthetic alternatives for flow cytometry quality control in cell therapy manufacturing.

By combining ScatterBridge Scatter Controls with their proprietary automated platform, this manufacturer was able to deploy identical QC methods across its network without requiring site-specific revalidation. Critically, ScatterBridge's synthetic, highly stable design eliminates the biological variability, limited shelf life, and shipping constraints associated with healthy-donor controls, enabling truly global standardization. The ability to deploy identical QC methods, monitor performance

continuously, and detect drift instantly positions this approach as a practical foundation for harmonized, lower-risk operations.

This case study highlights the capacity of ScatterBridge Scatter Controls to address one of the field's persistent challenges: achieving consistent, site-to-site scatter comparability in the expanding field of cell therapy development and manufacturing.



ScatterBridge™ synthetic hydrogel reference controls are available now through Slingshot Biosciences.

Visit us at slingshotbio.com to learn more.