



International Alliance for  
Biological Standardization

# WORKSHOP

## Analytics in Cell Therapy: Ensuring Quality in Flow Cytometry

Established Guidelines for Flow Cytometry  
and QC Needs in Cell Therapy



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Advanced cell and gene therapy has achieved remarkable success in blood cancers, regenerative medicine and genetic disorders. Most cell-based therapeutic products (cell, tissue and genetically modified cells) utilize flow cytometry as part of quality control; yet flow cytometry assays are still very much performed as a research assay designed to develop and optimize flow cytometry applications. The CLSI guidance document, H62, addresses the validation of flow cytometric methods but is primarily focused on translational and clinical applications. Currently there are no guidelines available for flow cytometry in quality control (QC) for cell therapy manufacturing.

This conference will bring together technical experts, QC personnel, regulators and other stakeholders to discuss how to ensure a flow cytometric method has appropriate reproducibility for QC in the manufacturing of cellular therapies. Discussions will cover sample preparation, suitability of analytical reagents (especially antibodies), instrument qualification (IQ, OQ, PQ) and data analysis.

### Scientific & Organizing Committee

- **Ruud HULSPAS**, Chair, Dana-Farber Cancer Institute (DFCI) - Harvard University
- **Chris BRAVERY**, IABS Chair of the Cell & Gene Therapy Committee, AdvBiols
- **Scott BURGER**, Advanced Cell & Gene Therapy
- **Tamara LASKOWSKI**, CTMC
- **Virginia LITWIN**, International Society for Advancement of Cytometry
- **Peter LOPEZ**, NYU Grossman School of Medicine

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