

CELLULAR THERAPY INSPECTION AND ACCREDITATION WORKSHOP AGENDA

- 7:00 am Registration
- 8:00 am Welcome Address *Patrick Hanley, PhD*
- 8:15 am Overview of FACT Accreditation Process *Phyllis I. Warkentin, MD*
- 9:15 am Building Quality into Clinical Immune Effector Cell Programs *Carlos Bachier, MD*
- 10:00 am Risk Evaluation and Mitigation Strategies *Dennis Gastineau, MD*
- 10:30 am **Break**

New Inspector Training	General Sessions
10:45 am The Importance of a Pre-Inspection Review <i>Jean Sanders, MD</i>	10:45 am Using the Tracer Methodology to Assess Compliance with Standards <i>Phyllis I. Warkentin, MD</i>
11:30 am Lunch	11:30 am Lunch
	Avoiding Citations
12:00 pm Exploring the On-Site Inspection <i>Abba Zubair, MD, PhD</i>	12:00 pm Common Citations Overview <i>Joseph Schwartz, MD, MPH, FACP</i>
12:45 pm Conducting an Effective Exit Interview <i>Joseph Lynch, MD</i>	12:30 pm Quality Management Citations <i>Patrick Hanley, PhD</i>
1:30 pm Viewing of an On-Site Inspection <i>Phyllis I. Warkentin, MD</i>	1:15 pm Personnel Citations <i>Donna Salzman, MD</i>
2:15 pm Writing a Clear and Compelling Inspection Report <i>Paul Eldridge, PhD</i>	1:45 pm Allogeneic and Autologous Donor Selection, Evaluation, and Management Citations <i>Jean Sanders, MD</i>
	2:30 pm Program Integration <i>Joseph Schwartz, MD, MPH, FACP</i>

- 3:00 pm **Break**
- 3:15 pm FACT Process for Reviewing Clinical Outcomes *Dennis Gastineau, MD*
- 4:00 pm Improving Data Management through Follow-Up *Phyllis I. Warkentin, MD*
- 4:45 pm Expert Panel
- 5:00 pm Adjourn