

## FACT CELLULAR THERAPY INSPECTION AND ACCREDITATION WORKSHOP September 12, 2019

7:00 am	Registration		
8:00 am	Welcome Address		
8:15 am	Overview of the FACT Accreditation Process Joseph Schwartz, MD, MPH		
9:15 am	Quality Management in Novel Cell Therapies Jean Sanders, MD		
10:15 am	<b>Break</b>		
	<b>Challenges Complying with Standards</b>		<b>Inspector Training Track</b>
10:30 am	Challenges with Compliance Lizette Caballero, BS, MT(ASCP)	10:30 am	The Making of a Model Inspector Joseph Schwartz, MD, MPH
11:30 am	Activity: Evaluating Compliance	11:15 am	Pre-Inspection Preparation Joseph Schwartz, MD, MPH
12:15pm	<b>Lunch</b>	12:15 pm	<b>Lunch</b>
12:45 pm	Occurrence Management, Auditing, and The Five Whys: Root Cause Analysis Activity: <i>Five Whys</i> Federico Rodriguez, SBB, MLS(ASCP) <sup>CM</sup>	12:45 pm	Inspection Process Activity <i>Inspection Checklist</i> <i>Document Review</i> Joseph Schwartz, MD, MPH Charles Branson, MS Federico Rodriguez, SBB, MLS(ASCP) <sup>CM</sup> Jean Sanders, MD
1:45 pm	Risk Assessment Activity: Risk Stratification Lizette Caballero, BS, MT(ASCP)		
2:45 pm	<b>Break</b>	2:45 pm	<b>Break</b>
3:00 pm	Environmental Monitoring Aisha Khan, PhD	3:00 pm	Inspection Process Activity Continued <i>Tour and Medical Record Review</i>
4:00pm	Transportation and Shipping Aisha Khan, PhD Activity	4:30 pm	Accreditation Doesn't End With the Inspection Federico Rodriguez, SBB, MLS(ASCP) <sup>CM</sup>
5:00 pm	<b>Adjourn</b>	5:00 pm	<b>Adjourn</b>