

# FACT Clinical Inspector Training Course

*prior to the* **TANDEM MEETINGS**

**February 3, 2026**
**8:00 AM - 5:00 PM**

**Wasatch Room | Hilton Salt Lake City Center**
*255 South West Temple | Salt Lake City, UT 84101*

## Host



**Phyllis I. Warkentin, MD**
Chief Medical Officer
FACT

## Speakers



**Joseph Schwartz, MD, MPH**
Senior Medical Officer
FACT



**Suzanne Birnley, MS, MBA**
Director of Operations
FACT

## Agenda

*Check-in will begin at 7:30 AM.*
*Breakfast is **not** provided.*

Early badge pickup is available February 2 from 5:00-5:30 pm at the Registration Room, across following the Quality Boot Camp.

**7:55 AM - 8:00 AM** (5 MIN)
**WELCOME**



**8:00 AM - 9:00 AM** (60 MIN)
**PREPARATION ESSENTIALS**



Inspector Trainees will receive a focused session to deepen their understanding of FACT inspections, starting with an in-depth review of the Eighth Edition Inspector Test and Knowledge Check results to guide discussion and preparation strategies.

**9:00 AM - 9:30 AM** (30 MIN)
**PORTAL SESSION 1** - REVIEWING THE COMPLIANCE APPLICATION



This session will focus on mastering the FACT Accreditation Portal and building key evaluation skills, with hands-on training in navigating features, using tools, and managing documentation.

**9:30 AM - 9:45 AM** (15 MIN)
**BREAK**

## Facilitators



**Kimberly Kasow, DO**
Vice-President, Medical and Quality Services
NMDP



**Jean Sanders, MD**
Professor Emeritus - Clinical Research Division, Fred Hutch Cancer Center



**Basem William, MD, MRCP(UK), FACP**
Clinical Director, BMT/IEC Program, Professor (Adj), John P. McConnell Endowed Chair in Cancer Research, OhioHealth



**Deepika KC, MS, BS(ASCP)**
Associate Director-Cell Therapy Lab
Banner MD Anderson Cancer Center



**Fen Fen Hsieh, MS, H(ASCP)CMQUIA, CM**
Apheresis and Processing Supervisor
University of Utah Transplant and Cellular Therapy Program at Huntsman Cancer Institute and Intermountain Primary Children's Hospital

FACT FOUNDATION FOR THE ACCREDITATION OF CELLULAR THERAPY

**9:45 AM - 10:15 AM** (30 MIN)

## INSPECTION PROCESS, PART 1



Inspector Trainees will explore key steps in the FACT inspection process, gain hands-on experience with inspector tools, and develop skills for evaluating pre-inspection documents against FACT requirements alongside experienced inspectors.

**10:15 AM - 11:45 AM** (30 MIN)

## PARTICIPATORY WORK WITH INSPECTORS

**11:45 AM - 12:15 PM** (45 MIN)

**LUNCH BREAK**

**12:15 PM - 12:45 PM** (30 MIN)

## INSPECTION PROCESS, PART 2



Inspector Trainees will deepen their understanding of inspection processes by exploring evidence gathering, compliance assessment, and on-site tour evaluations through real-world scenarios and checklist application.

**1:15 - 2:15 PM** (60 MIN)

## INSPECTION PROCESS, PART 3



This session trains Inspector Trainees to review on-site documents, identify key compliance issues, and determine areas needing further inspection, building skills for conducting effective inspections.

**2:15 PM - 2:30 PM** (15 MIN)

**BREAK**

**2:30 - 3:00 PM** (30 MIN)

## COMMON CITATIONS



This session will cover common deficiencies in cellular therapy programs, with a focus on identifying and clearly citing them per FACT guidelines. Inspector Trainees will build analytical skills through case examples and hands-on citation practice.

**3:00 PM - 3:30 PM** (30 MIN)

## PARTICIPATORY WORK WITH INSPECTORS - WRITING CITATIONS

**3:30 PM - 4:00 PM** (30 MIN)

## PORTAL SESSION 2 – ENTERING CITATIONS AND COMPLETING THE REPORT



This final portal session highlights key features of the FACT Accreditation Portal, with hands-on practice entering citations, marking checklist items, and completing inspection reports to support a consistent accreditation process.

**4:00 PM - 4:30 PM** (30 MIN)

## ACCREDITATION DOESN'T END WITH THE INSPECTION



Inspector Trainees will learn key components of a successful exit interview, analyze inspection reports and citations, and explore best practices for post-inspection activities to enhance their effectiveness.

**4:30 PM - 4:45 PM** (15 MIN)

## ASK FACT ANYTHING - FACILITATOR PANEL

**4:45 PM - 5:00 PM** (15 MIN)

## CLOSING