



THE KEY TO COMPLIANCE SUCCESS

9:00 AM

Cheryl Hutchins, PhD

Dr. Hutchins will review the entire compliance application process and identify documents required for submission.

ACTIVITY: EVALUATING COMPLIANCE

9:30 AM

Cheryl Hutchins, PhD

Dr. Hutchins will help facilitate case studies. The audience will identify what challenges the program faces after each case. She will poll the audience to determine what standards may not be in compliance. Ultimately, Dr. Hutchins, with the help of the audience, will answer how the program can achieve compliance with FACT Standards and continue FACT accreditation.

BREAK

10:00 AM

WHAT TO EXPECT DURING THE INSPECTION

10:15 AM

Eneida Nemecek, MD

Dr. Nemecek will review clinical program requirements during a FACT inspection. She will also list tips and identify strategies to help clinical programs navigate a successful inspection process.

ACTIVITY: INSPECTION TOUR

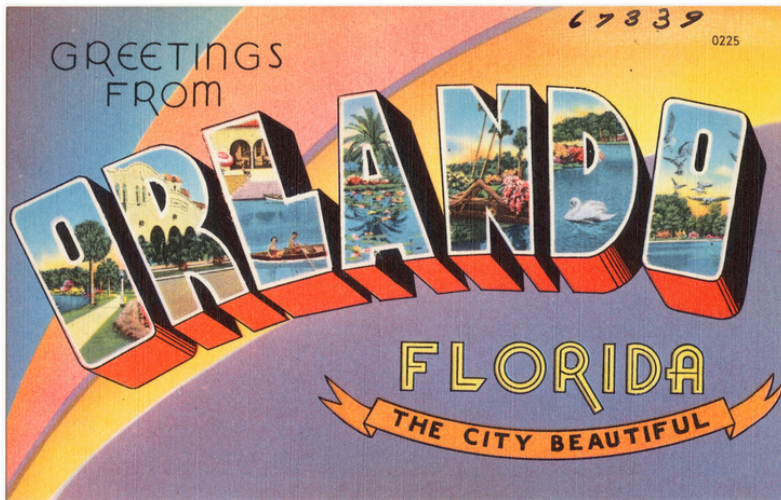
10:45 AM

Eneida Nemecek, MD

Dr. Nemecek will walk participants through guided tour of a clinical program unit.

ACCREDITATION SUCCESS STORY

11:15 AM



Cellular Therapy Accreditation Workshop

Tuesday, February 14, 2023

Speakers



Priti Tewari, MD
The University of Texas
M.D. Anderson Cancer Center



Joseph Schwartz, MD, MPH
H. Lee Moffitt Cancer Center &
Research Institute Blood and
Marrow Transplant Program



Ngaire Elwood, PhD
BMDI Cord Blood Bank



Phyllis I. Warkentin, MD
Chief Medical Officer of FACT



Cheryl Hutchins, PhD
The Royal Brisbane & Women's
Hospital and Queensland Children's
Hospital Cellular Therapy Program



Eneida Nemecek, MD
Northwest Marrow Transplant
Program at Oregon Health &
Science University, Legacy Good
Samaritan Hospital and Medical
Center and Doernbecher Children's
Hospital

REGISTRATION

7:30 AM

WELCOME

8:00 AM

OVERVIEW OF THE FACT ACCREDITATION PROCESS

8:05 AM

Phyllis I. Warkentin, MD

Dr. Warkentin will describe the accreditation process from application to accreditation. She will define common terminology for the accreditation process and explain the function of the accreditation coordinator. Dr. Warkentin will also summarize the inspector's role in the process of accreditation. The audience will participate in interactive knowledge checks throughout the presentation.

LUNCH

11:30 AM

LEVERAGING FACT ACCREDITATION TO REDUCE AUDIT BURDENS ON PROGRAMS

12:15 PM

Phyllis I. Warkentin, MD

Dr. Warkentin will discuss current activities aimed at leveraging FACT Accreditation to reduce commercial manufacturer audit burdens on programs.

QUESTIONS

12:45 PM

CORRECTION OF DEFICIENCIES

1:00 PM

Joseph Schwartz, MD, MPH

Dr. Schwartz will explain the most common challenges in complying with the clinical Standards, and construct a plan to correct the deficiencies.

ACTIVITY: DISSECTING AND RESPONDING TO DEFICIENCIES

1:30 PM

Joseph Schwartz, MD, MPH

Dr. Schwartz will practice evaluating and responding to deficiencies with the audience.

BREAK

2:15 PM

ACCREDITATION SUCCESS STORY

2:30 PM

COMPONENTS OF CORRECTIVE ACTION PLANS AND AUDITS FOR OUTCOMES AND DATA MANAGEMENT

2:45 PM

Priti Tewari, MD

Dr. Tewari will discuss FACT requirements for corrective action plans to improve clinical outcomes and expectations of applicants for data management.

MAINTAINING FACT READINESS

3:30 PM

Ngairé Elwood, PhD

Dr. Elwood will discuss developing a plan for continuous accreditation readiness. She will also explain how regular self-assessment of your program will help maintain readiness, and how to prepare employees so that accreditation is maintained.

ACTIVITY: STRATEGIES TO MAINTAIN READINESS

4:00 PM

Ngairé Elwood, PhD

Dr. Elwood will facilitate case studies and work with attendees to determine how to maintain compliance readiness.

CLOSING

4:45 PM

