

FACT Cellular Therapy Accreditation Workshop

FEBRUARY 20, 2024 | 8:00 AM - 5:00 PM

Presenters



Joseph Schwartz, MD, MPH
HOST
Director of Transfusion Services at H. Lee Moffitt Cancer Center & Research Institute Blood and Marrow Transplant Program



Kimberly Kasow, DO
Director of Pediatric Bone Marrow Transplant at University of North Carolina



Michele Sugrue, MS, MT(ASCP)SBB
FACT Inspectorate



Nic Prokopishyn, PhD
Cellular Therapy Lab Director for the Alberta Blood and Marrow Transplant Program



Patrick Hanley, PhD
Chief & Director of the Cellular Therapy Program at Children's National



Phyllis I. Warkentin, MD
FACT Chief Medical Officer



Premal Lulla MD, MBBS
Assistant Professor of Medicine at Baylor College of Medicine, Stem Cell Transplant Program, Texas Children's Hospital and Houston Methodist Hospital



Suzanne Birnley MS, MBA
FACT Director of Operations

Agenda

REGISTRATION
7:30 AM

WELCOME
8:00 AM

Joseph Schwartz, MD, MPH

OVERVIEW OF FACT ACCREDITATION
8:05 AM

Joseph Schwartz, MD, MPH

Dr. Joseph Schwartz describes the accreditation process from application to accreditation. He defines common terminology for the accreditation process and explains the function of the accreditation coordinator. Dr. Schwartz also summarizes the inspector's role in the process of accreditation. The audience participates in interactive knowledge checks throughout the presentation.

THE KEY TO COMPLIANCE SUCCESS
9:00 AM

Michele Sugrue, MS, MT(ASCP)SBB

Michele Sugrue reviews the entire compliance application process and identifies documents required for submission.

ACTIVITY: EVALUATING COMPLIANCE
9:30 AM

Michele helps facilitate case studies. The audience identifies what challenges the program faces after each case. Michele polls the audience to determine what issues may not comply with the standards. Michele, with help from the audience, answers how the program can achieve compliance with FACT Standards and continue FACT accreditation.

ACCREDITATION SUCCESS STORY
10:00 AM

BREAK
10:15 AM

WHAT TO EXPECT DURING THE INSPECTION
10:30 AM

Kim Kasow, DO

Dr. Kim Kasow reviews clinical program requirements, offering insights for both preparation leading up to and during a FACT inspection. The presentation includes valuable tips and strategies to assist clinical programs in successfully navigating the inspection process.

ACTIVITY: CLINICAL VIDEO TOUR
11:00 AM

Dr. Kasow shows a clinical tour video demonstrating an inspector conducting a clinical inspection. Applicants are provided with a tour checklist and can mark compliant or not compliant next to the Standards applicable to the tour.

LEVERAGING FACT ACCREDITATION TO REDUCE AUDIT BURDENS
11:30 AM

Phyllis I. Warkentin, MD

Dr. Phyllis I. Warkentin discusses current activities aimed at leveraging FACT Accreditation to reduce commercial manufacturer audit burdens on programs.

ASK FACT ANYTHING
12:00 PM

Attendees have the opportunity throughout the morning presentations to submit questions for FACT presenters to answer.

LUNCH
12:15 PM

WHAT TO EXPECT AFTER THE INSPECTION
1:00 PM

Suzanne Birnley MS, MBA

Suzanne Birnley provides an overview of the steps in the accreditation process that occur after the inspection, including receiving your report and responding to deficiencies.

STANDARDS TEASER
1:15 PM

Nic Prokopishyn, PhD

Dr. Nic Prokopishyn will give an overview of the Standards development process and an update on the 9th Edition HCT Standards.

ACCREDITATION SUCCESS STORY
1:45 PM

CORRECTION OF DEFICIENCIES
2:00 PM

Joseph Schwartz, MD, MPH

Dr. Schwartz explains the most common challenges in clinical transplant and construct a plan to correct the deficiencies.

ACTIVITY: DISSECTING DEFICIENCIES
1:45 PM

Dr. Schwartz practices evaluating deficiencies with the audience and recommend correction.

BREAK
2:45 PM

COMPONENTS OF CORRECTIVE ACTION PLANS AND AUDITS FOR OUTCOMES AND DATA MANAGEMENT
3:00 PM

Premal Lulla MD, MBBS

Dr. Premal Lulla discusses FACT requirements for corrective action plans to improve clinical outcomes and expectations of applicants for data management.

MAINTAINING FACT READINESS
3:30 PM

Patrick Hanley, PhD

Dr. Hanley discusses a plan to ensure continuous accreditation readiness and explains the self-assessment process and how to manage turnover, so accreditation readiness is maintained.

ACTIVITY: STRATEGIES TO MAINTAIN READINESS
4:00 PM

Dr. Hanley facilitates case studies and works with attendees to determine how to maintain compliance readiness.

ASK FACT ANYTHING
4:30 PM

Attendees have the opportunity throughout the afternoon presentations to submit questions for FACT presenters to answer.

CLOSING
4:45 PM

Access a full directory of FACT resources and social channels by scanning this QR code or visiting https://linktr.ee/factcelltherapy

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