FACT Cellular Therapy Accreditation & Quality Principles Workshop

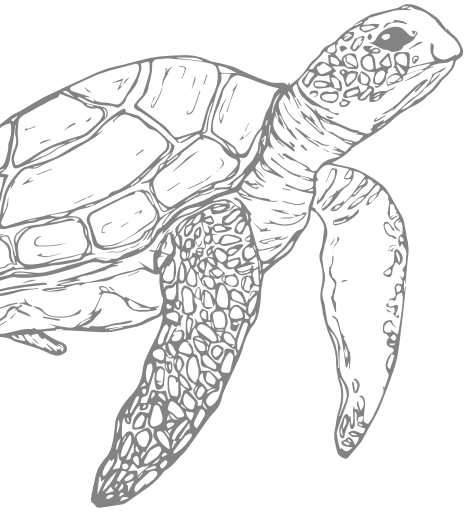
Tuesday, August 15, 2023

Speakers

Phyllis I. Warkentin, MD
Chief Medical Officer of FACT

TBD

TBD



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.

THE KEY TO COMPLIANCE SUCCESS
9:00 AM

TBD

The speaker will review the entire compliance application process and identify documents required for submission.

WHAT TO EXPECT DURING THE INSPECTION
9:30 AM

TBD

The presenter will review clinical program requirements during a FACT inspection. They will also list tips and identify strategies to help clinical programs navigate a successful inspection process.

BREAK
10:00 AM

CORRECTION OF DEFICIENCIES
10:15 AM

TBD

The presenter 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
10:45 AM

TBD

The presenter will practice evaluating and responding to deficiencies with the audience.

OUTCOMES & DATA MANAGEMENT
11:15 AM

TBD

LUNCH
12:15 PM

RISK ASSESSMENT
12:45 PM

TBD

The presenter will discuss quality tools for determining risk as well as guide attendees through the risk assessment process and execution.

ROUNDTABLE DISCUSSION - RISK ASSESSMENT
1:30 PM

Facilitators will guide attendees through performing a mock risk assessment using the quality tools discussed during the lecture.

VALIDATION
2:10 PM

TBD

The presenter will discuss will discuss how to choose what to validate, criteria to select when adding or changing a service, and performing the validation.

BREAK
2:50 PM

ROUNDTABLE DISCUSSION - VALIDATION
3:00 PM

Facilitators will guide attendees through a mock validation of a product or process using the information discussed during the lecture.

RISK MANAGEMENT
3:40 PM

TBD

The presenter will discuss quality tools and best practices for minimizing and managing risk.

ROUNDTABLE DISCUSSION - RISK MANAGEMENT
4:20 PM

Facilitators will guide attendees through a mock scenario of risk management using the quality tools and best practices discussed in the lecture.

CLOSING
5:00 PM