



## FACT Cellular Therapy Accreditation & Quality Principles Workshop

Tuesday, August 15, 2023

### Presenters



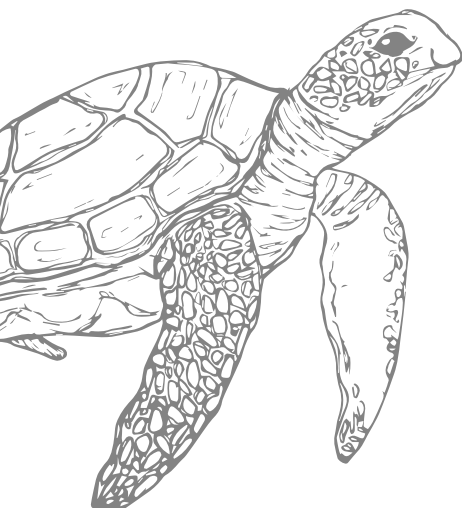
**Phyllis I. Warkentin, MD**  
Chief Medical Officer of FACT



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. Attendees will participate in interactive knowledge checks throughout the presentation.

### THE KEY TO COMPLIANCE SUCCESS

9:00 AM

**TBD**

The presenter 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 attendees.

### 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 presented quality tools.

**VALIDATION**

2:10 PM

**TBD**

The presenter 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 presented.

**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 presented quality tools and best practices.

**CLOSING**

5:00 PM

