



FACT Cellular Therapy Accreditation & Quality Principles Workshop

Tuesday, August 15, 2023

Presenters



Phyllis I. Warkentin, MD
Chief Medical Officer of FACT



Guy Klamer, PhD
Director of Sydney Cord
Blood Bank



Ngaire Elwood, PhD
Director of BMDI Cord
Blood Bank



Jennifer Postma, BSc
Quality Manager of Cell &
Tissue Therapies WA



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



Vicki Antonenas, BSc, MSc
Laboratory Director of Blood
Transplant and Cell Therapies,
The Children's Hospital at
Westmead

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

Guy Klamer, PhD

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

WHAT TO EXPECT DURING THE INSPECTION

9:30 AM

Guy Klamer, PhD

Dr. Klamer will review clinical program requirements during a FACT inspection. He 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

Ngaire Elwood, PhD

Dr. Elwood 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

Ngaire Elwood, PhD

Dr. Elwood will practice evaluating and responding to deficiencies with attendees.

OUTCOMES & DATA MANAGEMENT

11:15 AM

TBD

LEVERAGING FACT ACCREDITATION TO REDUCE AUDIT BURDENS ON PROGRAMS

11:45 AM

Phyllis I. Warkentin, MD

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

LUNCH

12:15 PM

RISK ASSESSMENT

12:45 PM

Jennifer Postma, BSc

Jennifer 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

Vicki Antonenas, BSc, MSc

Vicki 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.

AUDITS

3:40 PM

Cheryl Hutchins, PhD

Dr. Hutchins will discuss quality tools and best practices for minimizing and managing risk.

ROUNDTABLE DISCUSSION - AUDITS

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

