



FACT Cellular Therapy Accreditation Workshop

prior to the

**ANZ TCT ANNUAL
SCIENTIFIC MEETING**

**August 25, 2026
8:00 AM - 4:00 PM**

Pullman East Melbourne
192 Wellington Parade, East Melbourne VIC 3002

Hosts & Speakers



Phillip Johnson, MMedSc(Path)

*Director/Scientific Director
Queensland Cord Blood Bank
At The Mater*



Ngaire Elwood, AM PhD MAICD

*Director, BMDI Cord Blood Bank & Head,
Cord Blood Advanced Therapies
Research Laboratory, Stem Cell Medicine
BMDI Cord Blood Bank*

Speakers



Suzanne Birnley, MBA

*Director of Operations
Foundation for the Accreditation of
Cellular Therapy (FACT)*



Annette Trickett, PhD

*Processing Facility Director
Transplant and Cellular Therapies
Program, Kids Cancer Centre, Sydney
Children's Hospital*



Heather Conway

*Quality Manager
Foundation for the Accreditation of
Cellular Therapy (FACT)*



Daniel Kilmartin

*Quality Manager
Queensland Children's Hospital Blood
and Marrow Transplant Service*



Cheryl Hutchins, PhD

*Laboratory Director
The Royal Brisbane & Women's
Hospital and Queensland Children's
Hospital Cellular Therapy Program*



Michelle Trevisin

*FACT Project Officer
Peter MacCallum Cancer Centre,
Royal Melbourne Hospital*



Helen Impey

*BMTCT Program Quality Manager
Royal North Shore Hospital*



Clair Scott

*CAR-T Cell Coordinator
Fiona Stanley Hospital Blood and
Marrow Transplant Program*

Agenda

Check-in will begin at 8:00 AM - Breakfast is not provided.

8:25 AM - WELCOME



8:30 AM

ACCREDITATION 2.0: NAVIGATING THE PROCESS



This presentation will take a deeper dive into the evolving FACT Accreditation process, highlighting key updates, expectations, and practical strategies for successful preparation. Attendees will examine documentation, engage stakeholders, and integrate standards into everyday practice to streamline their next accreditation cycle.

9:00 AM

BEYOND THE REDLINES: 9TH EDITION HCT STANDARDS & IMPLICATIONS FOR PROGRAMS



This session reviews the key updates in the 9th Edition HCT Standards, the changes that extend beyond the redlined document, and their practical implications for transplant and cellular therapy programs. Participants will gain insight into how these revisions may impact program operations, quality management, and compliance strategies in preparation for upcoming accreditation cycles.

9:45 AM

DESIGNING FOR READINESS: HARDWIRING ACCREDITATION INTO YOUR QUALITY INFRASTRUCTURE



Presenters examine ways to embed accreditation requirements into a program's quality infrastructure to promote continuous readiness rather than episodic preparation. Participants will gain practical strategies for aligning processes, documentation, and quality systems to support sustained compliance and long-term program resilience.

10:15 AM - 15 MIN BREAK

10:30 AM

DATA AUDIT COMMITTEE: SIGNIFICANCE FOR CELL THERAPY PROGRAMS



This session focuses on the role and importance of the Data Audit Committee in ensuring data accuracy, integrity, and regulatory compliance within transplant programs. Participants will explore best practices for conducting audits, addressing discrepancies, and leveraging findings to strengthen data quality and program performance.

11:00 AM
**USING NUMBERS TO CREATE IMPACT:
CIBMTR DATA TO IMPROVE OUTCOMES**



Discover how programs can use data and statistical insights to drive meaningful improvements in clinical and operational outcomes. Participants will learn practical approaches to interpreting key metrics, identifying trends, and translating data into actionable strategies that support quality improvement and program performance.

11:30 AM
**UNTANGLING THIRD-PARTY
AGREEMENTS: NAVIGATING THE
CHALLENGES AND
COMPLEXITIES**



Uncover the complexities of third-party agreements within cellular therapy programs and the challenges they present for compliance and oversight. Participants will gain practical insights into identifying key requirements, clarifying responsibilities, and managing agreements to support regulatory and accreditation expectations.

12:00 PM - LUNCH BREAK

12:45 PM
**CLOSING THE LOOP: 9TH EDITION
EXPECTATIONS FOR CHAIN OF
CUSTODY AND CHAIN OF IDENTITY**



Review the 9th Edition expectations for chain of custody and chain of identity, with a focus on strengthening oversight and accountability across cellular therapy processes. Participants will explore practical approaches for documenting, verifying, and closing gaps to ensure products are consistently tracked and managed from collection through infusion.

1:15 PM
**LEARNING FROM THE
UNTHINKABLE + CASE REVIEW**



This session explores the FACT accreditation journey as a comprehensive organizational effort that uncovers critical operational, staffing, and financial limitations requiring strategic alignment. Through a case-based review, participants will compare pre- and post-accreditation workflows to identify inefficiencies, risks, and opportunities for improvement. Attendees will learn how to define and communicate a compelling value proposition that highlights cost efficiencies, operational gains, and new revenue streams to support executive-level funding decisions.

2:15 PM - BREAK

2:30 PM
**FACT READINESS: BUILDING A
CULTURE OF COMPLIANCE**



Explore how to go beyond “checking the boxes” to build a sustainable culture of compliance that supports ongoing FACT readiness. Attendees will learn practical approaches for engaging staff, embedding standards into daily workflows, and using education, feedback, and monitoring to make compliance a shared, living practice rather than a one-time event.

3:00 PM
**READY FOR REVIEW: NAVIGATING
EXPECTATIONS IN SAFETY AND
EFFICACY AUDITS**



Prepare for safety and efficacy audits by clarifying common expectations, documentation needs, and review processes. Through practical examples and tips, attendees will learn how to demonstrate safe, effective practice; respond to auditor questions; and use audit findings to drive continuous improvement.

3:30 PM
**ASK FACT ANYTHING
SPEAKER PANEL**

This open Q&A Session allows attendees to ask about FACT standards, accreditation, implementation, and other burning questions. FACT representatives will address common issues, clarify any gray areas, and share practical insights to help programs interpret requirements and apply them effectively in practice.

3:45 PM - CLOSING



4:00 PM
CONFERENCE ENDS