

## CELLULAR THERAPY and CORD BLOOD INSPECTION AND ACCREDITATION WORKSHOP

May 28, 2019

7:00 am Registration

8:00 am Welcome Address

Ngairé Elwood, PhD  
Phyllis I. Warkentin, MD  
Chrissy Gordon, URD Transplant Recipient

8:30 am Overview of FACT Accreditation Process

Phyllis I. Warkentin, MD

9:30 am Quality Management in Novel Cell Therapies

Patrick Hanley, PhD

10:30 am **Break**

### Challenges Complying with Standards: Cellular Therapy

10:45 am Importance of Compliance  
Dennis Gastineau, MD

11:15 am Top Five Challenges  
Dennis Gastineau, MD

12:15 pm **Lunch**

### Cellular Therapy and Cord Blood Inspector Training Track

12:45 pm The Making of a Model Inspector  
Ngairé Elwood, PhD

1:45 pm Pre-Inspection Review  
Robyn Rodwell, PhD

2:45 pm **Break**

3:00 pm Performing the Inspection  
Paul Eldridge, PhD

4:00 pm Accreditation Doesn't End with the Inspection  
Cheryl Hutchins, PhD

5:00 pm **Adjourn**

### Challenges Complying with Standards: Cord Blood

10:45 am: Importance of Compliance  
Robyn Rodwell, PhD

11:15 am: Top Five Challenges  
Phillip Johnson, MMedSc(Path)

12:15 pm **Lunch**

### Cellular Therapy and Cord Blood Applicant Track

12:45 pm Occurrence Management, Auditing,  
and The 5 Whys: Root Cause Analysis  
Phyllis I. Warkentin, MD

1:45 pm Risk Assessment  
Dennis Gastineau, MD

2:45 pm **Break**

3:00 pm Written Agreements  
Patrick Hanley, PhD

4:00 pm Shipping and Transportation  
Paul Eldridge, PhD

5:00 pm **Adjourn**