

# FACT Inspection & Accreditation Workshop

21 Sep 2020

## Workshop Objectives:

- Describe the accreditation process.
- Evaluate documentation to ensure compliance.
- Organize the on-site inspection process. • Plan a program tour.
- Identify strategies to support a successful inspection.
- Practice evaluating deficiencies.

■ Apheresis Presentation 
 ■ Break 
 ■ Opening/Closing 
 ■ Cord Blood Presentation 
 ■ Ice Breaker 
 ■ Cord Blood Activity 
 ■ Apheresis Activity

TIME	MINS	TITLE	DESCRIPTION
08:00	30'	Ice Breaker	Facilitators: Ngaire Elwood, PhD and Joseph Schwartz, MD, MPH <i>Description of session:</i> Join the FACT Inspection and Accreditation Virtual Workshop as early as 8:00 am. Connect with colleagues and participate in pre-workshop polling questions.
08:30		Introduction	
	08:30 15'	Introduction	Facilitators: Ngaire Elwood, PhD and Joseph Schwartz, MD, MPH Facilitator officially opens up the meeting Live message from Dennis Gastineau, MD, FACT President <i>Description of session:</i> Workshop hosts Ngaire Elwood, PhD, and Joseph Schwartz, MD, MPH, welcome all participants to the FACT Inspection and Accreditation Virtual Workshop. Drs. Elwood and Schwartz will introduce the workshop objectives and share tips to help make your virtual workshop experience flawless. FACT President, Dr. Dennis Gastineau will provide a live message to all participants to get the day started!
	08:45 45'	Presentation: The Overview of FACT Accreditation (recorded)	Facilitator: Phyllis I. Warkentin, MD <i>Description of session:</i> This session features FACT Chief Medical Officer, Dr. Phyllis I. Warkentin. Dr. Warkentin will describe the accreditation process from application to accreditation. Key areas will be addressed including the function of the accreditation coordinator, preparation for inspection, and the inspector role in the process of accreditation.

09:30	Break			
	15'	Both Tracks		
	09:30	15'	Morning Break	FACT Trivia Game
09:45				
	150'	Cord Blood		
	09:45	30'	<b>Presentation: The Key to Compliance Success</b>	<b>Facilitator: Phillip Johnson, MMedSc(Path)</b>  <i>Description of session: Phillip Johnson, Production Manager at Queensland Cord Blood Bank at the Mater, will review the entire compliance application process. He will identify documents required for submission and give appropriate examples.</i>
	10:15	45'	<b>Presentation: Evaluating Compliance</b>	<b>Facilitator: Linda Peltier, PhD, RN</b>  <i>Description of activity: Dr. Linda Peltier, Project Manager at McGill University Health Centre, will present three case studies. The audience will identify what challenges the bank faces after each case. Dr. Peltier will poll the audience to determine what standards may not be in compliance. Ultimately, Dr. Peltier, with the help of the audience, will answer how the bank can achieve compliance with FACT Standards and continue FACT accreditation.</i>
	11:00	30'	<b>Presentation: What to Expect During the Inspection: Inspection Strategies from the Applicant's Point of View</b>	<b>Facilitator: Andrew Deeming</b>  <i>Description of session: Andrew Deeming, Quality Manager at BMDI Cord Blood Bank, will review bank expectations during a FACT inspection. He will list tips and identify strategies to help banks navigate a successful inspection process. Andrew will also discuss what it is really like during the onsite inspection from an applicant point of view.</i>
	11:30	45'	<b>Activity: Practice a guided tour of a cord blood bank.</b>	<b>Facilitator: Diane Fournier, PhD</b>  <i>Description of activity: Diane Fournier, PhD, of Héma-Québec Cord Blood Bank, will walk the audience through a guided tour of Héma-Québec's cord blood bank. Dr. Fournier will identify information that will be evaluated during the tour of the bank inspection.</i>

150'	<b>Apheresis</b>		
09:45	30'	<b>Presentation: The Key to Compliance Success</b>	<p>Facilitator: Renee Smilee, BSMT(ASCP), CQIA (ASQ)</p> <p><i>Description of session: Renee Smilee, Performance Improvement Lead at H. Lee Moffitt Cancer Center, will review the entire compliance application process. She will identify documents required for submission and give appropriate examples.</i></p>
10:15	45'	<b>Activity: Evaluating Compliance</b>	<p>Facilitator: Michele Sugrue, MS, MT(ASCP)SBB</p> <p><i>Description of activity: Michele Sugrue, Coordinator of Research Programs at UF Shands Hospital, will present three case studies. The audience will identify what challenges the program faces after each case. Michele will poll the audience to determine what standards may not be in compliance. Ultimately, Michele, with the help of the audience, will answer how the program can achieve compliance with FACT Standards and continue FACT accreditation.</i></p>
11:00	30'	<b>Presentation: What to Expect During the Inspection: Inspection Strategies from the Applicant's Point of View</b>	<p>Facilitator: Alex Babic, MD</p> <p><i>Description of session: Dr. Alex Babic, of the Saint Louis University Blood and Marrow Transplant Program, will review program expectations during a FACT inspection. Dr. Babic will list tips and identify strategies to help programs navigate a successful inspection process. He will also discuss what it is really like during the onsite inspection from an applicant point of view.</i></p>
11:30	45'	<b>Activity: Practice a guided tour of an apheresis unit.</b>	<p>Facilitator: Charlie Branson, MS</p> <p><i>Description of activity: Charlie Branson, Manager of Biologics Production Facility at the Nebraska Medical Center, will walk the audience through a guided tour of The Nebraska Medical Center's Apheresis Unit. Charlie will identify information that will be evaluated during the tour of the apheresis inspection.</i></p>
12:15	<b>Break</b>		
30'	<b>Both Tracks</b>		
12:15	30'	<b>Lunch with Leadership</b>	<p><b>Description of activity:</b> Join Dr. Phyllis I. Warkentin, FACT Chief Medical Officer, Dr. Joanne Kurtzberg, Program Director at Duke University Medical Center Blood and Marrow Transplant Program, or Dr. Joseph Schwartz, Director of Transfusion Medicine &amp; Cellular Therapy at New York Presbyterian Hospital/Columbia University Medical Center - Blood and Marrow Transplant Program, and get all of your burning questions answered!</p> <ul style="list-style-type: none"> <li>• Phyllis I. Warkentin, MD</li> </ul>

- Joanne Kurtzberg, MD
- Joseph Schwartz, MD, MPH

12:45	<b>Afternoon Sessions</b>		
120'	<b>Cord Blood</b>		
12:45	30'	<b>Presentation: Correction of Deficiencies</b>	<p>Facilitator: Ngaire Elwood, PhD</p> <p><i>Description of session: Ngaire Elwood, PhD, Director of BMDI Cord Blood Bank, will explain the most common challenges in cord blood banking and construct a plan to correct the deficiencies.</i></p>
13:15	45'	<b>Activity: Dissecting Deficiencies</b>	<p>Facilitator: Robyn Rodwell, PhD</p> <p>Description of activity: Dr. Robyn Rodwell will practice evaluating deficiencies with the audience and recommend correction.</p>
14:00	45'	<b>Presentation: Maintaining FACT Readiness</b>	<p>Facilitator: Guy Klamer, PhD</p> <p>Description of session: Guy Klamer, PhD, of Sydney Cord Blood Bank, will discuss a plan to ensure continuous accreditation readiness. Dr. Klamer will explain the self-assessment process and how to manage turnover so accreditation readiness is maintained.</p>
120'	<b>Apheresis</b>		
12:45	30'	<b>Presentation: Correction of Deficiencies</b>	<p>Facilitator: Joseph Schwartz, MD</p> <p><i>Description of session: Dr. Joseph Schwartz, Director of Transfusion Medicine and Cellular Therapy at New York Presbyterian Hospital/Columbia University Medical Center - Blood and Marrow Transplant Program, will explain the most common challenges in apheresis and construct a plan to correct the deficiencies.</i></p>
13:15	45'	<b>Activity: Dissecting Deficiencies</b>	<p>Facilitator: Nicole AQUI, MD</p> <p>Description of activity: Dr. Nicole AQUI will practice evaluating deficiencies with the audience and recommend correction.</p>

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14:00	45'	<b>Maintaining FACT Readiness</b>	Facilitator: Leon Su, MD, MBA, FCAP, FASCP  Description of session: Dr. Leon Su of The Blood and Marrow Transplant Program at Mayo Clinic Arizona and Phoenix Children's Hospital, will discuss a plan to ensure continuous accreditation readiness. Dr. Su will explain the self-assessment process and how to manage turnover so accreditation readiness is maintained.
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14:45

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14:45      **Closing**

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15'      **Both Tracks**

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14:45	15'	<b>Closing</b>	Facilitators: Ngaire Elwood, PhD and Joseph Schwartz, MD, MPH  Description of closing: Drs. Elwood and Schwartz will recap the entire day, reflect on productive conversations, and invite participants to share a take-away, action step, or highlight from the workshop.
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15:00

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TOTAL LENGTH: 07:00

# FACT Inspection & Accreditation Workshop - block details

## Ice Breaker

08:00 | 30'

Facilitators: Ngaire Elwood, PhD and Joseph Schwartz, MD, MPH

*This session is live.*

**Description of session:** Join the FACT Inspection and Accreditation Virtual Workshop as early as 8:00 am. Connect with colleagues and participate in pre-workshop polling questions.

### ADDITIONAL INFORMATION

Pre-meeting: As people are joining, have polling questions for participants to answer:

1. What country, city, state, or province are you joining us from?
2. Which workshop track are you attending?
3. When free to travel without restriction, where is the first place you would like to visit?

## Introduction-Both Tracks

### Introduction

08:30 | 15'

Facilitators: Ngaire Elwood, PhD and Joseph Schwartz, MD, MPH

Facilitator officially opens up the meeting

Live message from Dennis Gastineau, MD, FACT President

*This entire block is live.*

**Description of session:** Workshop hosts Ngaire Elwood, PhD, and Joseph Schwartz, MD, MPH, welcome all participants to the FACT Inspection and Accreditation Virtual Workshop. Drs. Elwood and Schwartz will introduce the workshop objectives and share tips to help make your virtual workshop experience flawless. FACT President, Dr. Dennis Gastineau will provide a live message to all participants to get the day started!

### ADDITIONAL INFORMATION

**Step 1:** Participants join the workshop through their devices using the applicable log-in information

**Step 2:** Introduce the workshop objectives.

**Step 3:** Introduce Dennis Gastineau.

**Step 4:** Quick Ice Breaker

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## Presentation: The Overview of FACT Accreditation (recorded)

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08:45 | 45'

Facilitator: Phyllis I. Warkentin, MD

- *Live Q&A*  
35 minutes of recording and 10 minutes for Q&A.

Have presenters picture when they are presenting.

*Description of session: This session features FACT Chief Medical Officer, Dr. Phyllis I. Warkentin. Dr. Warkentin will describe the accreditation process from application to accreditation. Key areas will be addressed including the function of the accreditation coordinator, preparation for inspection, and the inspector role in the process of accreditation.*

### ADDITIONAL INFORMATION

#### Objectives:

1. Define common terminology for the accreditation process.
2. Describe the accreditation process from application to accreditation.
3. Explain the function of the Accreditation Coordinator.
4. Correlate preparation for inspection with the outcome.
5. Summarize the inspector's role in the process of accreditation.

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### Introduction-

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*End of Introduction*

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### Break-Both Tracks

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## Morning Break

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09:30 | 15'

FACT Trivia Game

### ADDITIONAL INFORMATION

1. Play a quick trivia game for those who stay on
2. Send winner/s prize/s

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### Break-Both Tracks 1

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*End of Break*

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### -Cord Blood

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## Presentation: The Key to Compliance Success

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09:45 | 30'

Facilitator: Phillip Johnson, MMedSc(Path)

30 minutes for presentation - recorded

*Description of session: Phillip Johnson, Production Manager at Queensland Cord Blood Bank at the Mater, will review the entire compliance application process. He will identify documents required for submission and give appropriate examples.*

#### ADDITIONAL INFORMATION

Objectives:

1. Review the compliance application process
2. Identify documents that are required for submission
3. Give examples of how cord blood banks address personnel requirements, training, and competency assessment for each position in the CBB.

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## Presentation: Evaluating Compliance

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10:15 | 45'

Facilitator: Linda Peltier, PhD, RN

30 minutes live activity

15 minutes Q&A (Linda will answer questions about Phillip's presentation before starting the activity, and answer questions about the activity after the activity is finished.)

*Description of activity: Dr. Linda Peltier, Project Manager at McGill University Health Centre, will present three case studies. The audience will identify what challenges the bank faces after each case. Dr. Peltier will poll the audience to determine what standards may not be in compliance. Ultimately, Dr. Peltier, with the help of the audience, will answer how the bank can achieve compliance with FACT Standards and continue FACT accreditation.*

#### ADDITIONAL INFORMATION

1. Evaluate case studies for compliance

Review Case Studies

1. Use polling questions to ask how many potential citations are in each case study.
2. Ask attendees to virtually raise hand and answer.
3. Leave attendees out of it and have facilitator read each case aloud and walk through what is wrong in each case. Attendees can ask questions via chat after each case.



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## Presentation: What to Expect During the Inspection: Inspection Strategies from the Applicant's Point of View

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11:00 | 30'

Facilitator: Andrew Deeming

Presentation recorded

*Description of session: Andrew Deeming, Quality Manager at BMDI Cord Blood Bank, will review bank expectations during a FACT inspection. He will list tips and identify strategies to help banks navigate a successful inspection process. Andrew will also discuss what it is really like during the onsite inspection from an applicant point of view.*

### ADDITIONAL INFORMATION

Objectives:

1. Review expectations of the program.
2. List tips to help navigate the inspection process.
3. Summarize the experience of what it is really like during an onsite inspection.
4. Identify strategies to support a successful inspection.

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## Activity: Practice a guided tour of a cord blood bank.

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11:30 | 45'

Facilitator: Diane Fournier, PhD

Live activity and Q&A

15 minutes Q&A (Diane will answer questions about Andrew's presentation before starting the activity, and answer questions about the activity after the activity is finished.)

*Description of activity: Diane Fournier, PhD, of Héma-Québec Cord Blood Bank, will walk the audience through a guided tour of Héma-Québec's cord blood bank. Dr. Fournier will identify information that will be evaluated during the tour of the bank inspection.*

### ADDITIONAL INFORMATION

Objectives:

1. List items to review on the tour
2. Identify information that can be evaluated during the tour

Show pictures and do polling or share google doc and let people type what they see/don't see. What would the citation fall under (policies and procedures, personnel, etc. Diane can then comment on things - "Very good... this is what I see."

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## -Apheresis

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### Presentation: The Key to Compliance Success

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09:45 | 30'

Facilitator: Renee Smilee, BSMT(ASCP), CQIA (ASQ)

30 minutes recorded

*Description of session: Renee Smilee, Performance Improvement Lead at H. Lee Moffitt Cancer Center, will review the entire compliance application process. She will identify documents required for submission and give appropriate examples.*

#### ADDITIONAL INFORMATION

Objectives:

1. Review the compliance application process
2. Identify apheresis collection documents that are required for submission.
3. Evaluate the adequacy of submitted documents.

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### Activity: Evaluating Compliance

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10:15 | 45'

Facilitator: Michele Sugrue, MS, MT(ASCP)SBB

This is all live

30 minutes for activity

15 minutes Q&A (Michele will answer questions about Renee's presentation before starting the activity, and answer questions about the activity after the activity is finished.)

*Description of activity: Michele Sugrue, Coordinator of Research Programs at UF Shands Hospital, will present three case studies. The audience will identify what challenges the program faces after each case. Michele will poll the audience to determine what standards may not be in compliance. Ultimately, Michele, with the help of the audience, will answer how the program can achieve compliance with FACT Standards and continue FACT accreditation.*

#### ADDITIONAL INFORMATION

Objective:

1. Evaluate case studies for compliance.

Review apheresis case studies

1. Use polling questions to ask how many potential citations are in each case study.
2. Ask attendees to virtually raise hand and answer.

3. Leave attendees out of it and have facilitator read each case aloud and walk through what is wrong in each case. Attendees can ask questions via chat after each case.

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## Presentation: What to Expect During the Inspection: Inspection Strategies from the Applicant's Point of View

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11:00 | 30'

Facilitator: Alex Babic, MD

This session is recorded

*Description of session: Dr. Alex Babic, of the Saint Louis University Blood and Marrow Transplant Program, will review program expectations during a FACT inspection. Dr. Babic will list tips and identify strategies to help programs navigate a successful inspection process. He will also discuss what it is really like during the onsite inspection from an applicant point of view.*

### ADDITIONAL INFORMATION

Objectives:

1. Review expectations of the program.
2. List tips to help navigate the inspection process.
3. Summarize the experience of what it is really like during an onsite inspection.
4. Identify strategies to support a successful inspection.
5. Discuss the evaluation process, from the applicants perspective, when things go wrong.

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## Activity: Practice a guided tour of an apheresis unit.

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11:30 | 45'

Facilitator: Charlie Branson, MS

This session is live

30 minute activity

15 minutes Q&A (Charlie will answer questions about Alex's presentation before starting the activity, and answer questions about the activity after the activity is finished.)

*Description of activity: Charlie Branson, Manager of Biologics Production Facility at the Nebraska Medical Center, will walk the audience through a guided tour of The Nebraska Medical Center's Apheresis Unit. Charlie will identify information that will be evaluated during the tour of the apheresis inspection.*

### ADDITIONAL INFORMATION

Objectives:

1. List items to review on the tour.
2. Identify information that can be evaluated during the tour.

Show pictures and do polling or share google doc and let people type what they see/don't see. What would the citation fall under (policies and procedures, personnel, etc. Diane can then comment on things - "Very good... this is what I see."

End of

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## Break-Both Tracks

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### Lunch with Leadership

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12:15 | 30'

Can you jump from room to room?

Have some questions prepared in case chat is silent.

This session is live - we will need three speak easy rooms.

Description of activity: Join Dr. Phyllis I. Warkentin, FACT Chief Medical Officer, Dr. Joanne Kurtzberg, Program Director at Duke University Medical Center Blood and Marrow Transplant Program, or Dr. Joseph Schwartz, Director of Transfusion Medicine & Cellular Therapy at New York Presbyterian Hospital/Columbia University Medical Center - Blood and Marrow Transplant Program, and get all of your burning questions answered!

#### ADDITIONAL INFORMATION

##### "Lunch with Leadership"

The idea is to have 2-4 breakout rooms with a FACT leader in each room. We can have participants sign up ahead of time so they are spread out fairly equally in each room. Leadership will include:

- Phyllis I. Warkentin, MD (FACT Chief Medical Officer)
- Joanne Kurtzberg, MD (Cord Blood) - **Invited, but not confirmed followed up with her on 8/9/2020**
- Joseph Schwartz, MD, MPH (Member of FACT Board of Directors, Co-chair of FACT Cord Blood Accreditation Committee, Former president of ASFA)

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## Break-Both Tracks 1

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*End of Break*

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## Afternoon Sessions-Cord Blood

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### Presentation: Correction of Deficiencies

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12:45 | 30'

Facilitator: Ngaire Elwood, PhD

This presentation is recorded.

*Description of session: Ngaire Elwood, PhD, Director of BMDI Cord Blood Bank, will explain the most common challenges in cord blood banking and construct a plan to correct the deficiencies.*

#### ADDITIONAL INFORMATION

Objectives:

1. Review the previous Inspection report and verify corrections from the last inspection.
2. Explain the most common challenges in cord blood banking (include collection and processing).
  1. Bank: B2.5

2. Collection: C1.6.2, C6.3
3. Processing: D3.2.4, D1.6
3. Construct a plan to correct the deficiencies.

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## Activity: Dissecting Deficiencies

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13:15 | 45'

Facilitator: Robyn Rodwell, PhD

30 minutes for activity

15 minutes Q&A (Robyn will answer questions about Ngaire's presentation before starting the activity, and answer questions about the activity after the activity is finished.)

Description of activity: Dr. Robyn Rodwell will practice evaluating deficiencies with the audience and recommend correction.

### ADDITIONAL INFORMATION

Objective:

1. Practice evaluating deficiencies and recommend correction.

Review three case studies (one in each category: banking, collection, and processing)

1. Use polling questions to ask how many potential citations are in each case study.
2. Ask attendees to virtually raise hand and answer.
3. Leave attendees out of it and have facilitator read each case aloud and walk through what is wrong in each case. Attendees can ask questions via chat after each case.

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## Presentation: Maintaining FACT Readiness

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14:00 | 45'

Facilitator: Guy Klamer, PhD

Presentation recorded (30)

15 minutes Q&A after presentation

Description of session: Guy Klamer, PhD, of Sydney Cord Blood Bank, will discuss a plan to ensure continuous accreditation readiness. Dr. Klamer will explain the self-assessment process and how to manage turnover so accreditation readiness is maintained.

### ADDITIONAL INFORMATION

Objectives:

1. Develop a plan for continuous accreditation readiness.
2. Explain how regular self-assessment of your bank will maintain readiness.
3. Manage turnover so that accreditation readiness is maintained.

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## Afternoon Sessions-Apheresis

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### Presentation: Correction of Deficiencies

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12:45 | 30'

Facilitator: Joseph Schwartz, MD

This presentation is recorded.

*Description of session: Dr. Joseph Schwartz, Director of Transfusion Medicine and Cellular Therapy at New York Presbyterian Hospital/Columbia University Medical Center - Blood and Marrow Transplant Program, will explain the most common challenges in apheresis and construct a plan to correct the deficiencies.*

#### ADDITIONAL INFORMATION

Objectives:

1. Review the previous Inspection report and verify corrections from the last inspection.
2. Explain the most common challenges in apheresis:
  1. C2.4: Critical Apheresis collection facility parameters that may affect cellular therapy products, shall be assessed for risk of the cellular therapy product.
  2. C2.6: The apheresis collection facility shall document facility cleaning and sanitation and maintain order sufficient to achieve adequate conditions of operations.
  3. C8.3: Equipment shall be inspected for cleanliness prior to each use and verified to be in compliance with the maintenance schedule daily prior to use. Equipment shall also be standardized and calibrated on a regularly scheduled basis and after a critical repair or move.
  4. C5.1 and C5.3
3. Construct a plan to correct the deficiencies.

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### Activity: Dissecting Deficiencies

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13:15 | 45'

Facilitator: Nicole AQUI, MD

This session is live

30 minutes for activity

15 minutes for Q&A (Nicole will answer questions about Yossi's presentation before starting the activity, and answer questions about the activity after the activity is finished.)

Description of activity: Dr. Nicole AQUI will practice evaluating deficiencies with the audience and recommend correction.

#### ADDITIONAL INFORMATION

Objective:

1. Practice evaluating deficiencies and recommend correction.

Review three apheresis case studies:

2. Use polling questions to ask how many potential citations are in each case study.
3. Ask attendees to virtually raise hand and answer.
4. Leave attendees out of it and have facilitator read each case aloud and walk through what is wrong in each case. Attendees can ask questions via chat after each case

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## Maintaining FACT Readiness

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14:00 | 45'

Facilitator: Leon Su

**This session is live**

**30 minutes for activity**

**15 minutes for Q&A after presentation**

**Description of session:** Dr. Leon Su of The Blood and Marrow Transplant Program at Mayo Clinic Arizona and Phoenix Children's Hospital, will discuss a plan to ensure continuous accreditation readiness. Dr. Su will explain the self-assessment process and how to manage turnover so accreditation readiness is maintained.

### ADDITIONAL INFORMATION

#### Objectives:

1. Develop a plan for continuous accreditation readiness.
2. Explain how regular self-assessment of your apheresis unit will maintain readiness.
3. Manage turnover so that accreditation readiness is maintained.

*End of Afternoon Sessions*

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## Closing -Both Tracks

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### Closing

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14:45 | 15'

Facilitators: Ngaire Elwood, PhD and Joseph Schwartz, MD, MPH

Live session

**Description of closing:** Drs. Elwood and Schwartz will recap the entire day, reflect on productive conversations, and invite participants to share a take-away, action step, or highlight from the workshop.

### ADDITIONAL INFORMATION

Recap the session, reflect back on productive conversations or note ideas that surfaced. Invite participants to share via chat a take-away, action step, or highlight from the session.

*End of Closing*