

## CELLULAR THERAPY INSPECTION AND ACCREDITATION WORKSHOP AGENDA

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| 7:30 am  | Registration and Networking  |  |
| 8:00 am  | ISBT 128 Coding and Labeling   | Phyllis I. Warkentin, MD   |
| 9:00 am  | Quality Management as a Bridge Between Basic Research and Translational Medicine         | Paul Eldridge, PhD   |
| 10:00 am | <b>Break</b>   |  |
| 10:15 am | Accreditation of Immune Effector Cellular Therapy Programs                               | Sarah Nikiforow, MD  |
| 11:15 am | Ask the FACT Experts   | Paul Eldridge, PhD<br>Ngair Elwood, PhD<br>Sarah Nikiforow, MD<br>Robyn Rodwell, PhD<br>Joseph Schwartz, MD, MPH<br>Phyllis I. Warkentin, MD |
| 12:00 pm | <b>Lunch</b>   |  |
|          | <b>New Inspector Training Orientation</b>  | <b>Common Citations Track</b>  |
| 12:30 pm | Overview of the FACT Accreditation Process<br>Phyllis I. Warkentin, MD                   | 12:30 pm Common Citations<br>Joseph Schwartz, MD, MPH  |
| 1:15 pm  | Pre-Inspection Review<br>Robyn Rodwell, PhD, MSc   | 1:15 pm Quality Management<br>Paul Eldridge, PhD   |
| 1:45 pm  | The Art of Performing Inspections<br>Ngair Elwood, PhD                                   | 1:45 pm Process Controls<br>Joseph Schwartz, MD, MPH   |
| 2:30 pm  | The Exit Interview<br>Robyn Rodwell, PhD, MSc  | 2:15 pm Cellular Therapy Product Storage<br>Phyllis I. Warkentin, MD   |
| 3:00 pm  | Making Your Case Via the Report<br>Ngair Elwood, PhD                                     | 2:45 pm Preparing for an Inspection to Avoid Citations<br>Joseph Schwartz, MD, PhD   |
| 3:30 pm  | <b>Break</b>   |  |
| 3:45 pm  | 7th Edition Hematopoietic Cellular Therapy Standards                                     | Paul Eldridge, PhD   |
| 4:30 pm  | Watch and Learn the Inspection Approach<br><i>Video example of an on-site inspection</i> |  |
| 5:00 pm  | <b>Adjourn</b>   |  |