### Monday, May 6

**7:00 a.m. – 6:30 p.m.**
Registration Open

**7:00 a.m. – 8:30 a.m.**
Continental Breakfast

**8:30 a.m. – 8:45 a.m.**
Welcome and Opening Remarks from Conference Co-Chair
Michael Blackton, MBA, Vice President, Quality, CMC, Adaptimmune, LLC

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| 8:45 a.m. – 10:15 a.m. | **P1: The Patient Perspective: How Innovative Therapies are Transforming Lives**  
**Moderator:** Michael Blackton, MBA, Vice President, Quality, CMC, Adaptimmune, LLC  
Innovative cell and gene therapies have drastically changed how we address the technical challenges in developing and manufacturing these medicines. These products have also drastically changed the patient experience by providing a new set of options for the patient that were, not very long ago, simply pipe dreams. This session will explore how these innovative therapies impact patient’s lives and therefore help provide the audience with the necessary context as we follow the path toward commercialization. |
| 10:15 a.m. – 10:45 a.m. | Refreshment Break and Poster Presentations |
| 10:45 a.m. – 12:15 p.m. | **P2: The A, B, C’s of Cell and Gene Therapy Facility Design**  
**Moderator:** Irving Ford, Head of CAR-T QC Laboratories, Celgene  
The facility design for cell and gene therapy products must take into consideration the many aspects of the manufacturing process. Most processes involve manual aseptic manipulations performed within a biological safety cabinet and/or a combination of manual aseptic manipulations and automation. Additionally, the facility design must incorporate flexibility in the manufacturing areas as well as the need for future expansion. This session will explore approaches to consider when designing and/or modifying a facility to ensure a compliant yet seamless end to end manufacturing process for cell and gene therapy products during evolving and non-harmonized regulatory landscapes. |
| 12:15 p.m. – 1:45 p.m. | Lunch on Your Own. |
| 1:45 p.m. – 3:15 p.m. | **P3: Tech Transfer and Comparability for Cell and Gene Therapies: Case Studies in Complexity**  
**Moderator:** Michael Kuczewski, Associate Director, Oncology CMC, bluebird bio  
Accelerated clinical development timelines and regulatory pathways, highly complex products, and a still-maturing manufacturing infrastructure can lead to significant challenges for C&GT CMC organizations. Multiple site transfers, limited batch sizes, high inherent process variability. These are just a few of the hurdles to be cleared on the sprint from first-in-human to commercial licensure. We will explore case studies that reveal strategies for technology transfer and comparability that help to navigate these unique challenges while maintaining the speed and flexibility that is critical to this rapidly maturing field. |
| 3:15 p.m. – 3:45 p.m. | Refreshment Break and Poster Presentations |
Cell and gene therapies present unique challenges related to product characterization and potency testing relative to traditional biologics. The link between product attributes/potency, starting material, methods, and clinical relevance can be poorly understood or may have little predictive value in many cases, while regulatory expectations are ambiguous. These case studies will explore recent challenges faced by companies during product characterization and development of potency methods.
4:15 p.m. – 5:45 p.m.
**P8: Panel Discussion on Global Harmonization**

**Moderator:** David Smith, PhD, Associate Director, Hitachi Chemical Advanced Therapeutics Solutions

With growing commercialization of cell and gene therapies, this session will tackle the variation in regulations across the globe. Compare and contrast the pathways across different geographic areas to include EU, US, Asia. We will look at where we have come from, how cell and gene therapies are viewed in comparison to more traditional biologics and what the future looks like to ensure the industry can drive to meet patient needs in a safe, effective, and efficient process.

5:45 p.m.

**Closing Remarks from Conference Co-Chair**

Michael Blackton, MBA, Vice President, Quality, CMC, Adaptimmune, LLC