

Virtual Mini-Conference: “COMMERCIALIZATION OF CELL & GENE THERAPY: ADVANCING TECHNOLOGY AND INNOVATION”

Event Schedule

Thu, Aug 05, 2021

9:00am

"Welcome To The Revolution in Healthcare"

🕒 9:00am - 9:10am, Aug 5

🗣️ Speaker



Devendra Mishra (Moderator, Panelist) Executive Director, BSMA

9:10am

KEYNOTE: “PACT Unique CGT Technology Platform: Eradication of Cancerous Tumors”

🕒 9:10am - 9:40am, Aug 5

Presentation will be about tackling these solid tumor cancer challenges with pioneering technologies in a clinical stage with the goal to treat each patient with personalized neoTCR-based therapies across a broad range of tumor mutational burdens and solid tumor cancer types. The technology platform provides the differentiated ability to identify these neoantigens, as well as validate them as targets specific to the person's cancer. Once validated, individualized, cancer-targeted neoTCR-T cell therapy products are manufactured for each person with cancer. It is now broadly accepted that cancer is a profoundly patient-specific disease, where no two tumors are alike.

🗣️ Speaker



Timothy Moore (Keynote Speaker) President, PACT Pharma

9:40am

PANEL: “Overcoming the Challenges of Cell and Gene Therapy: The Lifeline of the Healthcare Revolution”

🕒 9:40am - 10:40am, Aug 5

The pipeline of Cell and Gene Therapies has been growing rapidly since the first one, Kymriah of Novartis, was approved in 2019. Research suggests that by 2030, up to 60 new cell and gene therapies could be launched, treating upwards of 350,000 patients. How do you incorporate the technology, processes and insights necessary to ensure your clinical trial needs are met fully? How can scientific and operational expertise simplify and streamline complex trial design? Today's drug development environment was largely designed around small molecules and biologics such as proteins and monoclonal antibodies, a constrained system that has not significantly changed in 50 years. The executives will discuss their challenges and solutions.

 Moderator



Devendra Mishra (Moderator, Panelist) Executive Director, BSMA

 Speakers



Kevin Cast (Panelist) Partner, Archbow Consulting is part of Omnicom Health Group's Value and Access entities of Entree Health and Valuate. This allows Archbow to offer 360 degrees of commercial support.



Matt Yedwabnick (Panelist) VP, Global Supply Chain, Atara Biotherapeutics

 Panelist



Aileen Baquiran (Panelist) Vice President, Supply Chain, Orchard Therapeutics



Chris Bogart (Panelist) Vice President, Supply Chain, Bayer

10:40am

PANEL: "Harmonizing Best Supply Chain Practices for Apheresis"

 10:40am - 11:40am, Aug 5

Several Apheresis-related organizations are formulating standards for various aspects of the critical function of Apheresis in the evolving Cell and Gene Therapy. SMEs will explore how to simplify and improve the interface with Apheresis centers in areas of operations, systems, packaging, storage and logistics (particularly cold chain). Issues of compliance with regulatory standards will also be addressed. Listening to the Voice of the Customer and taking innovative, remedial steps will be the guiding principle for the exchange. Representatives from Standards Bodies (FACT and SCB) will present progress made and the challenges ahead.

 Speakers



Olive Sturtevant (Panelist) Sr. Administrative Director, Connell & O'Reilly Families, Cell Manipulation Core Facility, Dana-Farber Cancer Institute



Peter Holman (Moderator) VP of Quality, ArsenalBio

👤 Panelist



Dawn Henke (Panelist) Senior Technical Program Manager, Standards Coordinating Body (SCB)



Gary Hutchinson (Panelist) President, Modality Solutions



Gregg Bodnar (Panelist) Senior Client Engagement Manager, Be The Match BioTherapies

11:40am

“Navigating the Process Development Challenges of Cell & Gene Therapy”

🕒 11:40am - 12:05pm, Aug 5

Presentation will identify the unique challenges of developing and scaling out manufacturing processes of autologous cell therapies. Manufacturing for Cell and Gene Therapy has three intrinsic challenges, namely 1. The starting material, the blood or tumor cells of the patient to be cured, is always different and unique, 2. There is no buffer inventory for the production batch of one, and 3. Enabling technologies have not caught up to the needs of the industry. These systems-level challenges must be addressed early in development, where the direction of the organization's strategy can be molded appropriately.

👤 Speaker



Kenny Choi (Speaker) Senior Director, Process Sciences and Engineering, Instil Bio

12:05pm

FIRESIDE CHAT: “How to Industrialize Strategic Sourcing of Raw Materials and Supplies?”

🕒 12:05pm - 12:30pm, Aug 5

Challenges faced by the nascent industry to qualify suppliers who understand the stringent requirements and forge a business relationship will be addressed. The just in time nature of the therapy imposes an unprecedented demand on suppliers. A robust and resilient supply chain requires manufacturers to strategically source raw materials and identify backup suppliers where possible, and where backup options do not exist, work with suppliers to de-risk their supply chain. Manufacturers are also working with CMOs for certain critical raw materials and processes that are capacity constrained which impact both pricing and availability to service market demands. Industry approach to audit suppliers will be discussed.

👤 Speakers



David Karakas (Speaker) Director, Procurement & Sourcing, bluebird bio



Devendra Mishra (Moderator, Panelist) Executive Director, BSMA

12:30pm

“Labeling, Packaging & Logistics – The Achilles Heel of the CGT Delivery”

🕒 12:30pm - 12:55pm, Aug 5

Just-in-time packaging and labeling is critical to meeting the critical need of the patient. Labeling at the ultracold temperatures adds significant complexity in the primary and secondary packaging and labeling. The labels selected must be validated to perform at these ultracold temperatures. Subsequently, the design and documentation of temperature and the identity and security chains of custody in a 21 CFR part 11 environments have to be assured in the cold chain delivery network.

🗣️ **Speaker**



Albert Cooksey (Speaker) Senior Vice President and General Manager, 3PL, ICS

12:55pm

Wrap Up: "Where do we go from here?"

🕒 12:55pm - 1:00pm, Aug 5

🗣️ **Speaker**



Devendra Mishra (Moderator, Panelist) Executive Director, BSMA