ADVANCED MANUFACTURING IN CGT

DAY 1 - THURSDAY, MAY 16, 2024

8:00 – 8:45am Registration & Breakfast

8:45 – 9:00am **Opening Remarks**
Josephine Lembong, Senior Manager, Science and Industry Affairs, ARM

9:00 – 10:15am **Automation: Not If, But When**
David Smith, Vice President, Development, BioCentriq
- Review of the history of automation in cell therapy
- Define current state of automation in GMP manufacturing
- Highlight benefits and bottlenecks to getting there

Large-scale 2D Robotic System to Automate the Expansion and Differentiation of Allogeneic Cells
Jason Dowd, Global Cell Therapy Process Platform Lead, Bayer
- A modular, flexible, industrial approach to produce allogeneic CT assets
- Platform development for 3D and 2D, with focus on 2D robotic system
- Leveraging PAT and digitalization for end-to-end process demonstrating lower COGs, resulting in significantly lower development costs and timelines for follow-on assets

Automating Cell Line Manufacturing Process & Advanced Solutions for Monoclonality Assurance
Stefan Braam, President & CTO, Cellistic
- Automation for building complex gene edited iPSC Master Cell Banks in the shortest timeframe possible
- Use of automation for monoclonality assurance
- Use of automation to handle hundreds of clones in parallel

10:15 – 10:30am Morning Break

10:30 – 11:30am **A Case Study of Higher Volume Production for CAR-T Manufacturing through Process and Analytics Automation**
Junxia Wang, Head, Cell Therapy Global Product Development, Catalent
- Overview of CAR-T technologies
- CAR-T platform closed system and automation
- CAR-T PD study and data on process/method improvements
- Solutions on analytical testing

Getting Autologous Therapies COGs Down from ~$100k to ~$30k by Use of Transformative Processes and Technologies
Eytan Abraham, VP, Business Head of Cell, Gene and Nucleic Acids Franchises, Resilience

- High COGs and turnaround times of autologous cell therapies limits patient access
- Some biomanufacturing solutions are available or being developed, but much more is needed
- Combining advances in LVV biomanufacturing solutions, shorter cell manufacturing processes, and novel NGS-based QC release approaches significantly reduces COGs and vein-to-vein time

Exploring Cost Drivers for Current Cell Therapies and the Potential Benefits of Automation
Jason Foster, CEO, Ori Biotech

- Detailed overview of the cost drivers in the current manufacturing model
- Levers to reduce COGs in the short, medium, and long term
- Other ways to reduce costs, improve reliability and increase access

11:30 – 12:30pm **Panel Discussion**
Eytan Abraham, VP, Business Head of Cell, Gene and Nucleic Acids Franchises, Resilience (moderator)
Jason Dowd, Global Cell Therapy Process Platform Lead, Bayer
Jason Foster, CEO, Ori Biotech
Fabian Gerlinghaus, Co-Founder & CEO, Cellares
David Smith, Vice President, Development, BioCentriq

12:30 – 1:30pm Lunch Break

1:30 – 3:10pm **Using AI/ML to Predict Manufacturing Process Performance**
Carmen Warren, Director, Analytical Operations, Kite Pharma

Utilizing AI/ML for Improved Vector Design and Manufacturability
Anusha Sriraman, Lead, Life Sciences Insights, Form Bio

- Current challenges in CGT include extended drug development timelines, with vector design and manufacturing being the primary bottleneck.
- AI aids in addressing these challenges by optimizing and de-risking vector design through in silico assessments.
- Case studies support the effectiveness of AI in designing more efficient and manufacturable vectors for gene therapy.
- Overall, AI can help guide the selection of new lead candidates with reduced truncations, improve manufacturing yield and reduce cost of each therapeutic dose, thereby accelerating development of drug substance

Using AI to Reduce Human Operator Dependence & Improve Consistency in Automated Manufacturing of iPSC-based Therapies
Marinna Madrid, Co-Founder & Chief Product Officer, Cellino

- Building an automated, AI- and laser-based platform for closed, automated manufacturing of iPSC-based therapies
- Developing, training & assessing AI models for in-process cell characterization & decision making
- Use of AI & automation to reduce human operator dependence in a traditionally manual & labor-intensive cell manufacturing process

The Next Wave of CGT Manufacturing: Integrating AI and Global Opportunities
Nina Tandon, Co-Founder & CEO, EpiBone

- Integration of AI into CGT manufacturing presents a significant opportunity to transform the intricate and labor-intensive process of cell cultivation and management.
- Use of AI to enhance training and certification processes, potential of AI to autonomously generate batch records directly from bioreactors.
- Establishment of a self-reporting system that not only minimizes human error but also significantly expands the scalability of CGT manufacturing, setting a new standard for efficiency and reliability in CGT production
- There are opportunities to initiate clinical trials and incorporate AI in CGT manufacturing beyond the US, in regions with regulatory environments that are conducive to innovation and personalized medicine

3:10 – 3:30pm Afternoon Break

3:30 – 4:30pm **Panel Discussion**
Marinna Madrid, Co-Founder & Chief Product Officer, Cellino (moderator)
Anusha Sriraman, Lead, Life Sciences Insights, Form Bio
Nina Tandon, Co-Founder & CEO, EpiBone
Carmen Warren, Director, Analytical Operations, Kite Pharma

4:30 – 4:40pm **Day 1 Concluding Remarks**
Josephine Lembong, Senior Manager, Science and Industry Affairs, ARM

DAY 2 - FRIDAY, MAY 17, 2024

8:00 – 8:45am Registration & Breakfast

8:45 – 10:15am **Opening Remarks: Scope, Nomenclature around Decentralized Manufacturing**

Current State of the Emerging Decentralized CGT Manufacturing Wave: Drivers, Stakeholders and Models
Lee Buckler, Sr. Vice President, Advanced Therapies, Blood Centers of America

- An overview of current global activity and stakeholders around decentralized CGT manufacturing
- Summary of current regulatory and commercial thinking around the regulatory and commercial models of decentralized CGT manufacturing

- Exploration of the critical elements (opportunities and barriers) to success of the model referencing select examples of therapeutic and technology companies currently at the forefront of this wave.

Embracing Today, Shaping Tomorrow: Driving Innovation in Decentralized Manufacturing

Carol Houts, Chief Strategy Officer, Germfree

- Regulatory landscapes governing decentralized mobile manufacturing; aspects and challenges of deploying mobile manufacturing infrastructure
- Insights, experiences, and lessons learned from the field on setting up, managing, and optimizing mobile manufacturing operations
- Importance of implementing a robust digital framework to support Quality System requirements in decentralized settings; digital tools and technologies to facilitate compliance and enhance operational efficiency
- Achieving comparability in decentralized environments

Analytics Requirements in a Decentralized Model, Centralized QC, Interaction Paths between Manufacturing Sites / CDMOs and Regulators

Matthew Hewitt, Vice President, Technical Officer CGT & Biologics, Charles River Laboratories

- Current manufacturing and analytics strategy interplay overview
- Discussion about current analytical time sinks and potential automation opportunities
- Focus on a decentralized manufacturing use-case and review analytical strategies which would be specific to decentralized manufacturing.

10:15 – 10:30am Morning Break

10:30 – 12:00pm **Galapagos' Decentralized CAR-T Manufacturing Platform: A Case Study in the Transfer of a CAR-T Product in Clinical Development to Landmark Bio**

Michael Covington, Chief Quality and Regulatory Officer, Landmark Bio

- Overview of Galapagos: a decentralized point-of-care CAR-T manufacturing platform and manufacturing process
- Overview of Landmark Bio and the tech transfer of a CAR-T product in clinical development to support a US IND
- Key elements enabling scalable and consistent decentralized production at global scale

What Got Use Here, Won't Get Us There: Maturing of the Cell Therapy Field

Jane Koo, Head of Regulatory Affairs, CTMC

- Comparability is essential for process improvements, scale-out, and site-to-site transfer which are key to advancement of the cell therapy field
- Novel manufacturing technologies can play a role in facilitating robust comparability
- Feasibility study of using the Ori Biotech manufacturing platform to improve a clinical process and support site-to-site transfer

A Centralized Data Infrastructure for Decentralized Manufacturing

Ken Forman, Sr. Director, Product Strategy, IDBS

- Core business and technical drivers of a centralized data infrastructure.
- Evaluating and attacking the "scale-in" challenge of decentralized manufacturing and clinical data.
- AI initiatives data governance and near-term goal targeting.

CBER Perspective on Decentralized Manufacturing
Laura Ricles, Director, Office of Cellular Therapy and Human Tissue CMC, FDA

12:00 – 1:00pm Lunch Break

1:00 – 2:00pm **Panel Discussion**
Lee Buckler, Sr. Vice President, Advanced Therapies, Blood Centers of America (moderator)
Michael Covington, Chief Quality and Regulatory Officer, Landmark Bio
Patrick Hanley, Chief & Director, Cellular Therapy Program, Children's National Hospital
Matthew Hewitt, Vice President, Technical Officer CGT & Biologics, Charles River Laboratories
Jane Koo, Head of Regulatory Affairs, CTMC
Laura Ricles, Director, Office of Cellular Therapy and Human Tissue CMC, FDA

2:00 – 2:10pm **Day 2 Concluding Remarks**
Josephine Lembong, Senior Manager, Science and Industry Affairs, ARM