UNITE LIFE SCIENCES PRESENTS:

ADVANCED THERAPIES MANUFACTURING STRATEGY DIGITAL

Assess the current manufacturing landscape in the context of the COVID-19 pandemic. What are the short and long term implications for advanced therapeutics development?

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FREE VIRTUAL SUMMIT

JULY 14 - 15, 2020

www.advancedtherapiesmanufacturingstrategydigital.com

*vendor participation is not free

Join advanced therapies stakeholders to take stock of the first half of 2020 and the short and long term implications of the ongoing COVID-19 pandemic. Hear an update on FDA regulatory guidance for manufacturers, take part in a virtual Q&A, and gain insight on current consortia initiatives and priorities for cell and gene therapy manufacturing and commercial development.

FEATURED SPEAKERS

Steven Goodman
Head of Drug Product Manufacturing
Bluebird Bio

Kelvin H. Lee
Institute Director
National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL)

Craig Malzahn,
VP Manufacturing and Supply Chain
Regenexbio

Peter Marks MD, PhD
Director, Center for Biologics Evaluation & Research (CBER)
FDA

Michael Lehmicke
Director, Science and Industry Affairs
Alliance for Regenerative Medicine

Vlad Hogenhuis
Chief Operating Officer (fmr.)
Ultragenyx

Mark Plavsic
Chief Technology Officer and Head of Nonclinical Development
LYSOGENE

Patrick Silva, PhD
Executive Director, Clinical, Translation and Industry Collaborations
Texas A&M Health Science Center

DAY 1: TUESDAY JULY 14

10:30 AM ET

FDA Perspective on Addressing Quality Manufacturing Capacity for Advanced Therapies

- Identify the need for quality manufacturing of advanced therapies considerations to be made at the outset of development in order to be prepared for positive clinical outcomes
- Hear how the FDA is collaborating with a variety of stakeholders to develop more streamlined pathways that facilitate the manufacturing of advanced therapies
- Understand how the availability of high quality manufacturing capacity is currently limiting the development of certain advanced therapies, and why this barrier needs to be overcome

Q&A session to follow

45 min

Peter Marks, MD, PhD, *Director*, **CBER, FDA**

11:30 AM ET

ARM Industry Update: The Impact of the COVID-19 Pandemic on CGT Clinical Trials and Manufacturing

- Explore the effect of the pandemic on the execution of new and ongoing clinical trials in the CGT space
- Discuss the challenges and opportunities in the manufacturing of CGT during the pandemic
- Is this a bump in the road or a transformation of the regenerative medicine industry?

45 Min

Michael Lehmicke, *Director, Science & Industry Affairs*, **Alliance for Regenerative Medicine (ARM).**

12:15 PM ET

Break

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DAY 1: TUESDAY JULY 14

1:00 PM ET

Roundtable Discussion: Strategic Considerations for Manufacturing Scale-Out of Patient-specific cell therapies (PSCTs)

45 Min

Steve Goodman, *Head of Drug Product Manufacturing*, **Bluebird Bio**
Patrick Silva, *Executive Director, Clinical, Translation and Industry Collaborations*, **Texas A&M Health Science Center**

2:00 PM ET

Roundtable Discussion on Viral Vector Production

Unlocking the Supply Chain Bottleneck in Viral Vector Capacity and Scale Up

45 Min

Craig Malzahn, *VP Manufacturing and Supply Chain*, **Regenexbio**

3:00 - 5:00 PM ET

Pre-Scheduled Networking Meetings

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DAY 2: WEDNESDAY JULY 15

10:30 AM ET

Current Regulatory Initiatives and the 2020 Landscape for Manufacturers

The National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL) is a public-private partnership dedicated to advancing biopharmaceutical manufacturing innovation and workforce development. Gain insight into current regulatory and industry efforts to support, prepare and respond to challenges presented by the COVID-19 pandemic. 30 MinKelvin H. Lee, Chief Executive Officer, National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL).

30 Min

Kelvin H. Lee, *Chief Executive Officer*, **National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL).**

11:00 AM ET

Commercial Strategies for Advanced Therapeutic Development in 2020 & Beyond

Compare and contrast the Build, Buy or Partner question for advanced therapeutic manufacturing in the context of 2020 and the COVID-19 pandemic. What new considerations need to be taken into account and how might commercial strategy be impacted in the short and long term?

45 Min

Vlad Hogenhuis, Chief Operating Officer (fmr.) Ultragenyx

12:00 - 1:00 PM ET

Break

1:00 PM ET

Fireside Chat: Transitioning from a Clinical to Manufacturing Mindset

45 Min

Mark Plavsic, *Chief Technical Officer*, **Lysogene**

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DAY 2: WEDNESDAY JULY 15

1:45 PM ET

BREAKOUT FOR INTERACTIVE DISCUSSION GROUPS

Integrated Discussion Group I	Integrated Discussion Group II	Integrated Discussion Group III
Protein & Antibodies Production	**Viral Vector Manufacturing**	**Manufacturing Considerations for mRNA**
45 Min	45 Min	45 Min

2:30 - 4:30 PM ET

Pre-Scheduled Networking Meetings

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