



NUCLEIC ACIDS

cGMP Production of mRNA & Plasmid DNA

VIRTUAL EDITION

FEBRUARY 1-3, 2021

Chaired By:



Lawrence C. Thompson, PhD
Pfizer, Inc.

MONDAY • FEBRUARY 1, 2021

9:00 am – 9:20 am	Overview / Intro
9:20 am – 9:30 am	Break
9:30 am – 10:10 am	<i>New Sequencing and Mass Spectrometry Tools for Quantitative Analysis of DNA and RNA Modifications and Damage</i> Peter Dedon, MD, PhD Massachusetts Institute of Technology (MIT)
10:10 am – 10:20 am	Break
10:20 am – 11:00 am	<i>Therapeutic mRNA: Applications, Manufacturing, and Regulatory Considerations</i> Andreas Kuhn, PhD BioNTech
11:00 am – 11:10 am	Break
11:10 am – 11:40 am	Technology Workshop <i>Chromatographic Tools for a High-Yielding mRNA Production Process</i> BIA Separations
11:40 am – 12:30 pm	Lunch
12:30 pm – 1:10 pm	<i>US Pharmacopeia Standards Development to Support Nucleic Acid-Based Products</i> Diane McCarthy, PhD and Fouad Atouf, PhD US Pharmacopeial Convention (USP)
1:10 pm – 1:20 pm	Break
1:20 pm – 2:20 pm	Roundtable

*All of the presentations shown in the program are included with your registration fee.
Times are Eastern Standard Time (EST).*

TUESDAY • FEBRUARY 2, 20219:00 am – 9:20 am **Overview / Intro**9:20 am – 9:30 am **Break**9:30 am – 10:10 am
Minicircle DNA as Starting Material for Development of ATMPs
Ram Shankar, PhD
PlasmidFactory GmbH & Co. KG10:10 am – 10:20 am **Break**10:20 am – 11:00 am
Characterization of DNA Starting Materials
Lawrence C. Thompson, PhD
Pfizer, Inc.11:00 am – 11:10 am **Break**11:10 am – 11:40 am
Technology Workshop
Plasmids: from Seeds to Release Testing
Vigene Biosciences11:40 am – 12:30 pm **Lunch**12:30 pm – 1:10 pm
Regulatory Considerations for Plasmid DNA and mRNA Products for Gene Therapy, a CBER Perspective
Maitreyi Chattopadhyay, PhD
FDA CBER1:10 pm – 1:20 pm **Break**1:20 pm – 2:00 pm
Nucleic Acid Characterization
Paul Blainey, PhD
Broad Institute2:00 pm – 2:10 pm **Break**2:10 pm – 3:10 pm **Roundtable****WEDNESDAY • FEBRUARY 3, 2021**9:00 am – 9:20 am **Overview / Intro**9:20 am – 9:30 am **Break**9:30 am – 10:10 am
Integrated Production Process of mRNA from E. coli to Highly Purified mRNA
Aleš Štrancar, PhD and Peter Gagnon
BIA Separations

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WEDNESDAY (continued) • FEBRUARY 3, 2021

10:10 am – 10:20 am

Break

10:20 am – 11:00 am

A Rapid, Scalable, Low-Footprint, Enzymatic DNA Manufacturing Technology That Can Enable the Genetic Medicine Revolution

Antonio Marques, PhD

Touchlight Genetics Ltd

11:00 am – 11:50 am

Lunch

11:50 am – 12:30 pm

Large-Scale Production of Plasmid DNA and mRNA to Support Therapeutic and Vaccine Development

Nathan Spangler

Aldevron

12:30 pm – 12:40 pm

Break

12:40 pm – 1:40 pm

Roundtable and Meeting Recap

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Due to circumstances beyond the control of meeting organizers, this program is subject to change without notice.

REV 01/26/2021