



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

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

**TUESDAY • FEBRUARY 2, 2021**

9:00 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. KG

10:10 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 Biosciences

11:40 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 CBER

1:10 pm – 1:20 pm **Break**

1:20 pm – 2:00 pm  
*New Tools for High-Precision Nucleic Acid Analysis*  
**Paul Blainey, PhD**  
Broad Institute

2:00 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**  
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 02/03/2021