



# 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: Manufacturing and Regulatory Considerations</i> <b>Andreas Kuhn</b> BioNTech
11:00 am – 11:10 am	<b>Break</b>
11:10 am – 11:40 am	<b>Technology Workshop</b> 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>James Richardson, PhD</b> US Pharmacopeial Convention (USP)
1:10 pm – 1:20 pm	<b>Break</b>
1:20 pm – 2:20 pm	<b>Panel Discussion</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**  
PlasmidFactory GmbH & Co. KG

10:10 am – 10:20 am **Break**

10:20 am – 11:00 am  
**James McColgan**  
Pfizer, Inc.

11:00 am – 11:10 am **Break**

11:10 am – 11:40 am **Technology Workshop**

11:40 am – 12:30 pm **Lunch**

12:30 pm – 1:10 pm  
*Regulatory Framework of Plasmids and mRNA-Based 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  
*Nucleic Acid Characterization*  
**Paul Blainey, PhD**  
Broad Institute

2:00 pm – 2:10 pm **Break**

2:10 pm – 3:10 pm **Panel Discussion**

**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 with Outstanding Yield*  
**Aleš Štrancar, PhD and Peter Gagnon**  
BIA Separations

10:10 am – 10:20 am **Break**

10:20 am – 11:00 am  
**Antonio Marques, PhD**  
Touchlight Genetics Ltd

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**WEDNESDAY (continued) • FEBRUARY 3, 2021**

11:00 am – 11:10 am

**Break**

11:10 am – 11:40 am

**Technology Workshop**

11:40 am – 12:30 pm

**Lunch**

12:30 pm – 1:10 pm

*Characterization of DNA Starting Materials*  
**Lawrence C. Thompson, PhD**  
Pfizer, Inc.

1:10 pm – 1:20 pm

**Break**

1:20 pm – 2:00 pm

*Large-Scale Production of Plasmid DNA and mRNA to Support Therapeutic and Vaccine Development*  
**Nathan Spangler**  
Aldevron

2:00 pm – 2:10 pm

**Break**

2:10 pm – 3:10 pm

**Panel Discussion 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 12/23/2020