# ISPE Boston Area Chapter Presents:

# Bringing Cell and Gene Therapies to Patients: Innovating to Meet Unique Challenges

# Thursday, March 21, 2019

5:30 pm to 8:30 pm

# bluebird bio

60 Binney Street Cambridge, MA 02142

# **EVENT INFORMATION:**

You're invited to an evening at bluebird bio to hear about innovations in cell and gene therapy, and mingle with ISPE colleagues and friends. Registration includes access to the networking reception prior to the educational program. Don't delay – spots are limited!



Serving All of New England THANK YOU TO OUR PROGRAM SPONSORS







# **PROGRAM SUMMARY:**

Bluebird Bio is a clinical-stage company committed to developing potentially transformative gene therapies for severe genetic diseases and T cell-based immunotherapies. The company develops and brings to market the most advanced products based on the transformative potential of gene therapy. This personalized approach to medicine presents challenges in gene and cell longevity, process flow, and manufacturing scale-up. We will discuss bluebird's approach and innovations that address the resources, materials, and methods used to deliver these therapies to each patient.

### WHO SHOULD ATTEND:

This program will appeal to a wide variety of industry experts including Process Engineers, Facilities Engineers and Architects, Quality Assurance, and Logistics Professionals. Individuals or organizations involved in the manufacture of cell and gene therapy technologies should attend as the discussion will cover planning, design, quality / regulatory considerations and technology platforms utilized.

#### **SPEAKERS:**

### Kendrick Goss, Senior Scientist, bluebird bio

Kendrick Goss is a Senior Scientist in the Translational Research department at bluebird bio. In addition to his basic science work, he has been part of the Adrenoleukodystrophy patient advocacy group ALD Connect, serving as co-chair of the Disease Mechanisms Workgroup, and the Industry Advisory Council. Before joining bluebird, he developed CLIA certified biochemical (enzyme) and DNA diagnostics for rare disease at the Massachusetts General Hospital. He completed his Ph.D. at Boston University in the Program in Molecular Biology, Cell Biology, and Biochemistry.

### Michael Burns, Process Development Scientist, bluebird bio

Michael Burns has 16 years of experience in the biotechnology field specializing in late stage process development of viral vectors. Prior to joining bluebird bio, he was the upstream lead at Amgen for the

Continued on the next page...

commercialization of Imlygic®, the first oncolytic cancer therapy approved in the US market. Michael and his team are responsible for developing the cell culture commercial vector manufacturing process for LentiGlobin®, Lenit-D<sup>TM</sup>, and bb2121 (a chimeric antigen receptor targeting BCMA) at bluebird bio all of which has received PRIME and breakthrough designation.

# Steve Goodman, Head of Drug Product Manufacturing, bluebird bio

Steve Goodman is the head of drug product manufacturing at bluebird bio, where he oversees production of cellular therapies across their portfolio of products and is accountable for the long-term technology strategy to expand access of these treatments to serve global patient requirements. Before joining bluebird in January 2018, Steve was at GSK where he held a number of roles across research, development, manufacturing and supply chain. As Director of Manufacturing and Strategy for GSK's CGT unit, he was responsible for the external manufacturing of the entire value chain to support GSK's cellular therapies, and for defining and executing the vector manufacturing strategy. Steve joined GSK in 2002 following a Ph.D. and post-doctoral fellowship in organic synthetic chemistry at Harvard University.

# Anne Kantardjieff, Director, Plasmids and Small Molecules Manufacturing, bluebird bio

Anne Kantardjieff currently serves as Director of Plasmids and Small Molecules Manufacturing at bluebird bio. Prior to that, she was the Director of Early Stage Process Development at Alexion Pharmaceuticals, where her team was responsible for Cell Line Development, as well as Upstream and Downstream Process Development for Alexion's early clinical biologics portfolio. She is the recipient of the 2018 ACS BIOT Van Lanen award, recognizing her service to the Biotechnology Division of the American Chemical Society division, where she also currently serves as Secretary. She obtained her Ph.D. in Chemical Engineering from the University of Minnesota, and her B.Eng. in Chemical Engineering from McGill University.

### **MEETING MANAGERS:**

**Stephen Lahti, P.E.,** RG Vanderweil Engineers **Alan O'Driscoll**, Jacobs

# ISPE Boston Area Chapter Presents:

# **Bringing Cell and Gene Therapies to Patients: Innovating to Meet Unique Challenges**

# Thursday, March 21, 2019

5:30 pm to 8:30 pm

# bluebird bio

60 Binney Street Cambridge, MA 02142

# **PROGRAM SCHEDULE:**

5:30 - 6:30 PMRegistration & Networking Reception

6:30 - 8:30 PMPresentations

8:30 - 9:00 PMO&A



Serving All of New England THANK YOU TO OUR PROGRAM SPONSORS







#### **REGISTRATION FEES: Registration by Registration After** 03/14/2019 03/14/2019 \$50 \$60 Members Young Professional Members \$20 \$30 Nonmembers \$95 \$115 Student Members **FREE FREE**

# **REGISTRATION IS NOW OPEN ONLINE!**

Don't waste time filling in the form! Register online at www.ISPEBoston.org/Events. Pay by credit card OR check.

Name:	Title:			
Do you wish to opt out of being	g listed on the attendee roster?:			
Company:		Member #:		
Address:	City:	State:	Zip:	
Tel:	Fax:	Email:		
PAY BY CREDIT CARD:	□ Visa □ MasterCa	rd	ress	
Card #:		Expiration Date:		
Cardholder Name (as it appea	rs on card):	·		
Cardholder Signature:				

ISPE Boston Area Chapter Presents:

# Bringing Cell and Gene Therapies to Patients: Innovating to Meet Unique Challenges

# Thursday, March 21, 2019

5:30 pm to 8:30 pm

# bluebird bio

60 Binney Street Cambridge, MA 02142

# **DIRECTIONS AND PARKING:**

Click here for door to door directions.

All attendees will be asked to present photo ID.



Serving All of New England
THANK YOU TO OUR PROGRAM SPONSORS







Street parking and garage parking is available for a fee.

The venue is located within walking distance of the Kendall Square T Stop. <u>Click here</u> to view a Red Line T Stop schedule.