WHEN: Thursday, November 14th, 2024
4:00 pm – 8:00 pm

WHERE: Northeastern University Innovation Campus, Building 5
147 S. Bedford Street
Burlington, MA 01803

PROGRAM DETAILS:

Users and Providers: A Workshop of Exploring the Dialogue of Documents

Cell and gene therapies have distinct differences from monoclonal antibodies and vaccines. Autologous cell and gene therapies add another element to the uniqueness of these therapies. This presentation will inform those new to the topic on some of these differences and dig into three challenges and how they were addressed for bluebird bio's LYFGENIA™.

Come to Northeastern University's Burlington Campus for an opportunity to experience insightful presentations and Q&A on the cutting-edge field of Cell & Gene Therapy. There will be a short introductory "course" offered on the basics of C&G therapies and how they are developed.

The main presentation will showcase industry experts delving into challenges they encountered while ensuring product quality and navigating regulatory landscapes crucial for bringing novel therapies to market.

AGENDA:

4:00 PM – "Introduction to Cell & Gene Therapy" Session - OPTIONAL 101 Session for those new to the field
5:00 PM – Arrival, Networking, Welcome Appetizers, and Tour of Makers Space Facility
6:00 PM – Introductions by Moderators and University Representative
6:15 PM – Main Speaker Presentations
7:00 PM – Q+A Session
7:20 PM – Networking and Refreshments

SPEAKERS:

Paul O'Sullivan's early career included about 10 years in process and product development at a medical device manufacturer. Paul then moved over to biopharmaceuticals where he has spent the last 24 years for multiple companies including Shire (now Takeda) and Sanofi. His experience included equipment and utilities qualification as well as cleaning validation.

The last eight years have been in cell and gene therapy. Initially Paul's role was in Quality Validation, establishing programs for contract manufacturing organization (CMO) oversight, technology transfer, process validation, continued process verification and comparability.

Paul's team has provided Quality Validation oversight for the process development and process validation of four variations of lentiviral vectors across three CMOs and five variations of drug product across three CMOs. Recently Paul's team merged with Quality Operations after which Paul took on responsibilities for clinical lot release. He also has direct CMO quality oversight for the LYFGENIATM program.

Kelly Kral is a seasoned expert with over 20 years of experience in the pharmaceutical industry, and has held various leadership roles at bluebird bio, Percivia, and Genzyme. Kelly has spent the last few years serving as the Vice President of CMC Strategy & Operations at bluebird bio, and has recently also taken on leadership of the Regulatory CMC team. Throughout her career, Kelly has demonstrated expertise in process development, regulatory pathways, and the successful scale-up and scale-out of gene therapies, making significant contributions driving clinical-stage programs into commercial products. Kelly holds a B.S. in Chemical Engineering from Clarkson University and a M.S. in Chemical Engineering from the Massachusetts Institute of Technology.

REGISTRATION FEES:

Registration by EOD Wednesday, November 6
Members (Early Bird): $50
Non-Members (Early Bird): $95
Emerging Leaders Members (Early Bird): $20
Student Members: FREE

Registration Starting Thursday, November 7
Members: $60
Non-Members: $115
Emerging Leaders Members: $30
Student Members: FREE

****PLEASE NOTE: CANCELLATIONS RECEIVED ON/AFTER NOVEMBER 7 ARE SUBJECT TO BILLING****

REGISTRATION IS NOW OPEN ONLINE AT:
www.ISPEBoston.org/Events.