

ISPE Boston Area Chapter Presents:

# What's Your Strategy: Make vs Buy ... or Both?

## Achieving Operational Readiness for the Manufacture of ATMP's

**Wednesday, June 8, 2022**

5:00 PM – 7:30 PM EST

*ElevateBio BaseCamp*

200 Smith Street, Waltham, MA 02451

### PROGRAM SUMMARY:

Join ISPE and our host ElevateBio, 2021 ISPE FOYA Category Award Winner for Operational Excellence, for an informative and fun filled evening of Facility Tours and a Panel Discussion with industry experts on June 8<sup>th</sup> at ElevateBio's Basecamp facility in Waltham, MA. We will delve into the challenges of bringing manufacturing facilities to operational readiness and delivering life-saving therapies.

These days, it is critically important to think hard (but not too long) about your manufacturing strategy for advanced therapy medicinal products (ATMPs); should you focus your energy on site selection, design, construction and the challenges of achieving operational readiness and building an internal organization or enter into a partnership with a Contract Manufacturing organization capable of meeting your time to market, technical requirements and quality parameters?

Regardless of your chosen strategy, there is complexity and challenge throughout the project Lifecycle. At this Panel Discussion you will hear from a wide-ranging group of industry leaders with many years of experience in fields that play pivotal roles in the success of bringing a product to market in a fast-moving industry.

Learn about the perspectives and strategies of bringing a new multi-modal facility on-line from Mike Paglia (COO, ElevateBio BaseCamp); new process technologies, throughput modelling and designing for flexibility from Emily Heffernan (US Director, New Process Technology, DPS Group); the challenges that abound with site selection and leveraging local and state incentive programs from Bob Coughlin (Managing Director, JLL); and the considerations and planning required to develop manufacturing solutions in house from Brett Belongia (VP, CMC Operations, Oncorus Inc).



Serving All of New England

### PROGRAM SPONSORS:



### EVENT AGENDA:

#### Registration and Networking: 5:00 – 6:30 PM

Networking includes food and beverages

Facility Tours (Register for tour on-site, no pre-registration required):

- 5:30 PM: Josh Sorafine, SVP, Quality and Analytics, ElevateBio
- 5:30 PM: Tess Kitchener, VP, Business Development, ElevateBio
- 5:40 PM: Mario Miele, VP, Facilities and Engineering, ElevateBio
- 5:40 PM: Pete Gelinas, Head of Manufacturing and Technical Operations, ElevateBio

#### Opening Remarks and Intro to ElevateBio's BaseCamp: 6:30 – 6:45 PM

- Andrew Sandford, President, ElevateBio, BaseCamp

#### Panel Discussion and Q&A: 6:45 PM

- Panel Moderator:
  - Jim Grunwald, SVP, US Business Development, DPS Group
- Panellists:
  - Michael Paglia, COO, ElevateBio BaseCamp
  - Emily Thompson, US Director, New Process Technology, DPS Group
  - Robert Coughlin, Managing Director US Life Sciences Practice, JLL
  - Brett Belongia, VP, CMC Operations, Oncorus Inc.

**Dessert Immediately Following Panel Discussion**

## WHO SHOULD ATTEND THIS WEBINAR:

Any individuals considering the manufacture of ATMP's in today's dynamic environment

## DIRECTIONS AND PARKING:

[Click here](#) for door to door directions. Free parking is available onsite.

## MEETING MANAGER:

**Amy Gusky**, Director of Business Development,  
TRIA Architects

## ONSITE COVID POLICY:

**ElevateBio Covid Policy:** All visitors are required to show proof of vaccination and masks are optional.

## REGISTRATION FEES:

	Registration by 6/1/2022	Registration After 6/1/2022
<input type="checkbox"/> Members	\$50	\$60
<input type="checkbox"/> Emerging Leaders Members	\$20	\$30
<input type="checkbox"/> Nonmembers	\$95	\$115
<input type="checkbox"/> Student Members	FREE	FREE

**\*\*PLEASE NOTE: CANCELLATIONS RECEIVED AFTER June 1 ARE SUBJECT TO BILLING\*\***

## REGISTRATION IS NOW OPEN ONLINE!

Please complete the online registration at [www.ISPEBoston.org/Events](http://www.ISPEBoston.org/Events).

## SPEAKERS:



### **Andrew Sandford, President, ElevateBio, BaseCamp**

Andrew Sandford brings over 20 years of experience in building, operating, and leading life science technology and manufacturing companies and will continue to extend the ElevateBio BaseCamp strategic partnerships in the field of cell and gene therapy.

Prior to ElevateBio, Andrew worked in several leadership roles to oversee the successful implementation of strategic business development, marketing, and manufacturing operations. Notably, as Global Vice President of Business Development, Biologics for Catalent Pharma Solutions, Inc., his teams were responsible for driving revenue expansion, enabling the transformation of Catalent to a global biologics services provider.

Prior to Catalent, Andrew held various leadership positions at Selexis Inc, Lonza Corporation, and Dow Chemical Company, creating strategic value through global business and licensing opportunities and increasing business unit profitability.

Most recently, Andrew was an Executive in Residence for Anzu Partners, Co-founder and Chief Executive Officer of VREX Therapeutics, and Founder, Inventor and Managing Director of Arthropod Biosciences.

Andrew received a Bachelor of Science in Microbiology from the State University of New York at Plattsburgh.



### **Jim Grunwald, SVP, US Business Development, DPS Group**

Jim brings more than 30 years of experience in the AEC industry to his position of SVP, U.S. Business Development. He joined DPS Group in 2015 and previously served as Vice President of Strategic Development for Boston's Project Operations. In this role, he successfully led teams and delivered strategic capital projects for leading biotech/pharmaceutical and advanced technology clients. Jim supports all of DPS' internal and external client relationships with expert guidance in the areas of planning, risk assessment, site selection, estimating, CQV, and operational readiness. He also has special expertise in strategic planning, real estate development, and risk assessments associated with capital projects and product development in the regulated industry and advanced technology sectors. Additionally, Jim fulfills the role of project sponsor for many of DPS' strategic project initiatives, providing senior management oversight and guidance to project teams on behalf of clients including Moderna, Sanofi, AbbVie, Acorda, Brammer Bio, and Waters Corporation.

Jim is an active member of ISPE Boston, having previously served as president of the chapter's board of directors and helping to start the ISPE Boston Chapter Scholarship Fund. He is also a founding member of the I2SL New England Chapter.



### **Michael Paglia, COO, ElevateBio BaseCamp**

Michael has over 16 years of experience building, leading and motivating process development and manufacturing teams to support clinical programs from early development to late stage clinical trials.

Prior to ElevateBio, Mike was the Vice President of CMC Operations at Oncorus and Program Lead for the development of a next-generation oncolytic immunotherapy platform. Prior to Oncorus, Michael was the Sr. Director of Technical Operations and Head of Cellular Process Development and Manufacturing Operations at bluebird bio.

Mike received his BS in Biology from Providence College and MS in Biochemistry & Cell Biology from the University of New Hampshire.



### **Emily Thompson, US Director, New Process Technology, DPS Group**

Emily Thompson, US Director New Process Technologies, is a process Subject Matter Expert (SME), specializing in biological process and facility design. Working in the life sciences for 20 years, she has gained expertise in designing facilities for monoclonal antibodies, vaccines, novel therapies including cell and gene therapy production. She is industry-recognized for her subject matter expertise in multi-modal facilities where different product types are produced in the same facility, due to her deep knowledge of complex facility layouts, GMP flows, and regulatory considerations.

A graduate of North Carolina State University, Emily holds two degrees: a Bachelor of Science in chemical engineering and Bachelor of Science in biochemistry. She is also a licensed Professional Engineer in the state of North Carolina and an active member of the International Society of Pharmaceutical Engineers (ISPE).



### **Robert Coughlin, Managing Director US Life Sciences Practice, JLL**

As Managing Director of Life Sciences at JLL, Bob knows that for life science companies, solving complex human challenges is their top priority and that's why he is thrilled to make the transition into real estate. In this role, Bob will be a strong partner to life science companies to help them identify opportunities to optimize their portfolios, whether it's through site selection, tax incentives or operational efficiencies.

Most recently Bob served as the President and CEO at MassBio. In this role, Bob's mission was to advance Massachusetts' leadership in the life sciences to grow the industry, add value to the healthcare system and improve patient lives. Over the fourteen years, Bob truly became a champion for patients by ensuring innovative companies have the best environment possible to research, develop, and commercialize breakthrough therapies and cures for people around the world who need and deserve them. Bob played an integral role in making Massachusetts the best place in the world for the life science industry.

Bob has spent his career in both the public and private sectors. Before joining MassBio, he served as the Undersecretary of Economic Development within Governor Deval Patrick's administration, where he prioritized both healthcare and economic development issues and was a strong advocate for the life sciences industry in Massachusetts. Prior to that, he was elected as State Representative to the 11th Norfolk district for three terms.



**Brett Belongia, VP, CMC Operations, Oncorus Inc.**

Brett is the Vice President of CMC (Chemistry, Manufacturing, Control) Operations and the site head at Oncorus, a company dedicated to developing the next generation of oncolytic viruses for the treatment of cancer. Brett is responsible for the strategic direction and operational responsibilities related to the manufacturing, development, and quality of oncolytic viruses from early-stage clinical development through commercialization. Brett oversees the key process development and manufacturing personnel, both internal and external, that produce the drug products needed to treat patients in the clinic.

Under Brett's leadership, Oncorus has built significant internal process development expertise around the production of oncolytic viruses for both of Oncorus' technology platforms. This has allowed Oncorus to develop platform processes that can be adapted to fit many new oncolytic viruses and minimize the timing and resources needed to tech transfer and scale up to clinical manufacturing scale. In addition, Brett has led the construction of Oncorus' internal GMP manufacturing facility to support Oncorus' clinical drug product needs and minimize the operational risk and timelines. These accomplishments have put Oncorus in an excellent position to rapidly and effectively develop processes to support their clinical demands.

Brett is the inventor on 13 patents and an author on multiple publications. Brett received his Ph.D. in Chemical Engineering from The University of Arizona after completing his BS in Chemical Engineering at The University of Wisconsin – Madison.

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Pay by credit card OR check.