



Biomanufacturing and Process Development (BPD)

BPD New Company Welcome Event

Thursday, September 16, 2021
12:00 p.m. - Registration begins
12:30 p.m. - Presentations & Networking
North Carolina Biotechnology Center

Program Organizers:

Katie Stember, NCBiotech
Ronna Dornsife, NCCU
Rob Onyenwoke, NCCU

EVENT SPONSORED BY :



**North Carolina
Biotechnology Center**

AGENDA

12:00 – 12:30 pm	Registration
12:30 – 12:40 pm	Welcome from BPD, NC Virtual Networking Group, and Event Sponsor Metalytics
12:40 – 1:25 pm	Introductory Presentations from Company Representatives Part 1
12:40 – 12:55 pm	Amgen Wendy Acton - HR Site Head Tara Urban - Site Communication Lead
12:55 – 1:10 pm	Lilly Dan VonDielingen - RTP Site Lead
1:10 – 1:25 pm	Abzena Kimball Hall - Chief Operating Officer
1:25 – 2:15 pm	Networking Session Part 1 and Refreshments
2:15 – 3:15 pm	Introductory Presentations from Company Representatives Part 2
2:15 – 2:30 pm	Astellas Gene Therapies Don Mather - Executive Director, Manufacturing & Operations Site Head Dominic DeMuro - Executive Director, Quality Site Head Kenya Maddox - Associate Director, Operations Project Management
2:30 – 2:45 pm	Beam Therapeutics Tom Jede - North Carolina Site Head
2:45 – 3:00 pm	CARSgen Therapeutics Cristina Colon - US HR Manager
3:00 - 3:15 pm	Taysha Gene Therapies Greg Gara - SVP of Manufacturing
3:15 – 4:00 pm	Networking Session Part 2

FEATURED COMPANIES

Amgen

Company Bio:

Amgen is committed to unlocking the potential of biology for patients suffering from serious illnesses by discovering, developing, manufacturing and delivering innovative human therapeutics. This approach begins by using tools like advanced human genetics to unravel the complexities of disease and understand the fundamentals of human biology. Amgen focuses on areas of high unmet medical need and leverages its expertise to strive for solutions that improve health outcomes and dramatically improve people's lives. A biotechnology pioneer since 1980, Amgen has grown to be one of the world's leading independent biotechnology companies, has reached millions of patients around the world and is developing a pipeline of medicines with breakaway potential. In August 2021, Amgen [announced](#) a \$550M investment in Holly Springs, North Carolina that will create 355 jobs.

Speaker Bios:

Wendy Acton - Amgen, HR Site Head

Wendy Acton is the HR Site Head for Amgen's new, final product advanced assembly and packaging plant to be built in New Albany, Ohio, with additional responsibility as the Acting HR Site Head for Amgen's new multi-product drug substance manufacturing facility to be built in Holly Springs, North Carolina. Wendy started her career with Amgen in 2006 and since then has performed in roles of increasing responsibility supporting staff across 6 locations in the US and over a dozen locations globally, in a variety of business areas including Research and Development, Operations, Information Systems, Finance, Worldwide Compliance, Global Strategic Sourcing and Global Commercial Operations. Wendy's Amgen experience also includes oversight of a global HR investigations capability focused on supporting staff in the Middle East, Africa, Turkey, Latin America and Canada. Prior to Amgen, Wendy worked for 5 years at Merck in West Point, Pennsylvania providing HR support for the Research and Development area and oversight of R&D's diversity, inclusion and belonging programs.

Tara Urban - Amgen, Site Communication Lead

Tara Urban joined Amgen in 2016 as the Site Communication Lead for Amgen Rhode Island with increasing responsibility in supporting communication strategies for Amgen Woburn, Amgen Louisville and most recently Amgen North Carolina. Tara is responsible for site corporate communications, working with government affairs, while leading local philanthropy and social responsibility and sustainability efforts. Prior to joining Amgen, Tara began her career as the Director of Marketing for a Public

Relations Agency in Connecticut and held various positions in Marketing and Communications for Optum Health and Aetna. She was also the ghostwriter and publicist for a Best Selling Author and Hollywood Publicist. Tara is an active participant in Amgen's diversity, inclusion and belonging employee resource groups and the sponsor of Amgen's Black Employee Network group.

FEATURED COMPANIES

Lilly

Company Bio:

Lilly is a global healthcare leader that unites caring with discovery to create medicines that make life better for people around the world. We were founded more than a century ago by a man committed to creating high-quality medicines that meet real needs, and today we remain true to that mission in all our work. Across the globe, Lilly employees work to discover and bring life-changing medicines to those who need them, improve the understanding and management of disease, and give back to communities through philanthropy and volunteerism. In January of 2020, Lilly [announced](#) a \$470M investment in RTP, North Carolina that will create 460 jobs.

Speaker Bios:

Dan VonDielingen - Lilly, RTP Site Lead

Dan VonDielingen (DVD) is the Site Lead for the Lilly RTP manufacturing facility currently under construction. Dan joined Lilly in 2000 and has held roles of increasing responsibility in Engineering, Quality and Operations across multiple sites and networks. His most recent role was the Site Lead for the Indianapolis Device Assembly and Packaging facility responsible for the commercial supply and advancement of Lilly pipeline molecules.

FEATURED COMPANIES

Abzena

Company Bio:

Abzena is a life sciences group with its headquarters in San Diego, California with other sites across the US and Europe. Abzena provides the most complete set of solutions in integrated early discovery to mid-phase biotherapeutic and ADC drug development services in the pharmaceutical industry. Working with companies and academic groups all over the world, including most of the top 20 biopharmaceutical companies, Abzena supports the development and manufacture of better treatments for patients. Multiple antibodies which have been created using Abzena's technologies are currently being progressed through clinical development by their licensees. In April 2021, Abzena [announced](#) a \$213M investment in Sanford, North Carolina that will create 325 jobs.

Speaker Bios:

Kimball Hall - Abzena, Chief Operating Officer

Kimball Hall serves as Abzena's President and COO at Abzena. She is accountable for all operations across the company and sits as the member of Abzena's Board. Abzena is a Partner Research Organization delivering integrated outsourced discovery, development, and manufacturing to the Biologics and ADC industry. Kimball has more than 30 years in Commercial Operations with Sr. leadership roles in Manufacturing, Quality, and Regulatory Compliance. She has a wide range of experience in developing, licensing, and supplying Biopharmaceuticals for global markets.

FEATURED COMPANIES

Astellas Gene Therapies

Company Bio:

Astellas integrated its wholly owned subsidiary, Audentes Therapeutics, Inc. as of April 1, 2021 and established “Astellas Gene Therapies” within the organization as an Astellas Center of Excellence developing genetic medicines with the potential to deliver transformative value for patients. Based on an innovative scientific approach and industry leading internal manufacturing capability and expertise, they are currently exploring three gene therapy modalities: gene replacement, exon skipping gene therapy, and vectorized RNA knockdown and hope to also advance additional Astellas gene therapy programs toward clinical investigation. The company is based in San Francisco, with manufacturing and laboratory facilities in South San Francisco and Sanford, North Carolina. In February 2020, Astellas Gene Therapies [announced](#) a \$109.4M investment in Sanford, North Carolina that will create 209 jobs.

Speaker Bios:

Don Mather - Astellas Gene Therapies, Executive Director, Manufacturing & Operations Site Head

Don serves as Executive Director, Manufacturing and Operations Site Head at the Astellas Gene Therapies large scale drug substance manufacturing plant in Sanford, NC, which will manufacture the company’s portfolio of AAV-based gene therapies aimed at targeting rare neuro-muscular diseases. Throughout his 24-years of industry experience, Don has held positions of increasing responsibility manufacturing clinical and commercial large molecule biologics and accumulated significant facility start-up, commissioning, validation, and licensure experience. He joined Astellas Gene Therapies in 2020 from Grifols in Clayton, NC, where he was Director of Validation for a \$2BB+, 14 product facility and served as Director of Manufacturing, overseeing a team of 250. Prior to Grifols Don held the position of Sr. Director of Biologics Manufacturing and Program Management at ImaRx Therapeutics and worked in both manufacturing and R&D at Human Genome Sciences in Rockville, MD. Don holds a Bachelor of Science degree in Biochemistry from the University of Washington and Master of Science degree in Biotechnology from Johns Hopkins University with certifications in Management, Leadership, and Biostatistics.

Dominic DeMuro - Astellas Gene Therapies, Executive Director, Quality Site Head
Dominic serves as Executive Director, Quality Operations for the Astellas Gene Therapies manufacturing facilities in Sanford, and South San Francisco, CA. Dominic

has held positions of increasing responsibility in both manufacturing and quality operations in his 29-years of experience manufacturing clinical and commercial large molecule biologics, accumulating significant facility start-up, commissioning, validation, and licensure experience. He joined AGT in 2020 from Pfizer, where he was Director of Site Quality Operations for their multiproduct vaccines and gene therapies facility in Sanford and also served as Director of Manufacturing Operations for their mammalian cell culture clinical launch facility in Cork, Ireland. Prior to Pfizer, Dominic held positions in manufacturing and quality operations at Amgen and Synergen, Inc. Dominic holds a Bachelor of Science degree in Molecular, Cellular, and Developmental Biology from the University of Colorado and a Master of Business Administration degree from the University of Denver.

Kenya Maddox - Astellas Gene Therapies, Associate Director, Operations Project Management

Kenya serves as Associate Director, Operations Project Management, overseeing the startup of the Astellas Gene Therapies location in Sanford, NC. Throughout her 19-years in medical devices, medical diagnostics, and biotherapeutics industries; Kenya accumulated significant experience in process development, process engineering, technology transfer, and project management. She joined Astellas Gene Therapies from bioMerieux, where she was Senior Manager and Department Head of Industrialization and part of site leadership with oversight of tech transfer projects, process engineering, and analytical/raw material qualifications, and production compliance. Prior to bioMerieux Kenya worked for Grifols and Siemens Medical. Kenya holds a Bachelor of Science degree in Biological Engineering from North Carolina State University, a Master of Science degree in Engineering from Purdue University, a certificate in Global Management from Thunderbird School of Global Management, and project management certification from PMI.

FEATURED COMPANIES

Beam Therapeutics

Company Bio:

Beam Therapeutics is a biotechnology company committed to establishing the leading, fully integrated platform for precision genetic medicines. To achieve this vision, Beam has assembled a platform that includes a suite of gene editing and delivery technologies and is in the process of building internal manufacturing capabilities. Beam's suite of gene editing technologies is anchored by base editing, a proprietary technology that enables precise, predictable and efficient single base changes, at targeted genomic sequences, without making double-stranded breaks in the DNA. This enables a wide range of potential therapeutic editing strategies that Beam is using to advance a diversified portfolio of base editing programs. Beam is a values-driven organization committed to its people, cutting-edge science, and a vision of providing life-long cures to patients suffering from serious diseases. In August 2020, Beam Therapeutics [announced](#) a \$83M investment in RTP, North Carolina that will create 201 jobs.

Speaker Bios:

Tom Jede - Beam Therapeutics, North Carolina Site Head

Tom Jede is the Plant Manager Site Head, cGMP Manufacturing for Beam Therapeutic's new manufacturing facility in Durham, North Carolina. Tom's responsibilities include providing strategic and technical leadership throughout construction, commissioning, qualification, and start-up. Tom oversees the hiring and development of staff for the leadership and execution of manufacturing operations. He is accountable for the development of operational strategies to build a nimble, flexible, efficient operation and ensure safe and reliable supply of products.

FEATURED COMPANIES

CARsGen Therapeutics

Company Bio:

CARsGen Therapeutics is a biopharmaceutical company with operations in China and the U.S. focused on innovative CAR-T cell therapies for the treatment of hematological malignancies and solid tumors. The Company has internally developed novel technologies and a product pipeline with global rights to address major challenges of CAR-T cell therapies, such as improving the safety profile, enhancing the efficacy in treating solid tumors and reducing treatment costs. The Company's vision is to become a global biopharmaceutical leader that brings innovative and differentiated cell therapies to cancer patients worldwide and makes cancer curable. In May 2021, CARsGen Therapeutics [announced](#) a \$157M investment in Durham, North Carolina that will create 200 jobs.

Speaker Bios:

Cristina Colon - CARsGen Therapeutics, US HR Manager

Cristina Colón is the US HR Manager for CARsGen Therapeutics Corporation and is leading their hiring plan of staffing over 200+ positions for their new manufacturing facility in the Research Triangle Park area. Cristina has over 20 years of experience as an HR practitioner across multiple industries ranging from Oil & Gas, Manufacturing, Healthcare, and most recently Pharmaceutical and Biotech. Cristina has her Masters in Organizational & HR Development from Abilene Christian University (ACU) in Abilene, TX, and is currently pursuing her Doctorate in Organizational Leadership also from ACU.

FEATURED COMPANIES

Taysha Gene Therapies

Company Bio:

Taysha Gene Therapies is on a mission to eradicate monogenic CNS disease. With a singular focus on developing curative medicines, we aim to rapidly translate our treatments from bench to bedside. We have combined our team's proven experience in gene therapy drug development and commercialization with the world-class UT Southwestern Gene Therapy Program to build an extensive, AAV gene therapy pipeline focused on both rare and large-market indications. Together, we leverage our fully integrated platform—an engine for potential new cures—with a goal of dramatically improving patients' lives. In December 2020, Taysha Gene Therapies [announced](#) a \$75M investment in Durham, North Carolina that will create 201 jobs.

Speaker Bios:

Greg Gara - Taysha Gene Therapies, SVP of Manufacturing

Greg R. Gara has over 25 years of experience in the biotechnology field specializing in designing, constructing, and starting up large- and small-scale manufacturing facilities throughout the world. Greg is currently the SVP of Manufacturing for Taysha Gene Therapies. Prior to joining Taysha he was the VP of Pharmaceutical Engineering at Sarepta. Before Sarepta, he designed, constructed, and started up the facility located in North Chicago for AveXis, a Novartis company, led the team for the facility expansion in North Carolina, in addition to renovating the recently acquired Colorado site. Greg and his team were responsible for the design, construction, startup, and commissioning of the new facilities being constructed in Research Triangle Park and Colorado. Prior to AveXis, he led the facilities and engineering organization at Hospira prior to the Pfizer acquisition. Before joining Hospira, Greg spent 15 years working for Amgen and was part of the Cork Ireland construction project.



Program Schedule 2021 – 2022 Season

Month	Program
September 16, 2021	BPD New Company Welcome Event NC Biotechnology Center
October 21, 2021	Vaccines Symposium NC Biotechnology Center
November 18, 2021	Analytical Symposium NC Biotechnology Center
February 17, 2022	BioGrow Training and Education Across NC Symposium
March 10, 2022	Supply Chain Symposium NC Biotechnology Center
April 14, 2021	Cell and Gene Therapy Symposium and Full Day Vendor Show NC Biotechnology Center
	**Monthly Meeting and Vendor Sponsorship Packages available, for more information contact Hannah_cole@ncbiotech.org **



Biomanufacturing & Process Development Group

An Intellectual Exchange Group of the North Carolina Biotechnology Center

Mission and Goals

BPD's mission is to provide a forum for process development scientists and engineers to discuss bioprocessing issues. The group meets approximately six to seven times a season/year with speakers from academia, industry, technology, vendor experts, and regulatory experts.

Membership Guidelines

Faculty, students, postdocs and industry members with interest in BPD are welcome.

Meeting Format

Similar meeting format as previous years will be maintained in the 2021-2022 season. Each event will host multiple speakers centered around the event theme, allow a time for networking among attendees, and optionally include a vendor show or poster presentations.

Sponsorships

Monthly meeting and vendor sponsorship packages available. Please contact Hannah Cole, Hannah_cole@ncbiotech.org, for additional information.

Steering Committee

Interested in getting involved and helping to plan BPD events? Join our steering committee! Contact Katie Stember, Katie_Stember@ncbiotech.org, for additional information.

For More Information

Visit our website: www.ncbiotech.org/bpd

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