




# AMERICAN BIOMANUFACTURING SUMMIT 2022


APRIL 13-14, 2022

[biomanamerica.com](http://biomanamerica.com)

## TOMORROW'S CONNECTION TODAY

Designing a new future for manufacturing, quality and supply chain leaders

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 [info@generisgp.com](mailto:info@generisgp.com)

## PROGRAM

# PROGRAM • DAY 1

APRIL 13, 2022

\* JOIN US FOR THE PRE-EVENT HAPPY HOUR ON APRIL 12, 2022 FROM 6:00 PM – 7:00 PM

6:00 am – 6:55 am PST

## DELEGATE REGISTRATION AND NETWORKING BREAKFAST

7:00 am – 7:10 am PST

## CHAIR'S WELCOME AND OPENING REMARKS

### MANUFACTURING AND TECHNOLOGY



**JOYDEEP GANGULY**  
SVP, Operations  
*Gilead Sciences*

### QUALITY AND COMPLIANCE



**DIANE HAGERTY**  
SVP, Head, GxP Quality & Compliance  
*Allogene Therapeutics*

### SUPPLY CHAIN AND LOGISTICS



**RUBY CASARENO, PH.D.**  
SVP, Technical Operations  
*Allakos*

7:10 am – 7:45 am PST

## OPENING KEYNOTE



**PETER MARKS, M.D., PH.D.**  
Director, Center for Biologics Evaluation and Research (CBER)  
*Food and Drug Administration (FDA)*

## REFLECTING ON THE PAST AND SETTING GOALS FOR THE NEXT DECADE OF VACCINE INNOVATION

- Facilitating the development of biological products and providing oversight throughout the product life cycle
- Reviewing and providing advice during vaccine product development
- Evaluating applications and making approval decisions based on safety and effectiveness data
- Monitoring the safety of biological products

7:45 am – 8:20 am PST

## PLENARY



**ARLEEN PAULINO**  
SVP, Global Manufacturing  
*Amgen*

## REVOLUTIONIZING THE MANUFACTURING LANDSCAPE TO OPTIMIZE PATIENT OUTCOMES

- How is Amgen transforming biomanufacturing for a faster, more data-savvy future?
- Addressing unmet patient needs and creating new markets through connected technology and other manufacturing innovations (smart materials, process automation and more)
- Why building agile, high performance teams are at the heart of revolutionary manufacturing
- Case study: Looking back on COVID-19 risk management strategies as a cornerstone to gain a better understanding for the future of manufacturing

8:20 am – 8:55 am PST

## PLENARY



**RICH KILMER**  
CEO  
CargoSense

### MINIMIZING PRODUCT RISK AND MEASURING CARRIER PERFORMANCE WITH A VISIBILITY OS

- Following the GMP, with process measurement and controls, pharmaceuticals create incredibly high-quality products in a scalable fashion
- When products leave your manufacturing site, the risk to the quality of your product is extremely high, and SOPs are developed to minimize that risk and maximize delivered product quality and shelf-life, but measurements are not performed to ensure compliance
- This talk will focus on how to validate SOPs on every shipment using a Visibility Operating System, a combination of easy to use sensors and advanced software automation ensuring the quality of service is being met by forwarders and carriers
- Although every shipment handling process is automatically validated, personnel are only pulled in when exceptions occur, dramatically limiting workloads
- The aggregation of this analysis creates real-time dashboards that provide complete logistics supply chain visibility and trending performance
- All of this will be demonstrated to work at scale, globally, for a low service fee and minimal operational impact

9:00 am – 10:40 am PST

## REFRESHMENTS, NETWORKING, AND PRE-ARRANGED 1-2-1 MEETINGS

10:45 am – 11:20 am PST

## SESSIONS

### MANUFACTURING AND TECHNOLOGY



**QIAN RUAN**  
VP, Technical Operations and  
Manufacturing  
Arcturus Therapeutics

#### EXAMINING THE RAPID SCALE-UP AND CLINICAL ADVANCEMENT OF MRNA THERAPEUTICS AND LYOPHILIZED VACCINES

- Exploring the novel development and manufacturing technologies for mRNA therapeutics and lyophilized vaccines
- Discussing manufacturing capacity and production cycles in relation to mRNA
- Addressing the unmet medical needs of numerous patients worldwide through mRNA therapeutics
- Global technology transfer, process validation rapid commercialization, and supply strategies
- Examining unique collaboration and risk-sharing models to help achieve milestones and bring products to market

### QUALITY AND COMPLIANCE



**DEBORAH BALY**  
VP, Quality Business Partner  
(Biotechnology)  
Bayer

#### SETTING THE QUALITY PARADIGM AND DIRECTION FOR BAYER'S CURRENT AND FUTURE BIOLOGIC PRODUCT PORTFOLIO

- Leading the overall quality responsibility for Bayer's Biologic product portfolio
- How to support efficient and compliant development of clinical candidates supporting the rapid development timelines and seamless transition of development products into commercial production
- Bringing a holistic business perspective and innovation focus to the team
- Why quality is a valued partner and enabler in business processes and solutions

### SUPPLY CHAIN AND LOGISTICS



**BALA SREENIVASAN**  
VP, Global Supply Chain Management  
and Operations  
Merck

#### BIOPHARMA SUPPLY CHAINS: MAXIMIZING OPERATIONAL RESILIENCY OF TODAY, WHILE TRANSFORMING FOR TOMORROW

- Leading global supply chain operations at Merck across vaccines, biologics and small molecules portfolios
- Balancing priorities for manufacturing-commercialization interface, including supply chain design for the pipeline, and new modalities like cell therapy and antibody drug conjugates
- Supply Chains put to test with the pandemic: How well were we prepared for the onslaught of supply chain disruptions in 2020 and 2021. Where were the failings?
- Priorities for overcoming multi-node, multi-tier and opaque supply chains riddled with downstream exposure
- How did our ongoing digital transformation help overcome obstacles? Some key examples
- How operational resiliency has shifted focus to promote effective supplier sourcing like auto & semiconductor industries
- Supply Chain designs for the future & vision for digital, self-healing supply chains

11:25 am – 12:00 pm PST

## WORKSHOPS

### MANUFACTURING AND TECHNOLOGY



**BRAD LARSON**  
VP, Program Management  
*Bionova Scientific*

#### PHASE I-II BIOLOGICS MANUFACTURING: A RAPID PATHWAY TO-AND-THROUGH THE CLINIC WITH STREAMLINED CMC DEVELOPMENT & MANUFACTURING

- How we partner with customers to ensure early-stage timelines remain on track and on budget while still ensuring a robust process that positions you for late stage and commercial success
- Leveraging co-located & integrated process development, analytical and GMP manufacturing functions for speed and productivity
- How modern facility design and platform processes can contribute to faster manufacturing kick-off
- Improve visibility and eliminate slowdowns with electronic data-sharing and paperless collaboration systems

### QUALITY AND COMPLIANCE



**CHRISTIE WILLIAMS**  
Chief Transformation Officer  
*FUJIFILM Diosynth Biotechnologies*

#### BUSINESS TRANSFORMATION AS A PLATFORM FOR INTEGRATION AND INNOVATION

- Establishing a foundation for integration
- Scaling systems and teams to keep pace with growth
- Innovation as an enabler
- Leveraging organizational strengths to deliver on the strategy
- How governance keeps us accountable

### SUPPLY CHAIN AND LOGISTICS



**CHRIS TAYLOR**  
Head, Consulting, PAS-X Savvy  
*Korber Pharma Software Solutions*

#### DIGITAL TWIN IMPLEMENTATION IN BIOPROCESS FROM PROCESS CHARACTERIZATION TO COMMERCIAL MANUFACTURING

- The integrated process model (IPM) is the engine of the maturing technology of digital twins in bioprocessing. However, there few challenges to consider in deploying digital twins in commercial manufacturing
- Scale offsets, variance differences, and interactions with critical process parameters
- Upstream processing where product quality is difficult to assess analytically
- Extrapolation of models when outliers appear in manufacturing
- Real-time applications and connection as a true digital asset

12:05 pm – 1:05 pm PST

## LUNCH & LEARN ROUNDTABLE DISCUSSIONS

Benefit from additional learning by joining a moderated roundtable discussion on pressing issues in the industry. Registration is required, and attendance is limited. Choose from:



**ANDREW BESHORW**  
Technical Operations Manager  
*Singota Solutions*



**JAMES TIMMINS**  
Director, Business Development and Regulatory Affairs  
*ADS Biotec*



**GREGORY MARK**  
Territory Manager, Sr. Sales Executive  
*Boston Analytical*

#### INCREASING SPEED FROM DEVELOPMENT TO CLINIC WITH A ROBUST TECHNICAL TRANSFER



**SUSANNE ROMMEL, MBA**  
Site Quality Head  
*Boehringer Ingelheim Fremont, Inc.*

#### PHARMACEUTICAL MRNA/NUCLEIC ACIDS VIA HPLC – THE FASTEST ROUTE TO CLINICAL TRIALS?



**ASHLEY BAREY**  
Director, Strategic Development  
*Tempime, Zebra Technologies Corporation*

#### BUILD YOUR ANALYTICAL TOOLBOX TO IMPROVE TESTING, CHARACTERIZATION & VALIDATION STRATEGIES



**MARK DAVIS**  
Director, Tech Transfer, MSAT  
*AGC Biologics*

#### SMALL STRATEGIES TO FOSTER A LEAN AND INNOVATIVE QMS



**DAVID FRANK**  
VP, Client Development  
*Azzur Group*

#### STORAGE AND DISTRIBUTION OF TEMPERATURE SENSITIVE BIOLOGICS: HOW DO YOU KNOW WHAT'S HAPPENING TO YOUR PRODUCT AFTER IT'S LEFT YOUR FACILITY?



**HAL HIKITA**  
Senior Director, BIOVIA Strategy and Alliances  
*BIOVIA*

#### MANUFACTURING PROCESS EXCELLENCE: IT ALL BEGINS WITH TECH TRANSFER



**DAVONE PLATZ**  
Commercial Development Manager, Gene Therapies  
*Pall Corporation*

#### MANUFACTURERS DILEMMA: BUILD, BROKER, OR BLEND

#### OPTIMIZING BIOPHARMA OUTCOMES BY CONNECTING MANUFACTURING AND QUALITY PROCESSES

#### ACCELERATE DELIVERY OF COMMERCIALY VIABLE GENE THERAPIES TO PATIENTS

1:10 pm – 1:45 pm PST

## WORKSHOPS

### MANUFACTURING AND TECHNOLOGY



**KEITH DODSON**  
VP, Global Business Development  
AST

#### THE ADVANTAGES OF ROBOTICS IN ASEPTIC FILL FINISH

- How Robotics Offer New Answers to Today's Challenges
- Leveraging semi-automated to completely automated and integrated cGMP manufacturing systems for processing vials, syringes and cartridges
- Maintaining aseptic conditions throughout the product process for complex biologic compounds, recombinant proteins and monoclonal antibodies (MAbs)

### QUALITY AND COMPLIANCE



**MARTIN SCOTT**  
Principal  
ALULA

#### HOW ANSWERING 4 QUESTIONS DRIVES HIGH-PERFORMANCE

- Are you truly motivating your teams?
- Have you provided the resources necessary for success?
- Are you ensuring your team members have the skills they need?
- Have you really provided clear direction for your workforce?
- Research shows that leaders in high performing organizations accomplish the above in exceptional ways.

### SUPPLY CHAIN AND LOGISTICS



**ADAM PFEIFFER**  
VP, Strategy  
Project Farma



**JOHN KHOURY**  
EVP  
Project Farma



**CHRIS MCDONALD**  
SVP and Global Head, Manufacturing  
Kite Pharma



**KAREN WALKER**  
Chief Technology Officer  
Kyverna Therapeutics

#### FLEXIBLE MANUFACTURING: BUILDING THE FACILITIES OF THE FUTURE

- What are flexible manufacturing technologies?
- Design and construction considerations to improve success
- Advantages of using these technologies
- Future outlook of flexible manufacturing facilities

1:50 pm – 2:25 pm PST

## SESSIONS

### MANUFACTURING AND TECHNOLOGY



**JUSTIN SKOBLE**  
VP, Technical Operations  
Caribou Biosciences, Inc.

#### USING INNOVATION AS A CORNERSTONE TO BUILD FUTURE CELL AND GENE THERAPY PLATFORMS

- What challenges and opportunities are there when commercializing live modalities like Car-T/TCR?
- Strategies for engineering allogeneic car-t cells, improving potency and durability
- Leveraging industry best practices to help you achieve enhanced visibility, efficiency and robustness across your organization
- Outlining robust manufacturing processes to yield products that are more patient-centric over their lifecycle

### QUALITY AND COMPLIANCE



**JIM PLOUSIS**  
Senior Director, Supplier Quality  
The Janssen Pharmaceutical Companies of  
Johnson & Johnson

#### BUILDING AN AGILE ORGANIZATION THAT VALUES SUPPLIER QUALITY

- Building a nimble and flexible organization that values supplier quality
- Transforming quality planning into actionable insights
- How to structure a supplier quality organization for biomanufacturing and pharmaceutical organizations: Janssen's roadmap for success
- From reactive to proactive: Effectively managing risk
- Case study: Our "Fit For Purpose" model in action

### SUPPLY CHAIN AND LOGISTICS



**ANDY SKIBO**  
Chief Manufacturing Officer  
FluGen Inc.

#### VACCINE DEVELOPMENT RISK FACTORS: BIGCO. ENVIRONMENT VS SMALLCO. ENVIRONMENT

- Discussing the challenges around developing and delivering a COVID-19 vaccine, and how biotech leaders not making a COVID vaccine are managing flow and progress (managing scale-up and limitations for BigCo versus SmallCo)
- How manufacturing and supply chain plays a pivotal role in vaccine development
- Understanding the real risks to supply chain structure
- Why understanding risk factors is the key to being proactive

2:30 pm – 3:05 pm PST

## WORKSHOPS

### MANUFACTURING AND TECHNOLOGY



**RODRIGO HORACIO GONZALEZ**  
Senior Director and Head, R&D Center at  
AGC Biologics  
GORE

#### PROTEIN A MEMBRANE CHROMATOGRAPHY ENABLING HIGH-PRODUCTIVITY MAB PURIFICATION AT PILOT SCALE

- Advances in membrane technology have facilitated the generation of novel Protein A membrane devices with high capacity, suitable for affinity chromatography operations at short residence times
- Using these affinity membranes, high productivity modes of operation have been attained on standard liquid handling chromatography systems at lab and pilot scale
- In this presentation, we will show the results of a pilot scale evaluation of a GORE® Protein Capture Device operating at conditions targeting maximum productivity within typical operating pressures
- In addition to covering pilot scale operations, we will also discuss applications of the GORE® suite of ProA membranes towards 2000 L batches at manufacturing scale processing

### QUALITY AND COMPLIANCE



**KELLY STANTON**  
Director, Quality  
Qualio

#### THE SHIFT TO DIGITAL: LEVERAGING CLOUD- BASED QUALITY MANAGEMENT SYSTEMS

- Why uniting your teams, processes, and data is the key to get to market quickly and scale successfully
- Tips for migrating from a paper-based with case studies
- Audit best practices and gotchas to avoid with cloud-based quality software
- Open Q&A on digital QMS best practices

### SUPPLY CHAIN AND LOGISTICS



**DAVID FRANK**  
VP, Client Development  
Azzur Group

#### BUILD, BROKER, BLEND - TODAY'S BIOMANUFACTURING OPTIONS

- Explore the different options for biologics development and manufacturing
- Share results of a 2022 research study outlining the insights and challenges of today's bio manufacturers
- Present blended solutions to traditional development and manufacturing options

3:10 pm – 4:30 pm PST

## HAPPY HOUR, NETWORKING AND PRE-ARRANGED 1-2-1 MEETINGS

4:35 pm – 5:10 pm PST

## INNOVATION SPOTLIGHT



**RORY MULLEN**  
SVP, Biopharma and Food  
IDA Ireland



**JOYDEEP GANGULY**  
SVP, Operations  
Gilead Sciences



**ANDY RAMELMEIER**  
EVP, Technical Operations  
Sangamo Therapeutics



**CHARLES 'CHUCK' CALDERARO**  
Global Head, Technical Operations  
Kite Pharma

### OPERATING ACROSS THE GLOBE: INTEGRATION, TRANSFORMATION AND INNOVATION

- What we learned over the last year while serving the world critical biologics to suit evolving regulations
- Overviewing supply chain management and quality issues relating to manufacturing in-house vs. CMO, and regional manufacturing vs. centralized
- Leveraging innovation through digital transformation
- Updates to the ever-changing regulatory landscape (Brexit's role on biotech compliance, risks and opportunities, and more)
- Talking about quality culture as a constant work-in-progress. How do we continue to innovate and improve and evolve?

5:15 pm – 5:50 pm PST

## EMPOWER HOUR



**SMITA PILLAI**  
Chief Diversity & Inclusion Officer  
Regeneron



**LINDA FITZPATRICK**  
Chief People and Communications Officer  
Sutro Biopharma, Inc.



**ELLEN MCMAHON**  
VP, HR, Global Operations and IT  
AstraZeneca



**JACKIE KUNZLER**  
SVP and Chief Quality Officer  
Baxter

### DIVERSITY AND INCLUSION ROUNDTABLE

We invite our attendees to network at a Diversity and Inclusion Roundtable with discussion from inspirational leaders in biomanufacturing, quality, and supply chain.

5:50 pm – 6:25 pm PST

## CLOSING KEYNOTE



**CHRIS MCDONALD**  
SVP and Global Head, Manufacturing  
Kite Pharma

### SCALING UP CAR-T MANUFACTURING LEVERAGING AUTOMATION AND DIGITALIZATION

- Building a nimble, agile and responsive organization that applies lean thinking post-pandemic
- Defining and redefining the manufacturing network
- Understanding the role of real-time data in process improvement for high volume cell therapy manufacturing, and how to improve automation across the facility
- Why linking our people, processes and technologies leads to greater collaboration

6:25 pm – 6:30 pm PST

## CHAIR'S CLOSING REMARKS

### MANUFACTURING AND TECHNOLOGY



**JOYDEEP GANGULY**  
SVP, Operations  
Gilead Sciences

### QUALITY AND COMPLIANCE



**DIANE HAGERTY**  
SVP, Head, GxP Quality & Compliance  
Allogene Therapeutics

### SUPPLY CHAIN AND LOGISTICS



**RUBY CASARENO, PH.D.**  
SVP, Technical Operations  
Allakos

6:30 pm – 7:30 pm PST

## NETWORKING DRINKS RECEPTION



## PROGRAM • DAY 2

APRIL 14, 2022

\* ENJOY BREAKFAST REFRESHMENTS AND INFORMAL NETWORKING IN THE EXHIBITION HALL

7:00 am – 7:45 am PST

### BREAKFAST BRIEFS



**KENNY NG**  
Regional Director, Americas  
*Singapore EDB*



**LEON SONG**  
Senior Director, Key Account  
Management and Scientific Solutions  
*GenScript ProBio*



**PAR ALMHEM**  
Director, Business Development, North  
America  
*KeyPlants*

**PRIVATE-PUBLIC PARTNERSHIPS: HOW GOVERNMENTS CAN WORK WITH COMPANIES TO CREATE A WORLD CLASS MANUFACTURING ECOSYSTEM IN ASIA**

**PROCESS INTENSIFICATION: WAYS TO ACHIEVE EXTREME BIOLOGICS VOLUMETRIC PRODUCTIVITY**

**FLEXIBLE RAPID DEPLOYMENT MODULAR BIOPHARMA FACILITIES - INTRODUCTION AND DISCUSSION**

7:45 am – 7:55 am PST

### CHAIR'S WELCOME AND OPENING REMARKS

#### MANUFACTURING AND TECHNOLOGY



**JOYDEEP GANGULY**  
SVP, Operations  
*Gilead Sciences*

#### QUALITY AND COMPLIANCE



**DIANE HAGERTY**  
SVP, Head, GxP Quality & Compliance  
*Allogene Therapeutics*

#### SUPPLY CHAIN AND LOGISTICS



**RUBY CASARENO, PH.D.**  
SVP, Technical Operations  
*Allakos*

7:55 am – 8:30 am PST

### OPENING KEYNOTE



**LINZELL HARRIS**  
SVP, Global Supply Chain and Strategy  
*AstraZeneca*

#### EMBRACING DIGITAL TRANSFORMATION AND PIONEERING NEW STRATEGIES ACROSS THE SUPPLY CHAIN

- Optimizing the supply chain end-to-end to meet the needs of patients and anticipate how to meet their needs tomorrow in a transformational way
- Seeing digital technologies as the next driver of innovation and patient-centricity
- Utilizing the convergence of technologies to deliver value to patients and the organization
- Examining the shift in corporate culture, investment and the skill set of the personnel required to deliver on transformation
- Ensuring innovations are sustainably implemented into operations

8:30 am – 9:05 am PST

### PLENARY



**LARRY PITCHER**  
General Manager, Microbial Manufacturing Services  
*Thermo Fisher Scientific*

#### STANDARDIZATION AND SUT BEST PRACTICES FOR CELL AND GENE THERAPY

- How single-use technologies and standardization reduce plant start-up times
- Why SUT helps improve profitability through reduced manufacturing deviations
- What improved KPI performance looks like when using standardization



9:10 am – 10:30 am PST

## REFRESHMENTS, NETWORKING, AND PRE-ARRANGED 1-2-1 MEETINGS

10:35 am – 11:10 am PST

## WORKSHOPS

## MANUFACTURING AND TECHNOLOGY



**MICHAEL MARCINIAK**  
Director, Business Development, North America  
*Single Use Support GmbH*

### LOOK LEFT – LOOK RIGHT: UNLOCKING SYNERGIES BETWEEN ADJACENT PROCESS STEPS TO BUILD SUCCESSFUL PRODUCT TRANSFERS

- Learn how we accelerate speed-to-clinic by integrating & leveraging single-use assemblies with innovative fluid management technologies
- Adaptive process platforms win! Together, product safety, speed, simplicity & scalability optimize outcomes
- Case study: Value of Automated Bulk Filling
- Satisfying increasing demands for more medicines to more patients requires comprehensive frozen transfers with smart integration

## QUALITY AND COMPLIANCE



**ERIC FERGUSON**  
Account Manager – West Coast  
*ILC Dover*

### POWDER HANDLING IN UPSTREAM BIO MANUFACTURING – MULTIPLE SOLUTIONS TO FIT THE PROCESS

- Powder transfer bags to save time and reduce risks
- Drum bulk handling single use Cone Liner to eliminate cleaning
- Powder into liquid delivery system with premixing capability

## SUPPLY CHAIN AND LOGISTICS



**KEN FORMAN**  
Senior Director, Product  
*IDBS*



**RAHUL KAUSHIK**  
VP, Biologics Manufacturing & CMC  
Technical Operations  
*FibroGen*

### ADOPTING CLOUD TECHNOLOGY TO MEET DEMANDS FOR PROCESS DATA VISIBILITY AND INTEGRITY ACROSS MANUFACTURING SUPPLY CHAINS

- Transforming process control strategies, batch analysis, trending, CPV, and business and regulatory reporting
- Building a persistent, dynamic, and scalable digital data backbone regardless of the IT landscape
- Establishing reasonable expectations for data sharing across Sponsor/CMO networks

11:15 am – 11:50 am PST

## SESSIONS

## MANUFACTURING AND TECHNOLOGY



**JUDY CHOU, PH.D.**  
President and CEO  
*AltruBio, Inc.*

### A WORLD WITHOUT COVID: PAVING THE WAY FOR THE FUTURE OF BIOMANUFACTURING

- Answering the question: "Where do we go from here?"
- Focused insights on biologics and new modalities
- How organizational leaders can best ensure positive change and growth
- Highlighting the importance of workforce culture, strong leadership, agility, and clear communication in weathering storms and overcoming new challenges
- Getting back on track with automation goals, data, and the role IT plays in global operations success

## QUALITY AND COMPLIANCE



**ANDREW CHANG**  
VP, Quality and Regulatory Compliance, Quality Intelligence and Inspection  
*Novo Nordisk, Inc.*

### CHANGE MANAGEMENT OF PHARMACEUTICAL QUALITY SYSTEM (PWS): THE EXPECTATION FROM ICH Q12 GUIDELINE

- Exploring the historical role of PQS on change management during product lifecycle and what's needed to be successful in the future
- Current expectations from ICH and PIC(s)
- Discussing change management for gene and cellular products

## SUPPLY CHAIN AND LOGISTICS



**ROBERT BOTTOME**  
VP, Global Supply Chain  
*BioMarin Pharmaceutical Inc.*

### ROADMAP TO SUPPLY CHAIN RESILIENCE: TRANSLATING RISK ASSESSMENT TO MITIGATION

- Building back supply chain resiliency in your organization and across the commercial product portfolio
- How to defend against catastrophic events: discussing inventory investments, inventory dispersing, backup capacity, global warehouse strategies, and more
- Addressing gaps and using a balance between people and technology to mitigate them
- Real-time visibility solutions to support supply chain strategies and prepare organizations for future disruption

11:55 am – 12:30 pm PST

## WORKSHOPS

### MANUFACTURING AND TECHNOLOGY



**KELLEY DOWD**  
Associate Director, Process Development  
*Cytovance*



**ALLISON FARRAND**  
Associate Director, Analytical Development  
*Cytovance Biologics*

#### ANTIBODY MANUFACTURING: WHAT WE'VE LEARNED AND WHERE WE'RE HEADED

- Speed to manufacturing
- Common stock materials – Does it work in a pandemic?
- Alternate downstream resins

### QUALITY AND COMPLIANCE



**ANDY ALASSO**  
SVP, Product Management  
*Aizon, a SaaS company*

#### HOW A LEADING CDMO IS DISRUPTING THE INDUSTRY THROUGH IMPLEMENTATION OF PHARMA 4.0 TECHNOLOGIES

- GxP AI-powered solutions for optimizing life sciences manufacturing
- Using AI/ML to unlock data throughout the organization to enable real-time decision making, optimize manufacturing processes, mitigate risk and improve profitability
- Reducing manufacturing quality issues
- Creating transparency as added value for customers and regulator bodies
- Employing digital twins to compliantly ingest and monitor manufacturing data in real time

### SUPPLY CHAIN AND LOGISTICS



**MAGNUS SCHROEDER, PH.D.**  
VP, Process and Product Design  
*Just - Evotec Biologics*

#### ADVANCED CONTINUOUS MANUFACTURING SOLUTIONS TO ACCELERATE TIME TO CLINIC AND SECURE COST-EFFICIENT COMMERCIAL SUPPLY

- Applying a fully integrated biologics platform from discovery through clinical and commercial cGMP manufacturing to deliver upon a mission to expand global access to biotherapeutics
- Incorporating the most advanced, innovative technologies into a simpler facility design to reduce the cost of manufacturing, improve speed to clinic/market, while maintaining the highest quality for our partners
- Designing a geographically deployable platform approach throughout a global biologics manufacturing network

12:35 pm – 1:25 pm PST

## LUNCH & LEARN ROUNDTABLE DISCUSSIONS

Benefit from additional learning by joining a moderated roundtable discussion on pressing issues in the industry. Registration is required, and attendance is limited. Choose from:



**CLAUS WEISEMANN**  
VP, Quality  
*NGM Bio*



**MATTHEW MULDOON**  
Senior Director, Supply Chain  
*Allogene Therapeutics*



**MICHAEL HUSS**  
Executive Director, Drug Product Manufacturing  
*Genentech*

#### REINVENTING QUALITY AND UNDERSTANDING WHAT IT CAN DO FOR SMALL CLINICAL STAGE BIOTECH COMPANIES



**ZACHARY LANGE**  
Senior Director, BioProcess Development and Manufacturing  
*Amunix Pharmaceuticals*

#### PARTICULATE RISK MANAGEMENT IN CELL THERAPY PRODUCTION



**JACKIE KUNZLER**  
SVP and Chief Quality Officer  
*Baxter*

#### ATTRACTING AND RETAINING TALENT THROUGH BUSINESS TRANSFORMATIONS



**LAURA SAWARD, PH.D.,**  
SVP, Science & Innovation  
*Emergent BioSolutions*

#### SMALL BIOTECH, BIG IDEAS: HOW WE'VE REMAINED AGILE AND RESILIENT DURING AND BEYOND COVID-19

#### TIPS AND TRICKS FOR ADVANCING YOUR CAREER IN BIOTECH

#### LESSONS THE COVID PANDEMIC TAUGHT US ABOUT MANUFACTURING RESILIENCE

1:25 pm – 2:00 pm PST

## PANEL DISCUSSION



**EDUARDO JACOBO**  
VP, Global Manufacturing  
*Sangamo Therapeutics*



**TOM SPITZNAGEL**  
SVP, Biopharmaceutical Development and Manufacturing  
*MacroGenics*



**PETER GELINAS**  
VP, Technical Operations  
*ElevateBio*



**KINNARI PATEL**  
President and COO  
*Rocket Pharmaceuticals*

### DEVELOPING A MANUFACTURING STRATEGY AND ROADMAPING THE FUTURE OF BIOMANUFACTURING DURING AND BEYOND THE GLOBAL PANDEMIC

- Integrated manufacturing process and platform strategies to increase speed to clinic
- Driving higher productivity and achieve higher quality vector across all scales
- Strategies to accelerate and optimize manufacturing for novel modalities
- Industry 4.0 projects to invest in to deliver ROI, such as IoT, robotics, RPA and data analytics

**MODERATED BY:**

Scott Weiss, VP, Product Strategy and Innovation, IDBS



2:00 pm – 2:10 pm PST

## CHAIR'S CLOSING REMARKS AND SURVEY PRIZE GIVEAWAY

### MANUFACTURING AND TECHNOLOGY



**JOYDEEP GANGULY**  
SVP, Operations  
*Gilead Sciences*

### QUALITY AND COMPLIANCE



**DIANE HAGERTY**  
SVP, Head, GxP Quality & Compliance  
*Allogene Therapeutics*

### SUPPLY CHAIN AND LOGISTICS



**RUBY CASARENO, PH.D.**  
SVP, Technical Operations  
*Allakos*

2:15 pm – 3:15 pm PST

## EMPOWER HOUR



**MARY BETH PELLETIER**  
Head, QA and QC, Gene Therapy Manufacturing  
*Biogen*



**LAURA SAWARD, PH.D.,**  
SVP, Science & Innovation  
*Emergent BioSolutions*



**JACQUELINE BERRETTA**  
VP, Quality and Compliance  
*Johnson & Johnson*



**BALA SREENIVASAN**  
VP, Global Supply Chain Management and Operations  
*Merck*

### WOMEN IN LEADERSHIP ROUNDTABLE

We invite our attendees to network at an exclusive Women in Leadership Roundtable with discussion from inspirational leaders in manufacturing, quality, and supply chain. Registration is required, and seating is limited, so please sign up early.

**MODERATED BY:**

Danielle Geissler, Ph.D., Senior Principal, ALULA



3:15 pm – 4:15 pm PST

## THANK YOU RECEPTION