GENERIS

AMERICAN BIOMANUFACTURING SUMMIT 2024

April 10-11, 2024

biomanamerica.com

TOMORROW'S CONNECTION TODAY

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

+1-416-298-7005
info@generisgp.com

PROGRAM

PROGRAM · DAY 1

APRIL 10, 2024

* JOIN US FOR THE PRE-EVENT HAPPY HOUR ON APRIL 9TH, 2024 FROM 6:00 PM – 7:00 PM

7:00 am – 8:00 am PST

REGISTRATION AND NETWORKING BREAKFAST

8:00 am – 8:10 am PST

CHAIR'S WELCOME AND OPENING REMARKS

MANUFACTURING AND TECHNOLOGY

ANDREW WIRTHS
SVP, Supply Americas
AstraZeneca

QUALITY AND COMPLIANCE

JACKIE ELBONNE
Chief Quality Officer and SVP, Global Quality
Amgen

SUPPLY CHAIN AND LOGISTICS

ROBERT BOTTOME
VP, Global Supply Chain
BioMarin Pharmaceuticals

CELL AND GENE THERAPY

CHRIS HOLT
VP and Site Head, Cell Therapy Manufacturing
Bristol Myers Squibb

8:10 am – 8:40 am PST

KEYNOTE

PAM CHENG
EVP, Global Operations and IT, Chief Sustainability Officer
AstraZeneca

OPTIMIZING BIOMANUFACTURING: STRENGTHENING SUPPLY CHAIN RESILIENCY THROUGH INNOVATING, COLLABORATING, AND ADAPTING

- Navigating the evolving VUCA landscape and its impact on supply chain resilience for biomanufacturing
- Ensuring supply chain resiliency in the development and delivery of new modalities, such as cell therapy products
- Lessons learned :Reducing vulnerabilities and disruptions within your supply chain
- Exploring how industry partnerships and global alliances bolster supply chain resilience
- Examining sustainable practices and the critical role they play in ensuring long-term supply chain resiliency

8:40 am – 9:10 am PST

PLENARY

THOMAS POTGIETER, PH.D.
SVP, Cell Therapy Development and Operations
Bristol Myers Squibb

REVOLUTIONIZING CELL THERAPY MANUFACTURING: INNOVATING, SCALING, AND OPTIMIZING

- Exploring methods for increasing cell therapy production rates while maintaining quality and consistency
- Implementing efficient, end-to-end processes to reduce manufacturing bottlenecks and minimize production costs
- Leveraging cutting-edge technology for real-time monitoring and quality assurance in cell therapy manufacturing
- Adopting strategies to flexibly scale production to meet fluctuating market demands and regulatory requirements
- Harnessing the power of automation and robotics to improve the reliability and repeatability of cell therapy manufacturing
- Discovering best practices and case studies for continual optimization of biomanufacturing processes in the cell therapy industry

9:10 am – 9:40 am PST

PLENARY

GREG GARA
SVP
ProjectFarma

ADAM PFEIFFER
VP
ProjectFarma

ANTINEA CHAIR
VP, Technical Operations
Cellares

THOMAS POTGIETER, PH.D.
SVP, Cell Therapy Development and Operations
Bristol Myers Squibb

REDEFINING TECHNICAL OPERATIONS FOR TRANSFORMATIVE MEDICINES

- Discuss opportunities and innovations in technical operations to optimize manufacturing
- Gain insights into best-in-class practices for facility planning, operational readiness and startup
- Learn strategies for commissioning and qualification, quality, automation & engineering

9:45 am – 11:25 am PST

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

11:30 am – 12:00 pm PST

SESSIONS

MANUFACTURING AND TECHNOLOGY

ANDREW SKIBO
Chief Manufacturing Officer
FluGen Inc.

CAREER GROWTH AND DEVELOPMENT IN BIOMANUFACTURING

- How to get a head start on the job market
- Navigating career changes, challenges, and curve balls
- Understanding your skills and value for new roles or stretch assignments
- Designing a career path that leads to advancement and leadership
- To stay, or go: Knowing when you're ready to take next steps in your career
- What I've learned along the way: Leadership lessons and insight from the top
- Finding resources for connecting with mentors or working groups in the field

QUALITY AND COMPLIANCE

PETER MARKS, PH.D.
Director, Center for Biologics Evaluation and Research
FDA

ACCELERATING INNOVATIVE BIOMANUFACTURING GROWTH THROUGH THE FDA'S INSIGHTS AND TREND ANALYSIS

- How the FDA-CBER regulates and oversees biomanufacturing processes, ensuring adherence to stringent quality standards, safety measures, and ethical guidelines for the benefit of patients and global health
- Advancing biomanufacturing practice and driving innovative technologies with cutting-edge therapies and treatments
- Embracing current biomanufacturing trends, from cell and gene therapies to bioprocessing advancements, fostering a transformative landscape for personalized medicine

SUPPLY CHAIN AND LOGISTICS

KEVIN BROWER, PH.D.
Global Head, Purification Development, Mammalian Platform
Sanofi

STREAMLINING THE INDUSTRY'S MANUFACTURING FUTURE: HIGHLIGHTS FROM A PROCESS INTENSIFICATION JOURNEY

- Defining process intensification, with a focus on purification
- Intensified processing for streamlined process validation
- Engineering principles and their relevance for filing continuous processes
- Flexible modular manufacturing for an intensified, simplified network

CELL AND GENE THERAPY

DOMINIQUE DE JAEGER
VP, CAR-T Supply Chain
Johnson & Johnson

THE ART AND SCIENCE OF SCALING A COMMERCIAL CAR-T THERAPY

- How is Johnson and Johnson supporting the development and growth of its portfolio of personalized medicines?
- Identifying weak links and critical dependencies in current supply chains to mitigate distributions
- Navigating the evolving regulatory landscapes and compliance requirements to enable quick commercialization of CAR-T therapies
- Case study: Lessons learned from managing supply operations of Carvykti

12:05 pm – 12:40 pm PST

WORKSHOPS

ROOM 1

DAVID SHENBERGER
VP, Strategic Development
CAI

THE IMPORTANCE OF EARLY PLANNING IN SPEED TO PATIENT

- What all needs to be done? Making the list
- When does it need to be done? Building an integrated schedule
- Who needs to do it? Aligning all the stakeholders
- How do we plan for it? Taking time for workshops
- Why early planning is the key to speed to market

ROOM 2

JULIE PACHECO
VP, Service
Integrant

BISHOY LABIB
Senior Architect
Integrant

DATA-DRIVEN BIOTECH MANUFACTURING: BUILDING A COMPREHENSIVE PLATFORM

- How effective data management and planning can lay the foundation for streamlined biotech manufacturing operations
- The importance of governance and design in ensuring data integrity and usability throughout the manufacturing process
- Leveraging analytics to drive insights and optimize production efficiency in real-time
- Strategies for scaling data platforms to accommodate growth and technological advancements in the biotech industry
- Preparing for the integration of AI and advanced analytics to stay ahead in the rapidly evolving biotech landscape

ROOM 3

BOB LENICH
Business Director, Process and Knowledge Management
Emerson

GETTING THE MOST FROM DIGITAL RECIPE MANAGEMENT LIFECYCLE TRANSFORMATION

- Reviewing the current state of typical enterprise recipe management and tech transfer business processes
- Discussing a vision for transforming paper and people based manufacturing recipe management
- Providing project examples of what can be achieved with digital recipe management transformation
- Proposing a methodology for where to start in order to get there

ROOM 4

SARA MILLER
Associate Director, Cell Therapy Business
FUJIFILM Diosynth Biotechnologies

AN ALLOGENEIC COMMERCIAL JOURNEY

- Discussing the path of preparing a GMP cell therapy manufacturing facility to become a full service commercial CDMO
- Focusing on the journey taken to support the first approval of an allogeneic T- cell immunotherapy from inception through its PAI inspections and commercial approval as well as advancing other cell therapy programs
- Introducing pre-IND programs to devising flexible systems to support programs at all phases to the acquisition by FUJIFILM Diosynth Biotechnologies
- Allogeneic cell therapy as the next breakthrough in making cell therapy available to larger groups of patients who need it

12:45 pm – 1:45 pm PST

LUNCH & LEARN ROUNDTABLES AND OPEN SEATING LUNCH

Benefit from additional learning by joining a moderated roundtable discussion on pressing issues in the industry. Registration is required, and attendance for moderated roundtables on Day 1 is limited to attendees and speakers. Choose from:

SHAWN OLSEN, PH.D.
Director, North American Sales
Rapid Micro

REMOVING MANUFACTURING BARRIERS TO BATCH RELEASE WITH RAPID QC PRODUCT TESTING

WILLIAM HERMANS
Senior Director and General Manager, Large Molecule Development
Curia

BIOMANUFACTURING BEYOND BOUNDARIES: EXPLORING NEW HORIZONS IN BIOPROCESSING

JASON JAKOB
Chief Software Architect
Adlib

CONQUERING THE PROCESS HURDLE: AUTOMATE LABOR-INTENSIVE DOCUMENT PROCESS

JAYA TIKHE
Senior Offer Marketing Manager
Biovia

AI-POWERED BIOPHARMA QUALITY MANAGEMENT HARNESSING VIRTUAL TWINS FOR A COMPREHENSIVE END-TO -END SOLUTION

MARY LEE SCHIESZ
Senior Director, CMO Sales
Samsung Biologics

DRIVING SUCCESS IN BIOMANUFACTURING: EXPLORING GLOBAL PORTFOLIO EXPANSION FOR ACCELERATED EXCELLENCE

DAVID FRANK
VP, Client Development
Azzur Group

NAVIGATING YOUR MANUFACTURING JOURNEY FROM DISCOVERY TO DELIVERY™

DUSTIN LAFFERTY
Senior Pharmaceutical Scientist
Singota Solutions

NAVIGATING EARLY-PHASE ANALYTICAL VALIDATION

INDRANEEL SANYAL
Senior Director and Head of the Biologics Development
Aragen

EXPLORING CASE-SPECIFIC APPLICATIONS OF PROCESS INTENSIFICATION IN BIOLOGICS MANUFACTURING: ADVANTAGES AND CHALLENGES

ROSS TURMELL
Principal Scientist
Cytiva

INNOVATING PROCESSING CAPABILITIES FOR ENHANCED YIELD AND QUALITY

GIACOMO M. DI MAURO, PH.D.
Scientist II, Large Molecules Division
BA Sciences

ENSURING ETHICAL AND TRANSPARENT PRACTICES IN THE BIOMANUFACTURING SUPPLY CHAIN

PETE GENEST
Director, Business Development
Smart Labs

IDENTIFYING THE RIGHT CGMP MANUFACTURING SOLUTION FOR NOVEL THERAPIES

PAT YANG, PH.D.
Executive Vice Chairman and Co-Founder
Resilience

DWIGHT BAKER
Chief Innovation Officer
Resilience

ACCELERATING CELL THERAPIES TO THE CLINIC WHILE ASSURING COMMERCIAL SUCCESS – IS THERE A SOLUTION?

1:50 pm – 2:20 pm PST

SESSIONS

MANUFACTURING AND TECHNOLOGY

THOMAS SPITZNAGEL, PH.D.
SVP, Technical Operations
MacroGenics Inc.

STRATEGIES IN BIOMANUFACTURING TO BUILD RESILIENT AND ROBUST OPERATIONS

- Leveraging platform processes to accelerate tech transfer and time to production
- Supply chain approaches to ensure availability of raw materials
- Designing facilities to ensure flexibility in scale, operations, and capacity
- Utilizing partnerships to keep capacity full

QUALITY AND COMPLIANCE

SCOTT GOODBERLET
VP and Head, Quality Americas Region and Device Quality
AstraZeneca

ADVANCING PROACTIVE QUALITY OPERATIONS AND NURTURING A CULTURE OF EXCELLENCE

- What does proactive quality culture and excellence look like at AstraZeneca?
- How to inspire teams to prioritize quality, fostering a culture of excellence
- Discovering strategies for seamlessly integrating quality standards into manufacturing processes
- Utilizing effective monitoring and control measures that uphold quality standards
- Exploring methods to empower your workforce to take ownership of quality control
- Discussing sustainable practices for continuous quality improvement
- Examining the role of collaboration in building a robust quality culture
- Understanding how to adapt to industry changes while maintaining a strong quality culture

SUPPLY CHAIN AND LOGISTICS

LEE SPACH
VP, Cell Therapy Global Supply Chain
Bristol Myers Squibb

UNVEILING THE FUTURE: REVOLUTIONIZING PHARMACEUTICAL SUPPLY CHAINS FOR CELL THERAPY SUCCESS

- Focus on achieving end-to-end transparency in pharmaceutical supply chains to improve decision making, responsiveness, and network optimization
- Utilize digital planning to maximize capacity and scalability, allowing for the treatment of a larger number of patients
- Prioritize patient operations to ensure highly responsive service throughout the supply chain
- Emphasize the critical role of reliable transport services in delivering a consistent and positive patient experience
- Acknowledge the need for unconventional talent in the future workforce to navigate the complexities of the industry

CELL AND GENE THERAPY

PHILLIP RAMSEY
SVP, Technical Operations
Sangamo Therapeutics, Inc.

THE EVOLVING AND EMERGING CAR-T THERAPY SUPPLY CHAIN: CURRENT CHALLENGES AND DEVELOPMENTS

- Analyzing the unique supply chain challenges posed by personalized cell therapies
- Adapting current supply chain models to prioritize patient access and safety
- Strategies for managing hand-off points and improving shipping conditions
- Building stronger industry partnerships and establishing crisis-ready contingency plans

2:25 pm – 3:00 pm PST

WORKSHOPS

ROOM 1

JOSH RUSSELL
VP, Sales and Marketing
AST

A CASE STUDY IN FLEXIBILITY: MODULAR, AUTOMATED FILL-FINISH SOLUTIONS

- Maximizing machine uptime for multiformat operations
- Harnessing comprehensive vision and sensor checks for quality control
- Utilizing modular setups to optimize operational requirements
- Implementing best practices for fill-finish, small batch production in an automated setting, including strategies for Annex 1 compliance

ROOM 2

ERIK NORDWALD
Associate Director, Process Technology and Innovation
KBI Biopharma

FAST, CHEAP DRUG DEVELOPMENT WITH PURECOLI

- E. coli, a workhorse for protein expression
- Bacterial vs mammalian expression modalities
- PUREcoli, redefining microbial expression

ROOM 3

KUNAL BARGOTRA
Product Manager
Adlib

THE NEW WAY: MODERNIZING DOCUMENT MANAGEMENT FOR MORE EFFICIENT OPERATIONS

- Don't get left behind with outdated document management strategy and processes
- Understanding how the new way helps ensure adherence to regulatory compliance
- Exploring how new technologies are disrupting industry-specific automation in document management

ROOM 4

JESSE CUGLIOTTA
Global Industry Lead, Healthcare and Life Sciences
Snowflake

A UNIFIED DATA PLATFORM WITH BUILT-IN AI: SNOWFLAKE'S SOLUTION FOR LIFE SCIENCES SUPPLY CHAINS

- Demonstrating Snowflake's transformative Generative AI capabilities for optimizing supply chain operations within the life sciences sector
- Leveraging LLM's and real-time data from both internal and third party sources to provide analytics around visibility, efficiency, and collaboration across the entire supply chain
- Addressing the unique challenges of biomanufacturing, such as regulatory compliance and sensitive product handling
- Ensuring more resilient, agile, and real-time supply chain management

3:05 pm – 4:25 pm PST

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

4:30 pm – 5:15 pm PST

PANEL DISCUSSION

AINE HANLY
EVP and Chief Technology Officer
Vir Biotechnology

KATHARINE MILLER
VP and Global Head, Biologics Development Analytics and Quality
Bayer

DAFNI BIKA
SVP, Global Head Pharmaceutical Technology and Development
AstraZeneca

EVELYN MARCHANY GARCÍA
SVP and Chief Quality Officer
BioMarin Pharmaceuticals

KARA RENAI KING
VP and Site Lead
Pfizer

WOMEN IN LEADERSHIP

- What's one leadership lesson you've learned in your career?
- What has been the most significant barrier in your career as a leader?
- How do you and your organization empower the next generation of skilled professionals?
- What is the best piece of advice you've received from leadership?
- What advice would you give to the next generation of leaders?

5:15 pm – 5:45 pm PST

PLENARY

DAN DERNBACH
SVP, Global Operations, Azzur Cleanrooms on Demand™
Azzur Group

FROM DISCOVERY TO DELIVERY™ : AN INTEGRATED MODEL FOR ACCELERATION OF ATMP DEVELOPMENT

- Addressing the 5 Pillars of GMP manufacturing
- Strategies to ease transition from R&D and pre-clinical to early-phase GxP clinical production
- Mitigating hurdles impacting the ability to achieve, mature, and maintain GxP compliance
- Improving delivery capabilities to ensure a safe and expeditious time to market
- Integrating critical systems, processes to maintain optimal facilities and operations

5:45 pm – 6:30 pm PST

PANEL DISCUSSION

LAUREN SMITH
Chief Quality Officer
Orca Bio

SCOTT BRADLEY
VP, PSS Platform Strategy and Delivery
Novartis

CENK ÜNDEY, PH.D.
VP, and Global Head, PTD Data and Digital
Roche

JIM FRIES
CEO
Rx-360

KATHARINE MILLER
VP, Head, Biologics Analytical Development and Quality - Global
Bayer

DAVE WATROUS
VP, Sales, Customer Success, and Marketing
IDBS

DEFINING AND SUPPORTING DIGITAL MATURITY IN BIOMANUFACTURING OPERATIONS

- What does digitization look like in today's manufacturing, quality and supply chain operations?
- Utilizing predictive analytics to prevent disruptions and enable proactive operational management
- Equipping sites to support better human-machine collaboration
- Assessing how digital network services helps sites navigate the highly globalized development landscape whilst optimizing quality

6:30 pm – 6:40 pm PST

CHAIR'S CLOSING REMARKS

6:40 pm – 7:40 pm PST

NETWORKING DRINKS RECEPTION

PROGRAM · DAY 2

APRIL 11, 2024

7:00 am – 8:00 am PST

NETWORKING BREAKFAST

8:00 am – 8:10 am PST

CHAIR'S WELCOME AND OPENING REMARKS

MANUFACTURING AND TECHNOLOGY

ANDREW WIRTHS
SVP, Supply Americas
AstraZeneca

QUALITY AND COMPLIANCE

JACKIE ELBONNE
Chief Quality Officer and SVP, Global Quality
Amgen

SUPPLY CHAIN AND LOGISTICS

ROBERT BOTTOME
VP, Global Supply Chain
BioMarin Pharmaceuticals

CELL AND GENE THERAPY

CHRIS HOLT
VP and Site Head, Cell Therapy Manufacturing
Bristol Myers Squibb

8:10 am – 8:40 am PST

KEYNOTE

JOYDEEP GANGULY
Chief Sustainability Officer and SVP, Corporate Operations
Gilead Sciences

SUSTAINABILITY TRANSFORMATION: A PRACTITIONER PLAYBOOK

- Looking at Gilead's transformation in the environmental sustainability space
- Outlining best practices from a technology, systems, and culture perspective from a practitioner perspective
- Discussing examples of digital transformation within Operations
- Highlighting the potential of emerging technologies to catalyze sustainability progress

8:40 am – 9:10 am PST

PLENARY

JENS VOGEL
SVP and Global Head, Biotech
Bayer

DELIVERING ON MULTI-MODALITY PORTFOLIOS: INNOVATION AND FLEXIBLE GLOBAL NETWORKS

- Examining broadening pipelines and external factors (wars, pandemics, inflation) that are driving the need for transformation
- How Bayer Biotech leverages technology innovation, diverse global teams, entrepreneurial culture, digitalization/AI and flexible networks to drive speed, agility, efficiency and resilience
- Analyzing real world examples ranging from both the large molecule and cell therapy space

9:10 am – 9:40 am PST

PLENARY

KEVIN SHARP
SVP and Head, Global Sales
Samsung Biologics

ENHANCING CDMO CAPABILITIES FOR COLLABORATIVE SUCCESS

- Embracing sustainable growth initiatives and ongoing expansion to effectively respond to client needs
- Achieving seamless ADC service by collaborating with promising ADC partners
- Overcoming supply chain challenges to establish a resilient and agile supply network
- Ensuring streamlined technology transfer to fulfill the needs of global clients

9:45 am – 11:05 am PST

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

11:10 am – 11:45 am PST

WORKSHOPS

ROOM 1

BRAD WYNJA
VP of Business Development
INCOG BioPharma Services

BETTER PARTNERSHIPS: BUILDING A CDMO TO ACCOMMODATE THE EVOLVING MANUFACTURING COMPLEXITIES AND INCREASING SUPPLY CHAIN CHALLENGES FOR DRUG DEVELOPERS

- Incorporating 20+ years of leadership talent and experience into a forward-thinking manufacturing facility
- Considerations and best practices when building partnerships with customers at varying stages of clinical stages and commercial manufacturing needs
- Avoiding common pitfalls in tech transfer and addressing today's manufacturing challenges

ROOM 2

PETE GENEST
Director, Business Development
Smart Labs

ENABLING YOUR PROCESS FROM THE BENCH TO THE CLINIC: A HYBRID RESOURCING SOLUTION FOR YOUR MANUFACTURING NEEDS

- Accessing cGMP manufacturing environments and compliance expertise without the financial and administrative burden of owning a facility
- Processing Development and Scale-Up: Challenges and Solutions
- Developing and run your own processes with your scientists, maintaining control over your intellectual property
- Co-locating process development and R&D to mitigate risk around failures and enable accelerated therapeutic development

ROOM 3

KEN FORMAN
Lead Product Manager, Manufacturing
IDBS

ABHIJIT RAY
Co-Founder and CTO
Aventior

DATA IS THE ASSET YOU NEED FOR YOUR MANUFACTURING AI INITIATIVES

- Looking at how companies hope to improve process understanding with AI models based around predictive analytics.
- Exploring how good training data is needed and lots of it, whether building statistical or mechanistic models,
- Identifying strategies for attacking the challenge of finding relevant data for use, and leveraging unstructured legacy data into GMP data to support meaningful model development.

ROOM 4

MARC HUMMERSONE
Senior Director, R&D
Astrea Bioseparation

DOWNSTREAM PROCESS INTENSIFICATION FOR CHALLENGING CELL AND GENE THERAPY BIOPROCESSING

- Amplifying downstream processing efficiency of viral vectors, extracellular vesicles, and nucleic acid targets with next-generation nanofiber technology
- Developing strategies to address the rapidly expanding pipeline of complex and diverse modalities.
- Achieving intensified productivity through an integrated approach that combines disruptive technologies with existing single-use infrastructures

11:50 am – 12:20 pm PST

SESSIONS

MANUFACTURING AND TECHNOLOGY

Bristol Myers Squibb

LEE SPACH
VP, Cell Therapy Global Supply Chain
Bristol Myers Squibb

Bristol Myers Squibb

IMARA CHARLES
VP, Process and Digital Excellence, Global Supply Chain
Bristol Myers Squibb

BUILDING RESILIENCE: COMBATING SUPPLY RISK WITH EFFECTIVE AND EFFICIENT CONTINGENCY PLANNING SOLUTIONS

- Developing a contingency plans that address both risks in business continuity and manufacturing excellence
- Utilizing historical data to identify alternative sourcing options that maintain profitability
- Improving assessments of vendor-level risks to seamlessly switch between supply partners and prevent disturbances to manufacturing timelines
- Maintaining proactive redundancy planning in the face of widespread disruptions

QUALITY AND COMPLIANCE

GRAIL

MITCH LEWANDOWSKI
VP and Head, Quality
GRAIL Inc.

MAINTAINING A BALANCE: INNOVATION CHANGE AND QUALITY RISKS

- Strategies for implementing proactive risk measures that enable real-time monitoring and development improvements
- Leveraging advanced analytics models to help manufacturing leaders determine risk
- Optimizing metrics and analytics through digitization to upgrade and enhance quality systems

SUPPLY CHAIN AND LOGISTICS

Genmab

BOLETTE BJERREGAARD
Director and Team Lead, Project Management, Late Stage Manufacturing Development
Genmab

ELEVATING CMC OPERATIONS: INNOVATING, OPTIMIZING, AND EXCELLING IN BIOMANUFACTURING

- Exploring innovative approaches to streamline CMC operations for biomanufacturing excellence
- How to ensure seamless compliance with evolving regulations in the field
- Discovering the latest tech solutions for optimizing CMC processes
- Discussing strategies to maximize resource utilization and cost-effectiveness in CMC operations
- Exploring cutting-edge methods to enhance product quality while driving efficiency in biomanufacturing

CELL AND GENE THERAPY

VERTEX

LEELA PARIS
VP, Process Engineering and Manufacturing, Cell Therapy
Vertex Pharmaceuticals

VERTEX

STACEY VEYSEY
Senior Director, Talent Acquisition, Research, Manufacturing and Technology,
Vertex Pharmaceuticals

UNLOCKING PROFESSIONAL POTENTIAL IN THE CELL AND GENE THERAPY SPACE

- Creating an environment that values creativity and encourages employees to think outside the box
- Exploring innovative methods to identify and recruit individuals with the potential to lead advancements in cell and gene therapy
- Establishing robust professional development programs to equip employees with the latest skills and knowledge required in today's rapidly evolving landscape
- Recognizing the importance of DEI in driving innovation and excellence in the cell and gene therapy industry

12:25 pm – 1:00 pm PST

WORKSHOPS

ROOM 1

SUN CHAU SIU
Executive Director and Head, Technology
Altruist

ACCESSING THE CHINA MARKET USING A LOCALIZATION STRATEGY: OPPORTUNITIES AND CHALLENGES

- Exploring how China has emerged as a cost-effective biomanufacturing hub for both the rapidly growing Chinese market and the rest of the world
- Examining new the new guidelines set by the Center for Drug Evaluation (CDE) that clarify the requirements for "localization" and encourage global biopharma companies to adopt a "China for China" manufacturing strategy
- How can global biopharma companies leverage this trend, and what challenges and pitfalls should they avoid?
- How can a reliable CDMO assist in navigating China's complex regulatory landscape and expediting the commercialization process?

ROOM 2

JON GUNTHER
VP, Business Development
Just-Evotec Biologics

THE SHIP HAS LANDED – CONTINUOUS MANUFACTURING: A PARADIGM SHIFT IN BIOLOGICS

- Pioneering a 10x leap in biomanufacturing, our approach stands out amidst incremental innovations in the industry
- Leveraging a highly diversified tech stack, continuous manufacturing platform,Leveraging our advanced continuous manufacturing platform, including commercial GMP facilities
- Revolutionizing antibody development through our proprietary AI/ML-based mAb discovery platform, we accelerate the journey from lab to clinic
- Exploring Validation from a prestigious client base, including recent collaborations with Sandoz and the Department of Defense, underscores the credibility of our approach
- Redefining industry dynamic as a trailblazer between equipment manufacturers and CDMOs Contract Development and Manufacturing Organizations (CDMOs)

ROOM 3

DENNIS J. YOON
Senior Director, Manufacturing Science and Technology
Azbena

NAVIGATING A COMPLEX DOWNSTREAM MANUFACTURING STRATEGY TO ENSURE CLINICAL & COMMERCIAL SUCCESS

- How an established routine, expertise and single-use technologies can provide a solid foundation for success for your antibody
- How a modular downstream process can be designed for plug-n-play flexibility while maintaining agility to meet development timelines
- How scalable process trains can seamlessly take your biologic from benchtop to commercial scale manufacturing
- How quality documentation can aid in quality improvements

1:05 pm – 2:05 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 for moderated roundtables on Day 2 is limited, but open and available to all. Choose from:

SNEHAL PATEL
EVP and Head, Technical Operations
Sana Biotechnology

THE POWER OF PREDICTIVE MAINTENANCE: PREVENTING BREAKAGE BEFORE IT HAPPENS

ROBERT BOTTOME
VP, Global Supply Chain
BioMarin Pharmaceuticals

OPTIMIZING OPERATIONS: ENHANCING EFFICIENCY IN BIOMANUFACTURING SUPPLY CHAINS

BOLETTE BJERREGAARD
Director and Team Lead, Project Management, Late Stage Manufacturing Development
Genmab

PROMOTING EFFECTIVE COMMUNICATION AND COLLABORATION BETWEEN RESEARCH, DEVELOPMENT, AND PRODUCTION TEAMS FOR SEAMLESS CMC OPERATIONS

DERRELL PORTER
CEO
cTRL Therapeutics

SUPPORTING SUCCESSFUL SCALE-UPS THROUGH INVESTMENTS IN TALENT

ALYSSA MESA
Director and Head, Learning and Operational Excellence, Clinical Supply Center
Genentech

TAKING LEGACY SYSTEMS INTO THE FUTURE: IMPROVING DIGITAL STRATEGIES AND GAPS IN DATA MANAGEMENT

JIM DEKLOE
Director and Founder, Industrial Biotechnology Program
Solano College

SKILLED LABOR SHORTAGES IMPACT CELL AND GENE THERAPY MANUFACTURING

2:10 pm – 2:40 pm PST

SESSIONS

MANUFACTURING AND TECHNOLOGY

COLETTE JUE
Senior Director, Site Compliance
Genentech

THOMAS SPITZNAGEL
SVP, Technical Operatons
MacroGenics Inc.

MEREDITH GIBSON
CEO
Association of Women in Science

PANEL DISCUSSION: DIVERSITY, EQUITY, AND INCLUSION

- How do you define diversity and inclusion in an ever-changing work environment?
- Where are we now and where is the conversation headed?
- How does your organization build diversity and inclusion into its structure?
- What can you do in your career and organization to continue to improve?
- How do you empower for the diversity you don't see (i.e. - LGBTQ+, economic class)?
- What pieces of advice, practical examples, or action items would you give to leaders and managers to drive DEI initiatives in their organization?

CELL AND GENE THERAPY

MARK PISKADLO
VP, Cell Therapy Manufacturing, NJ Site Leader
Bristol Myers Squibb

MANUFACTURING EXCELLENCE: LEVERAGING OPEX TO ADVANCE AUTOLOGOUS CELL THERAPY MANUFACTURING

- Creating a culture of excellence to create a competitive advantage
- Ensuring Manufacturing reliability and robustness
- Creating agile capacity to meet patient needs

2:40 pm – 3:10 pm PST

FIRESIDE CHAT

JACKIE ELBONNE
Chief Quality Officer and SVP, Global Quality
Amgen

JOHN HEARTY
VP, Life Sciences
IDA Ireland

DEFYING IMAGINATION TO DRIVE QUALITY

- What are the pillars of quality and compliance at Amgen?
- Utilizing quality as a differentiator of superior patient and customer outcomes and business performance
- Building a culture of excellence that engages and empowers our cross-functional teams
- Coaching and mentoring the next generation of biopharmaceutical leaders
- Tools and techniques for driving quality and compliance performance
- Harnessing quality as a strategic driver to fulfill our mission to serve patients

3:10 pm – 3:40 pm PST

PLENARY

MATT GARDNER
Chairman of the Board
California Biomanufacturing Center

JIM DEKLOE
Director and Founder, Industrial Biotechnology Program
Solano College

PETER CONTE
National Director, Laboratory and Life Sciences
Trans Western

BIOMANUFACTURING LANDSCAPE TODAY

- Cell and Gene Therapy Talent – The need and where to find it.
- Space Requirements for 21st Century Biomanufacturing
- Financial flexibility for emerging biotech in the Build - Buy Partner Process
- Manufacturing Operations and Speed to Market

3:40 pm – 3:50 pm PST

CHAIR'S CLOSING REMARKS AND SURVEY PRIZE GIVEAWAY

3:55 pm – 4:55 pm PST

THE GROVE THANK YOU RECEPTION