BIOMANUFACTURING WORLD SUMMIT BMWS21

November 15-16, 2021 | The Omni La Costa Resort & Spa | San Diego, CA | biomanworld.com

NOVEMBER 14, 2021

AGENDA

6:00 - 7:00 pm

Boehringer Ingelheim

Proud Sponsor of the

Drinks Reception

NOVEMBER 15, 2021

7:00 - 7:45 am — **Registration and Breakfast**

7:45 - 7:50 am — **Opening Remarks and Important Announcements**

7:50 - 8:00 am — **Co-Chairs' Welcome Address**

RESILIENCE

Pat Yang
Vice Chairman & Co-Founder
National Resilience, Inc.

Allogene THERAPEUTICS

Alison Moore
Chief Technology Officer
Allogene Therapeutics

8:00 - 8:35 am — **The World of Tomorrow: Serving Patients Through Transformational Change**

How learnings from the global pandemic combined with the introduction of new technology will enable the patient-centric manufacturing of the future

- Highlighting what the industry should do differently to achieve an ambitious future where all patients can receive lifesaving medicines safely, swiftly, reliably and affordably
- Exploring how and where products will be made, and how those products will be delivered by adopting system-driven planning and automation capabilities, leveraging the power of data and advanced analytics
- Describing a patient-centric pipeline the industry needs in order to deliver transformative therapies for all humanity
- A glimpse of how the world will evolve as molecular complexity increases in the future for large molecules

MERCK

Sanat Chattopadhyay
EVP, President, Merck Manufacturing Division
Merck

8:35 - 9:10 am

Fighting COVID-19 with Innovation – What We Have Achieved, What We Have Learned, and What Comes Next

- Offering an overview of how our industry responded to the global pandemic
- Highlighting how our organization adapted our existing processes and programs to continue to work under extraordinary circumstances
- Discussing some of the key takeaways and lessons learned from the past year and a half
- Where do we go from here? How will AstraZeneca and the biopharmaceutical industry at large move forward from here? What are we doing today to pave the way to those objectives?

AstraZeneca

Pam Cheng
EVP, President
Global Operations & IT
AstraZeneca

ROOM 1 CHAIR

RESILIENCE
Allogene THERAPEUTICS

Pat Yang
Vice Chairman & Co-Founder
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Alison Moore
Chief Technology Officer
Allogene Therapeutics

ROOM 2 CHAIR

COMPLIANCE ARCHITECTS®
CONSULTING • TECHNOLOGY • OUTSOURCING

Jack Garvey
CEO
Compliance Architects LLC

ROOM 3 CHAIR

KÖRBER

Jan-Henrik Dieckert
EVP Marketing
Körber Pharma Software

9:15 - 9:50 am

Progress on the Industrialization of Autologous Ex Vivo Genetically Modified Cell Therapies

- Product milestones achieved
- Impact **BACCELERATE**™ can have on industrial scale viral vector manufacturing and their costs
- Cell processing improvements that can impact patients' dose
- Progress in rapid analytics and digital ecosystems

BREAKOUT ROOM 1
STRATEGIC MANUFACTURING

gsk GlaxoSmithKline

Joseph Tarnowski
SVP, Cell & Gene Therapy, R&D
Medicinal Science and Technology
GSK

9:15 - 9:50 am

Staying at the Cutting Edge of Quality by Investing in Your People, Processes, and Technology

- What makes biopharmaceutical workforce development challenges fundamentally different from other industries?
- Challenges of maintaining Quality Culture through the pandemic and shifting culture as we move back to the "new normal"
- Cross-pollinating new ideas and innovations throughout the company and up and down our supply chain.
- Talking about Quality Culture as a constant work-in-progress. How do we continue to innovate and improve and evolve?

BREAKOUT ROOM 2
QUALITY

Biogen

Melissa Seymour
Head of Global Quality and
Chief Quality Officer
Biogen

9:15 - 9:50 am

Taking Commercial Cell Therapy Supply to the Next Level

- How should our industry build upon current cell therapy advances to create even more advanced and complex biopharmaceutical treatments
- Understanding how facility and process validation considerations change and become even more important when dealing with cell therapies
- Illustrating how investing in the relevant science directly informs product knowledge
- Demonstrating that this hard-won internal expertise can be harnessed into developing a successful new modality for cell therapies
- How to manage and maximize internal and external capacity to overcome product supply challenges

BREAKOUT ROOM 3
CELL & GENE THERAPY

Kite
A GILEAD Company

Chris McDonald
SVP & Global Head, Manufacturing
Kite Pharma

9:55 - 11:35 am

Pre-Arranged One-to-One Meetings

10:00 am – 10:20 am: Meeting Slot 1/Networking
10:25 am – 10:45 am: Meeting Slot 2/Networking
10:50 am – 11:10 am: Meeting Slot 3/Networking
11:15 am – 11:35 am: Meeting Slot 4/Networking

11:40 AM - 12:15 PM

Quality 4.0: Where Do I Start?

- Discussing the current Quality 4.0 environment and addressing the most common challenge of how to get started
- Applying what we've learned to help companies begin their quality and compliance digital initiatives by leveraging behavioral and predictive analytics
- Ensuring quick results and getting the most value out of your investments in Quality 4.0 initiatives

WORKSHOP
BREAKOUT ROOM 1

OQSIE

Jaime Velez
Co-founder
Operations & Quality Systems Improvement Experts (OQSIE)

11:40 AM - 12:15 PM

Building a Safe World When It's Falling Apart

On January 9th, 2020, the WHO announced a mysterious coronavirus-related pneumonia in Wuhan, China. We have come to know this virus as COVID-19 in the years since. COVID-19 vaccines became available after a series of quarantines shut down the global economy and overwhelmed healthcare services. This presentation discusses the fundamental steps required to prepare, implement, and sustain exponential vaccine growth during global chaos:

- Creating, and sharing the vision
- Identifying the fundamentals
- Dealing with changes in the ever-changing regulatory landscape
- Implementing and sustaining near impossible growth

WORKSHOP
BREAKOUT ROOM 2

PROPHARMA GROUP®
Complex Challenges. Exceptional Solutions.

Robert Beall, PMP
Director, Product Lifecycle Management
ProPharma Group

11:40 am - 12:15 pm

WORKSHOP
BREAKOUT ROOM 3

Are We There Yet? The Digital Transformation Journey

- The buzzwords abound: digital transformation.....Industry X.0....Industry 4.0.....but what are some practical approaches to achieving the promised benefits?
- What does digitalization actually mean in terms of transforming the biopharma product lifecycle?
- What are best practices to accurately assess and benchmark the capabilities of my organization and develop a transformation plan?
- Hear some recent experiences of successful digitalization initiatives in biopharma R&D and manufacturing
- Learn from a variety of diverse perspectives for quantifying real benefits and what pitfalls to avoid (hint: don't focus just on technology)

EMERSON

Sean Buckley
Sr. Industry Consultant, Life Sciences
Emerson Automation Solutions

12:20 - 12:55 pm

BREAKOUT ROOM 1
STRATEGIC MANUFACTURING

From Big Pharma to Mid-Size Biotech: Understanding What Drives Innovation

- Sharing learnings on moving from big pharma into mid-sized biotech
- Comparing and contrasting elements that drive innovation, and how they manifest differently in large pharma versus specialty biotech
- Exploring how to accelerate the innate features that drive innovation, while purposefully building around those that stifle it

BIOMARIN®

Greg Guyer
EVP and Chief Technical Officer
BioMarin Pharmaceuticals

1:35 - 2:10 pm

BREAKOUT ROOM 2
QUALITY

Improving Global Medicines Supply with Science, Trust, an Effective Quality System and Leadership

- It usually takes a minimum of 3-5 years for global health authority approval of a single post approval change even when the change reduces risk to patients. The global regulatory complexity disincentivizes companies to continually improve and it's a threat to the medicines supply
- This problem has been known for more than two decades and no solution has fixed the problem, which has only become bigger
- Chief Quality Officers of the top Pharma companies have come together to speak with One Voice of Quality on Post Approval Changes and are suggesting a path to reduce drug shortages and enhance continual improvement
- No single stakeholder can fix the OAC problem alone. Only when leaders in the industry and at regulatory agencies come together will this decade long problem be solved. Now is the time!

KRONOS·BIO

Anders Vinther
VP Quality
Kronos Bio

12:20 - 12:55 pm

Cell Therapy Manufacturing Commercialization - Strategy and Challenges

BREAKOUT ROOM 3
CELL & GENE THERAPY

- Understanding the unique manufacturing challenges for Autologous Cell Therapy, including the paradigm shift from IND to Commercial
- How does Development By Design, Quality By Design, and Cell Therapy COGs optimization engage with one another in this newly emerging space?
- Creating a Cell Therapy Technology Road Map Vision to address scale-out challenges
- Recognizing the current weaknesses in the Technology landscape and seeking ways to overcome these challenges moving forward
- Offering final thoughts on where we are as an industry today, and what we need to be doing right now to get ready for tomorrow

药明巨诺 JW Therapeutics

Harry Lam
Chief Technology Officer
JW Therapeutics

12:55 - 1:55 pm

Executive Lunch

Sponsored By: MaxCyte®

12:55 - 1:55 pm

LUNCH-AND-LEARN ROUNDTABLE DISCUSSIONS

Themed lunches are sponsor- or delegate-led roundtable discussions on specific industry issues and challenges during Day One's lunch hour. Each roundtable will be led by an expert in the field. Limited seating is available, so please sign up for your preferred topic on site. Choose from:

Accelerating Development Timelines and Reducing Risk with Flexible GxP Solutions

AZZUR GROUP
From Discovery To Delivery™

Ravi Samavedam
President and COO
Azzur Cleanrooms on Demand™

Industry Trends, Challenges, and Opportunities in Process and Technology Platforms for the Industrialization of Cell Therapy Products

BAYER

Nuno Fontes
SVP, Global Head of Development
Bayer

New Manufacturing Strategies for Pipeline Acceleration

cytiva

Joe Makowiecki
Director
Cytiva

John Harmer
Head of Marketing
Cytiva

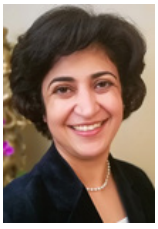
Analytical Considerations/ Challenges for Cell & Gene Therapeutics

Lilly

Babita Parekh
VP, Analytical Sciences and Global Bioassay Steward
Eli Lilly

Strategies and Opportunities for Enabling and Accelerating Patient-Centric Flexible Care Solutions

Genentech
A Member of the Roche Group



Gargi Seth
Director, Global Technical Development Project and Portfolio Management
Genentech

Strategies in Effective Tech Transfer

gsk GlaxoSmithKline

Sid Advant
VP GMP Operations
GSK

Experiences in Building Virtual Networks for Start Ups

INTERGALACTIC

Eileen Higham
SVP Technical Operations
Intergalactic Therapeutics

Manufacturing Digital Twin

BIOVIA

Dan Szot
VP WW Sales and Operations
BIOVIA, Dassault Systèmes

Lessons Learned for Effective Process Development and Technology Transfer When Using an Outsourcing Model

pharmatech associates | a USP company

Bikash Chatterjee
Chief Executive Officer
Pharmatech Associates

Using Cloud Technology in CMO Networks To Ensure Data Integrity and Timely Process Monitoring and Reporting

Skyland Analytics

Mark Isaacs
VP
Skyland Analytics

Pharma 4.0: Unlocking Rapid Tech Transfer

Spark THERAPEUTICS

Eric Hacherl
VP of Manufacturing
Spark Therapeutics

Maximizing Diversity to Build High-Performing Teams

TCR² THERAPEUTICS

Stan Russell
VP, Quality
TCR2 Therapeutics

1:55 - 2:30 pm

Redefining the COVID-19 Global Pandemic as a Catalyst for Change

- Science Will Win: Pfizer's 5-point plan and industry pledge to finding solutions to the global health crisis
- Making the impossible possible: "Lightspeed" and the development, manufacture, and distribution of the COVID-19 vaccine
- Where do we go from here? Ensuring this experience is a catalyst for change for our industry
- Key takeaways: upending our conventional ways of working and the resilience of our amazing colleagues

Pfizer

Lynn Bottone
VP Biotech Operations
Pfizer

2:35 pm - 3:10 pm

WORKSHOP
BREAKOUT ROOM 1

Becoming Patient-Centric, Do You Have What it Takes?

- Today's biopharma companies are energized by the unprecedented progress and speed in manufacturing COVID vaccines and therapeutics, advancements in personalized therapies and breakthrough treatments
- How can we keep up with the intricate manufacturing, supply chain and quality control processes necessary to bring them to patients who need them?
- We highlight how scaling-up technologies like Cloud, AI, and Machine learning develop a digital thread that will connect siloed teams and datasets that allow companies to meet the challenges of shortened timelines and increasing product complexity
- We share examples of industry leaders who are engaged in near-term and long-term transformation efforts using data to accelerate pipelines and optimizing their supply chains and operations to become more patient-centric

accenture

Anne Marie O'Halloran
Global Supply Chain/X.0 Life Sciences Lead
Accenture

2:35 pm - 3:10 pm

The Therapeutic Diabetes Vaccine Diamyd® – Precision Medicine to Navigate Complexity

- Diamyd Medical is a company developing disease-modifying therapies for Type 1 Diabetes
- The therapeutic diabetes vaccine Diamyd® has shown effects on preserving endogenous insulin production and improving blood glucose control in individuals with type 1 diabetes that carry a specific HLA haplotype
- We will highlight the rational of taking a precision medicine approach to developing a disease-modifying therapy for Type 1 Diabetes
- We will share how internal and external events have shaped the clinical development and manufacturing strategy for the diabetes vaccine Diamyd®

WORKSHOP
BREAKOUT ROOM 2

cytiva

DIAMYD MEDICAL

Ulf Hannelius
President & CEO
Diamyd

2:35 pm - 3:10 pm

Digital Twin Applications for Quality by Design in Bioprocess Development and Manufacturing

- The integrated process model (IPM) is the engine that drives to a digital twin in manufacturing
- QbD and CPV applications can be easily run from a working digital twin
- FMEA rankings can be algorithmically established
- Control Strategies can be determined based on impact on final drug product
- Process monitoring improved as it compares results not against a full process variation (e.g. 3SD), but within the context of the full model RMSE given concrete process settings

WORKSHOP
BREAKOUT ROOM 3

KÖRBER

Christopher Taylor
Head of Consulting PAS-X Savvy
Körber Business Area Pharma

3:15 - 4:25 pm

Pre-Arranged One-to-One Meetings

3:15 pm – 3:35 pm: Meeting Slot 5 / Networking
3:40 pm – 4:00 pm: Meeting Slot 6 / Networking
4:05 pm – 4:25 pm: Meeting Slot 7 / Networking

4:30 - 5:05 pm

How to Make the Bio-Revolution a Reality: Building Bayer's Cell & Gene Therapy Platform

- How Bayer AG built its Cell & Gene Therapy unit
- New business model joining best of Biotech and best of Pharma
- How to build a sustainable pipeline?
- How to manage complexity and keep focus?
- What are the "must haves"? what are the learnings on common threats of significant transformations?
- New ways of working accelerated by COVID-19 pandemic

BAYER

Wolfram Carius
EVP, Cell and Gene Therapy
Bayer AG

5:05 - 5:50 pm

The Transformational Potential of the Advanced Manufacturing of Biologics

- Describe the potential for advanced manufacturing
- Review case studies illustrating the potential of advantages advanced manufacturing
- Provide resources for product developers

FDA

Peter Marks
Director – Center for Biologics Evaluation and Research (CBER)
FDA

5:50 - 6:00 pm

Co-Chairs' Closing Remarks

RESILIENCE

Pat Yang
Vice Chairman & Co-Founder
National Resilience, Inc.

Allogene THERAPEUTICS

Alison Moore
Chief Technology Officer
Allogene Therapeutics

6:00 - 7:00 pm

SAMSUNG BIOLOGICS Proud Sponsor of the

Drinks Reception

6:00 - 7:00 pm

HANGOUTS

From 6:00 pm onwards there will be three different 'Hangout' areas set up in the Exhibition Hall, each beside a bar. These are unmoderated opt-in networking opportunities for attendees to engage with their peers about the content and issues they enjoyed during the day's sessions. Choose the topic that interests you most and congregate at the appropriate Hangout.

STRATEGIC MANUFACTURING HANGOUT

At Bar 1 in the Exhibition Hall

QUALITY HANGOUT

At Bar 2 in the Exhibition Hall

CELL & GENE THERAPY HANGOUT

At Bar 3 in the Exhibition Hall

6:45 - 8:45 pm

It's Tac-O' Clock!

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QbDVision®
Powered By CherryCircle Software

Join us for Fresh Tacos and Margaritas at the Taco Truck in the Costa Del Sol Porch. Open to all attendees.

7:30 - 8:25 am

Registration and Breakfast

7:45 - 8:20 am

BREAKFAST WORKSHOP

BREAKOUT ROOM 2

Digital Transformation in Pharma Manufacturing for Quality and Productivity

- How pharma can learn state-of-the-art manufacturing from a more digitally advanced industry
- Connecting the plant: Turning data into knowledge and end-to-end business orchestration
- Successful industry 4.0 pharma use cases
- Integrating systems to create transparency and effective and timely decision-making
- Examining how improved quality also creates efficiencies and measurable cost savings

APPLIED MATERIALS® make possible

Lucas Vann
CTO - Solutions Engineering
Applied Materials

8:25 - 8:35 am

Co-Chairs' Welcome Remarks

RESILIENCE

Pat Yang
Vice Chairman & Co-Founder
National Resilience, Inc.

Allogene THERAPEUTICS

Alison Moore
Chief Technology Officer
Allogene Therapeutics

8:35 - 9:10 am

A Changing Biopharmaceutical Landscape: How Operations Must Be Front and Center to Enable Business Success

- Discussing the changing landscape for our industry, from pricing to innovation
- How Operations leaders must prepare their organizations to succeed in this environment
- Offering a framework for balancing the need to execute in the short-term with the imperative to invest in innovation for the future

AMGEN

Esteban Santos
EVP, Operations
Amgen

9:10 - 9:45 am

Cell and Gene Therapies and the Dawn of the Next Chapter of Biopharmaceutical Production

- Challenges and Opportunities in commercializing live modalities like Car-T/TCR
- Weighing the Pro's and Con's of centralized vs decentralized production platforms for new treatments
- Lessons Learned from first generation cell and gene therapies to advance operations
- Innovation of technology to advance the manufacturing and supply chain

PACT pharma

Tim Moore
President & COO
PACT Pharma

ROOM 1 CHAIR

RESILIENCE

Allogene THERAPEUTICS

Pat Yang
Vice Chairman & Co-Founder
National Resilience, Inc.

Alison Moore
Chief Technology Officer
Allogene Therapeutics

ROOM 2 CHAIR

COMPLIANCE ARCHITECTS®
CONSULTING • TECHNOLOGY • OUTSOURCING

Jack Garvey
CEO
Compliance Architects LLC

ROOM 3 CHAIR

KÖRBER

Jan-Henrik Dieckert
EVP Marketing
Körber Pharma Software

9:50 - 10:25 am

BREAKOUT ROOM 1
STRATEGIC MANUFACTURING

Fast End to End, Then and Now!

- There is a clear need for rapid scale up, launch and tech transfer to meet global demand
- The regulatory, quality and compliance, and technical environment is evolving through key triggers
- Discussion of various quality and regulatory approaches and technical advances to support strategic acceleration

Roche

Andrea Goddard
SVP, Global Head of
Quality and Compliance
for Pharma Technical Operations
Roche

9:50 - 10:25 am

BREAKOUT ROOM 2
QUALITY

Staying Ahead of the Curve in an Increasingly Complex Regulatory World

- Discussing the growing regulatory complexity in the world of pharmaceutical manufacturing. How are new guidelines and regulators' expectations during inspections changing?
- Taking a process-based approach to impact assessment, and customizing a setup that identifies and acts on signals proactively
- Bringing a structured approach to your advocacy within you network of industry and trade organization connections
- Embracing the idea that keeping things simple even in a complex environment generates the best outcomes

novo nordisk

Søren Thuesen Pedersen
Sr. Director, External Affairs
Quality Intelligence and Inspection
Novo Nordisk

9:50 - 10:25 am

BREAKOUT ROOM 3
CELL & GENE THERAPY

Navigating the Unique Manufacturing and Supply Chain Challenges in Commercializing Cell and Gene Therapy

- Highlighting the 3 pillars of the Sangamo manufacturing strategy
- Achieving a balanced investment in manufacturing capacity and how to build a strong supply chain
- Identifying the key challenges and areas for improvement in 3 case studies
- Options to increasing AAV yield and scalability
- Achieving scale and COGs in allogeneic cell therapy products
- Streamlining cold chain and delivery to patients for AAV and cell therapy products
- How to lead a CMC team in an emerging and growing industry

Sangamo THERAPEUTICS

Andy Ramelmeier
EVP Technical Operations
Sangamo Therapeutics

10:25 - 11:15 am

Pre-Arranged One-to-One Meetings

10:30 am – 10:50 am: Meeting Slot 8 / Networking
10:05 am – 11:15 am: Meeting Slot 9 / Networking

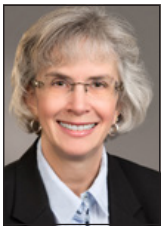
10:25 - 11:00 am

Industry Focus Group

INDUSTRY FOCUS GROUP

ATMPs— Characterized Well, or Well-Characterized? Let's Debate This.

kyverna



Karen Walker
Chief Technology Officer
Kyverna Therapeutics

11:20 - 11:55 am

The Rise of mRNA Vaccines and Therapeutics – CMC Development During a Once-in-a-Lifetime Pandemic

- The push for a COVID-19 vaccine – from a CMC perspective
- The challenges of rapid vaccine scale-up to meet world-wide demand
- The next chapter: the future of mRNA vaccines and therapeutics development and manufacturing

moderna

Jason Murphy
VP, Nucleic Acid Process Development and Applied Technologies
Moderna

12:00 - 12:35 pm

Building Capacity and Capabilities to Realize the Promise of Cell and Gene Therapies

- Challenges and opportunities with bringing cell and gene therapies to market
- The importance of building capacity and capabilities to enable successful commercialization of therapies
- Criticality of high quality raw materials to ensure a seamless transition from early development to late phasee

WORKSHOP
BREAKOUT ROOM 1

ThermoFisher SCIENTIFIC

Lawrence (Larry) Pitcher
General Manager, Microbial Manufacturing Services, Part of Thermo Fisher Scientific
Thermo Fisher Scientific

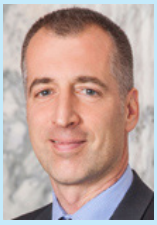
12:00 - 12:35 pm

Leading Through Change: Adjusting your Leadership and Talent Strategy During an Unforeseen Crisis

- Global talent trends in biopharma operations – an updated view
- The knee-jerk reaction to the pandemic and initial solutions planned
- Driving leadership performance & development in a crisis
- The three critical dimensions of resilience: individual resilience, team resilience and organizational resilience

WORKSHOP
BREAKOUT ROOM 2

Russell Reynolds Associates



Pascal Bécotte
Global Executive Committee, Global Sector Leader – Functional Practices, Country Manager – Canada & Managing Director
Russell Reynolds Associates

12:00 - 12:35 pm

J.POD 1 US: Delivering Low-Cost, Flexible and Deployable Manufacturing

- Applying a fully integrated biologics platform from discovery through cGMP manufacturing – J.DESIGN – 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
- Building a cost-effective plant that has capacity flexibility to adjust to demand fluctuations
- Designing a geographically deployable platform approach throughout a global biologics manufacturing network

WORKSHOP
BREAKOUT ROOM 3

Just EVOTEC BIOLOGICS

Renae Dill
VP, Manufacturing Operations
Just – Evotec Biologics

12:35 - 1:35 pm

Executive Lunch

Sponsored By: MaxCyte®

12:35 - 1:35 pm

LUNCH-AND-LEARN ROUNDTABLE DISCUSSIONS

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Rise to the Challenge: How to Find and Keep Your Next Successor

Allakos

Ruby Casareno
SVP Technical Operations
Allakos

How to Ensure Supply Chain Resiliency in the Face of Volatility and Uncertainty

AMGEN

Som Chattopadhyay
VP Global Supply Chain
Amgen

Considering Today's Environment and Challenges of Tomorrow, How Do We Use Quality as a Strategic Driver for Improved Business Outcomes?

Bristol Myers Squibb™

RJ Doornbos
VP Global Quality Systems
Bristol-Myers Squibb

COVID-19 Disruptions in the Ecosystem of Materials and Components Supply— Challenges and Opportunities

Mihaela Simianu
Executive Director
Global Vaccines
Technical Operations
Merck

Building Quality in Small Clinical Stage Biotech Companies

Claus Weisemann
VP Quality
NGM Biopharmaceuticals

Raw Material Constraints and Opportunities for the Production of mRNA-Based Vaccines and Therapeutics

Murali Muralidhara
Chief Manufacturing Officer
RVAC Medicines

1:35 - 2:10 pm

Commercialization and Technology Transfer of mRNA Therapeutics and Lyophilized Vaccines

- The novel development and manufacturing technologies for mRNA therapeutics and lyophilized vaccines
- Current challenges and success in large-scale production of the latest mRNA vaccines
- Global technology transfer, process validation rapid commercialization, and supply strategies

Dushyant Varshney
EVP & Chief Technology Officer
Arcturus Therapeutics

2:15 - 3:15 pm

Panel: Looking Backwards, Looking Forwards —How Did the Last Two Years Change Us?

- How has working through a global pandemic impacted the way we do business?
- Taking stock of how we changed and why we changed. What are some of the net positives? What are some of the things where we do want to return to how things used to be?
- Reviewing where our organizations were five years ago and where we planned to be today, how much has COVID-19 changed the trajectory of our journeys?
- What are some of the lessons learned that we plan to take with us into the future?
- Is the community of biopharmaceutical manufacturers stronger for this experience? Where do we go from here?

Jerry Cacia
Chief Technology Officer
Graphite Bio

Stephen Hill
Chief Technical Officer
Lyell Immunopharma

Aine Hanly
Chief Technology Officer
Vir Biotechnology

Michael Kamarck
BioPharma Advisor & Board Member

Rahul Singhvi
Co-Founder & CEO
National Resilience, Inc.

3:15 - 3:25 pm

Co-Chairs' Closing Remarks

Pat Yang
Vice Chairman & Co-Founder
National Resilience, Inc.

Alison Moore
Chief Technology Officer
Allogene Therapeutics