BIOMANUFACTURING WORLD SUMMIT

BMWS22

November 13-15, 2022 | The Omni La Costa Resort & Spa | San Diego, CA | biomanworld.com

NOVEMBER 13, 2022

AGENDA

2:00 - 5:00 pm **Site Tour**

We are pleased to announce the Biomanufacturing Experience during BMWS22!

The Biomanufacturing World Summit brings together the "who's who" of pharmaceutical executives as well as cutting-edge service and solution providers for North America's premier Biopharma and Cell and Gene Therapy event. Azzur Group proudly invites you to this complimentary tour preceding BMWS22!

Biomanufacturing Experience @ BMWS22 is an opportunity to learn first-hand about hybrid biomanufacturing options and GMP operational excellence.

Activities include:

- Transportation to and from the Azzur Cleanrooms on Demand™ Vista Facility
- Personal tour of state-of-the-art on-demand cleanroom facility
- Feedback and insights
- Happy Hour at Dogleg Brewing Company

By-invite only

Sponsored By: AZZUR GROUP
From Discovery To Delivery™

5:00 - 6:00 pm

Welcome Day Panel: Planning for Biomanufacturing of the Future: What are the Five Big Things We Need to Talk About??

- Has the example of COVID-driven vaccines changed the speed of development and manufacturing?
- What technology breakthroughs may be required?
- What Regulatory reforms or changes might be needed?
- How can we improve the access of biologic medicines globally?
- Is talent and workforce development in our industry changing?

Moderator:

Alison Moore
Chief Technology Officer
Allogene Therapeutics

Panelists:

Wolfram Carius
EVP Pharmaceuticals
Bayer AG

John Tomtishen
VP Operations
Cellares

Rahul Singhvi
Co-Founder & CEO
Resilience, Inc.

Andy Ramelmeier
EVP Technical Operations
Sangamo Therapeutics

6:00 - 7:00 pm

Boehringer Ingelheim

Proud Sponsor of the

Welcome Drinks Reception

NOVEMBER 14, 2022

7:00 - 7:45 am

Registration and Breakfast

Sponsored By: FLUOR®

7:45 - 7:50 am

Opening Remarks and Important Announcements

7:50 - 8:00 am

Chair's Welcome Address

Alison Moore
Chief Technology Officer
Allogene Therapeutics

8:00 - 8:35 am

Building a "Lightspeed" Culture: How a Global Pandemic Transformed Manufacturing and Distribution

- Bolstering our supply chain: Strengthening relationships with industry partners to overcome a global health crisis
- Making the impossible possible: "Project 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

Mike McDermott
Chief Global Supply Officer, EVP
Pfizer

8:35 - 9:10 am

The Successful History of Biologics Manufacturing Provides Foresights and Strategies for New Bio Modalities

- Establishment of broad communities of practitioners in both manufacturing and process development accelerated maturation of both disciplines
- Convergence of these process and manufacturing technologies was driven by excellence and capacity in selected CMOs
- Manufacturing portability has provided remarkable stories of win-win capacity-exchange between proprietary companies
- Process convergence has resulted in remarkable progress in process yields and cost improvement

Susanne Hundsbaek-Pedersen
Global Head Pharma of Technical Operations
Roche

ROOM 1 CHAIR

Alison Moore
Chief Technology Officer
Allogene Therapeutics

ROOM 2 CHAIR

CONSULTING • TECHNOLOGY • OUTSOURCING

Jack Garvey
CEO
Compliance Architects LLC

ROOM 3 CHAIR

Dr. Judith Koliwer
Principal Consultant, Cell & Gene Therapy
Körber Pharma Software

9:15 - 9:50 am

Revolutionizing The Manufacturing Landscape to Optimize Patient Outcomes

- How the pandemic has impacted innovation, technology, people and our ways of working and thinking
- How is Amgen transforming biomanufacturing for a faster, more data-savvy future and strengthening the balance of resiliency and efficiency
- Addressing unmet patient needs and establishing new markets through connected technology and other manufacturing innovations (smart materials, process automation and more)
- Why building integrated, collaborative, agile, high performance teams are at the heart of revolutionary manufacturing
- Amgen Ecovation™ - creating value through innovative and sustainable manufacturing operations

BREAKOUT ROOM 1
STRATEGIC MANUFACTURING

AMGEN

Arleen Paulino
SVP Global Manufacturing
Amgen

9:15 - 9:50 am

Global Quality in Takeda: Integration, Transformation, and Innovation

- Overview of Takeda
- Learnings from Integration of two large pharma companies
- Global Quality roadmap and transformation of Quality Management Systems
- Innovation through digitalization
- Quality Culture

BREAKOUT ROOM 2
QUALITY

Takeda

Gerard Greco
Global Quality Officer
Takeda

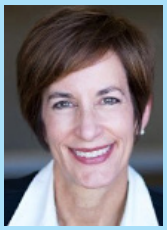
9:15 - 9:50 am

Expanding Scalability Potential of T-Cell Therapies with Allogeneic Approaches

- Supply constraints: autologous vs allogeneic therapy production
- Allogeneic manufacturing process, scalability considerations, and optimizing patient supply
- Balancing in-house and external capabilities through strategic partnerships

BREAKOUT ROOM 3
CELL & GENE THERAPY

ATARA BIO



Charlene Banard
EVP, Chief Technical Officer
Atara Biotherapeutics

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

WORKSHOP
BREAKOUT ROOM 1

Pushing the Efficient Frontier of Biomanufacturing to Speed Up Drug Development and Enhance Productivity

- The Need for Speed and Accessibility: Post-pandemic expectations to develop and make medicines faster and more accessible than ever before
- Optimize key capabilities to push the "efficient frontier" of biomanufacturing
- Balance the trade-offs of speed, cost and flexibility: leveraging learnings from high product mix in manufacturing
- Key takeaways: focusing on getting it right from the start, standardization at the right level, digital enablement, scale variety and integrated solutions.

ThermoFisher SCIENTIFIC

Joao Paulo Mattos
Director, Global Process Validation and CMC Lead
Thermo Fisher Scientific

11:40 am - 12:15 pm

WORKSHOP
BREAKOUT ROOM 2

Realizing Gilead's 2030 Ambition: Advancing a Diverse Portfolio with a Complex Manufacturing Network

- Gilead's ambition is moving from a predominantly virology focused portfolio to a more diverse one with an emphasis on adding oncology and inflammation asset
- To accomplish this a wide net needed to be deployed to rapidly build a portfolio through external sourcing and internal innovation
- This has resulted in a diverse set of acquisitions, partnerships, opt-ins, and collaborations across program phases and modalities, resulting in a complex manufacturing network
- This talk will cover the strategies being deployed across the pillars of Process Development, Supply Chain, Quality, Regulatory, and External Manufacturing to realize Gilead's 2030 ambition

cytiva

GILEAD

Art Hewig
VP of Biologics Process Development
Gilead Sciences

11:40 am - 12:15 pm

WORKSHOP
BREAKOUT ROOM 3

Achieving Manufacturing Excellence through Digital Transformation

The growth of biologics and precision and personalized medicine is driving the need for new types of solutions across automation, manufacturing, and quality and compliance. Learn how to modernize your operations and achieve manufacturing excellence using a future forward, agile, integrated, manufacturing solution that supports compliance and real-time quality management. Take an industry standard approach to reach new levels of maturity in your digital transformation journey.

In this session you'll learn how to:

- Identify process bottlenecks and reduce cycle time
- Get end-to-end production visualization to enable better decision making
- Validate production faster and speed up batch release
- Identify issues and deviations early and take remedial actions

Honeywell

George Peters
Sr. Offering Manager, Life Sciences
Honeywell Process Solutions

12:20 - 12:55 pm

Fireside Chat: Integrating Customer Centricity and Innovative Technology into a Forward-Looking Manufacturing Strategy

BREAKOUT ROOM 1
STRATEGIC MANUFACTURING

- How are biology and patient needs influencing risk-based investment and networking structure in the manufacturing space?
- Discussing route and location of administration, including MDCP considerations, components and suppliers, design standards including image selection, and packaging network design
- Exploring flexible facilities, integrated clinical launches, and capital risk avoidance in the quest to get fast to clinical and fast to respond
- Understanding the need for early investment in platform changes. How is the emergence of ADCs, modality blurring, and market considerations changing the way we traditionally work?
- Talking about access issues including regionalization and localization, IP considerations, and how higher order BSL and/or OEB availability impacts what we can do, and where we can do it

MERCK

David Maraldo
SVP, Global Biologics Operations
Merck

Bala Sreenivasan
SVP Global Supply Chain Management
Merck

Michael Kress
SVP Development Sciences and Clinical Supply
Merck

Courtney Breen
Executive Director, Oncology Marketing
Merck

12:20 - 12:55 pm

Agility in Quality: Applying Lessons Learned from Cell and Gene Therapy to Accelerate the Transition from Clinical to Commercial

BREAKOUT ROOM 2
QUALITY

- Cell and gene therapy is unique given the nature of the products and hyper-accelerated development and regulatory timelines
- Accelerated timelines require agility. How do you apply 'phase-appropriate' standards when there is less distinction between phases? How can you leverage this agility across other modalities?
- When process history is limited and analytical complexity is high, how do we apply lessons learned from biologics and early approvals in CGT to improve CMC and operational success?
- Session will cover lessons learned and practical advice for navigating these and other aspects of Quality & Compliance for successful transition from clinical to commercial and from development to launch across modalities

Intercept

Kathleen Munster
Chief Quality Officer & SVP, Technical Operations
Intercept Pharmaceuticals

12:20 - 12:55 pm

TCR² and the Path to Registration: The Road in Scaling a TCR Platform and Organization to Un-Lock a Therapy for Solid Tumors

BREAKOUT ROOM 3
CELL & GENE THERAPY

- Walking through how we built our Cell Therapy unit. What did we duplicate? What did we innovate? What did we adapt from others, and how did we make it our own?
- How are we building a sustainable pipeline, managing complexity, and keeping our focus?
- What are the "must haves"? What are the learnings on common threats of significant transformations?
- Lessons learned from the TCR² journey to provide innovative therapies for patients in need

TCR² THERAPEUTICS

Peter Olagunju
Chief Technical Officer
TCR² Therapeutics

12:55 - 1:55 pm **Executive Lunch**

Sponsored By: Sharp

12:55 - 1:55 pm **LUNCH-AND-LEARN ROUNDTABLE DISCUSSIONS**

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

What to Expect in 2023: Andelyn Biosciences: How an Expert CDMOs in Gene Therapy Manufacturing Will Reduce Manufacturing Time by 50% Through End to End Capabilities

Andelyn BIOSCIENCES Reliably Expert. Purposefully Driven.

Eric T. Blair
Chief Commercial Officer
Andelyn Biosciences

New Product Launch Readiness

Arcutis BIOTHERAPEUTICS

Patricia Turney
SVP Operations
Arcutis Biotherapeutics

Next Generation Biologics Manufacturing

AstraZeneca

John Higgins
Sr. Director Global Technical Operations
AstraZeneca

Moving from Reactive Improvement to True Process Understanding

DASSAULT SYSTEMES

Yuxian Zhang
Life Sciences Solution Consultant
Dassault Systèmes

Smart Risk Taking: Strategies to Accelerate IND Filings

GSK

Sid Advant
VP Manufacturing Operations
GSK

Biomanufacturing In Space on the International Space Station National Lab

ISS NATIONAL LABORATORY®

Michael S. Roberts, PhD
Chief Scientific Officer
International Space Station National Laboratory

From Approvals to Patients— Ensuring Ongoing Inspection Readiness and Manufacturing Success

Kite A GILEAD Company

Jose Caraballo
VP Corporate Quality
Kite Pharma

Commercial Process Readiness for Cell & Gene Therapies

Lonza

Dr. Behnam Ahmadian Baghbaderani
Global Head of Process Development, Cell & Gene Technologies
Lonza

Designing Flexible Strategies for Mixed Modality Launches

MERCK

Colette Ranucci
AVP Global Technical Operations
Merck

Best Practices for Effectively Managing Supply Chain Complexities with External Partnerships and Manufacturing

RENOVACOR

Kumar Dhanasekharan
SVP Technical Operations
Renovacor

Is it time to Create a Platform Manufacturing Process for C&GT?

Spark THERAPEUTICS

Eric Hacherl
Head of Manufacturing
Spark Therapeutics

Scaling Cell & Gene Therapy Networks within the Current Capital Constrained Environment

TCR² THERAPEUTICS

Aaron Vernon
VP, Manufacturing
TCR² Therapeutics

Strategies for Navigating CDMOs as a Small Biotech and the Value of Early Engagement

ThermoFisher SCIENTIFIC

Larry Pitcher
Sr. Director and General Manager, MMS, mRNA, Advanced Therapies
Thermo Fisher Scientific

Enable Proactive Quality Management Across the Product Lifecycle

Veeva

Danielle Pund
Director of Vault Quality
Veeva Systems

Making The Most of Your Product: Approaches to Minimizing Loss For Testing and Stability

VERTEX

Steve Goodman
Executive Director, AAV CMC
Vertex

1:55 - 2:30 pm

BREAKOUT ROOM 1
STRATEGIC MANUFACTURING

Towards Industrialization of Cell Therapy

Cell therapy, such as regenerative therapies based on iPSCs and adoptive cell therapies targeting cancer with CAR-T cells, CAR-NKs or TCRs hold enormous potential for the future of medicine, enabling for the first time curative approaches. However, the field is still in its infancy and CMC remains a critical bottleneck in bringing these therapies to patients on a global scale.

This discussion will focus on the scientific, technical and cultural transformations required to drive towards true industrialization of cell therapies, including:

- The critical challenges in CMC for cell therapies today
- How more in-depth understanding of cells, their critical quality attributes and control thereof will help drive safety, efficacy and more efficient manufacturing paradigms
- Approaches to manufacture autologous, allogeneic and “next generation” autologous therapies
- Our roadmap to creating an innovative flexible and modular platform to enable true industrialization of CT in the near future
- Partnering models that combine innovation engines with global supply networks to “make it real”

BAYER

Jens Vogel
SVP & Global Head of Biotech
Bayer AG

1:55 - 2:30 pm

BREAKOUT ROOM 2
QUALITY

Culture of Quality Excellence Driving Competitive Advantage for Operations

- Why a Culture of Quality Excellence is foundational to achieving manufacturing excellence and leads to competitive advantage for operations. Driving a culture that recognizes the Value of Quality Excellence.
- How to establish a Culture of Quality Excellence by focusing not only on processes and digital infrastructure but also focusing on people.
- Real-world examples of how Quality excellence is translated into manufacturing excellence, including Vendor Management, Investigational Excellence and End to End QMS..
- Using Quality data in a proactive and predictive manner in order to deliver value and achieve manufacturing excellence.

Bristol Myers Squibb™

RJ Doornbos
VP, Global Quality Systems
Bristol Myers Squibb

1:55 - 2:30 pm

BREAKOUT ROOM 3
CELL & GENE THERAPY

How to Deploy Fit-for-Growth Capabilities to Drive Operational Scalability

- 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

celularity

Ramji Krishnan
Head of Technical Operations
Celularity

2:35 pm - 3:10 pm

WORKSHOP
BREAKOUT ROOM 1

Build or Buy: What are the Key Considerations in Choosing the Right CDMO Partner?

In recent years, the standardization of biologics manufacturing processes has given product developers multiple viable options for producing biologics. These options include building an in-house production system or partnering with a contract biologics manufacturer. Although building in-house does offer the advantage of direct control; the time, labor, and spend required to implement this often makes it the inefficient choice. On the other hand, working with an experienced contract manufacturer can help you save time and costs by leveraging a deep pool of industry experience. However, the process of selecting the right CDMO partner needs to be performed after careful analysis of many factors: any of which, if overlooked, can create risk of delay or cost overrun. In this session, we will discuss the key parameters that you can easily assess when choosing the right innovative CDMO partner that will keep you competitive in a rapidly evolving market.

SAMSUNG BIOLOGICS

Kevin Sharp
VP of Strategic Operations,
Global Sales Center
Samsung Biologics

2:35 pm - 3:10 pm

Acceleration of Clinical Timelines Using Azzur Cleanrooms on Demand™, a Novel Approach to Biopharmaceutical Manufacturing

WORKSHOP
BREAKOUT ROOM 2

- Current industry challenges and opportunities related to biopharma manufacturing
- Internal manufacturing capability establishment challenges for biopharma
- Challenges related to outsourcing of technology and process throughout product lifecycle
- The Azzur Cleanrooms on Demand™ model
- Case Studies

AZZUR GROUP
From Discovery To Delivery™

Ravi Samavedam
Chief Innovation Officer
Azzur Group

2:35 pm - 3:10 pm

The Iterative Approach to a Digital Cell and Gene Therapy Process – An Overview & Best Practice

WORKSHOP
BREAKOUT ROOM 3

- Specific challenges in the digitization of CGT manufacturing
- A best practice approach to implementing electronic batch records for CGT
- An overview of digital data management for CGT processes

KÖRBER

Dr. Judith Koliwer
Principal Consultant, Cell & Gene Therapy
Körber Pharma Software

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

Fireside Chat: Building the Future from a Distinguished Tenure in CMC

- Introducing Prime Medicine and its vision for the future of medicine
- How are we thinking about the inclusion of novel types of automation into molecular medicine workflows?
- Examining how we view Talent in the emergent technology space, and how do we best deploy remote and hybrid work?
- Historically, pharmaceutical manufacturing leaders were predominantly men; however, many important CMC leadership positions are now held by women. Why is this the case, and how do we sustain this pattern?
- What are the most significant learnings from having achieved success in licensing autologous cell therapies?

prime medicine

Ann Lee
Chief Technical Officer
Prime Medicine

5:05 - 6:00 pm

Unlocking the Promise of Gene Therapy

- Review the current state of gene therapy
- Discuss overcoming barriers to product development
- Make the case for global regulatory convergence
- Describe FDA actions facilitating gene therapy development

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

6:00 - 6:05 pm

Chair's Closing Remarks

Alison Moore
Chief Technology Officer
Allogene Therapeutics

6:05 - 7:05 pm

SAMSUNG BIOLOGICS Proud Sponsor of the

Drinks Reception

7:05 - 8:50 pm

It's Tac-O' Clock!

Sponsored By: COMPLIANCE ARCHITECTS® CONSULTING • TECHNOLOGY • OUTSOURCING

QbDVision®

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

NOVEMBER 15, 2022

7:30 - 8:25 am **Registration and Breakfast**

Sponsored By: FLUOR®

7:45 - 8:20 am

BREAKFAST WORKSHOP
BREAKOUT ROOM 2

Sustainability for Process Development to Manufacturing: How Can We Leverage Digital Technology to Capture Quality and Productivity Efficiencies?

- The Control Tower: Providing visibility with actionable insights into the health of your manufacturing
- Yield Improvement: Process understanding and advanced modeling for significant ROI
- Digital twin: simulation and improved productivity by employing Smart Scheduling
- Successful industry 4.0 pharma use cases
- How to effectively build programs to deploy and maintain technology to continuously improve and capture value

APPLIED MATERIALS® make possible

Rick Johnston
Sr. Director
Applied Materials

RESILIENCE

Jennifer Staffin
Director, Biomanufacturing Automation
Resilience

8:25 - 8:35 am **Chair's Welcome Remarks**

Allogene THERAPEUTICS

Alison Moore
Chief Technology Officer
Allogene Therapeutics

8:35 - 9:10 am

Building a Global Cell Therapy Network to Put More Patients on a Path to a Cure

Eric Hahn, SVP, Global Cell Therapy Operations at Bristol Myers Squibb joins us to discuss how he is leading cell therapy manufacturing operations through rapid transformation, while integrating leading-edge technology into BMS. Among the highlights, Eric will discuss:

- How the overall Global Product Development and Supply (GPS) arm of BMS has evolved, including the integration of Cell Therapy Operations into GPS.
- BMS' history in Cell Therapy and its strategy to building a global manufacturing network to put more patients on a path to a cure.
- Key considerations that impact cell therapy manufacturing and delivery today and into the future.

Bristol Myers Squibb™

Eric Hahn
SVP, Global Cell Therapy Operations
Bristol-Myers Squibb

9:10 - 9:45 am

Fireside Chat: Considerations from CTOs in Our Industry Today

- Examining the various journeys to the CTO role and what the path there has taught us
- How will the role of the CTO evolve and grow given the evolving complexities with production and the industry as a whole?
- How is the CTO viewed by other C-suite colleagues? Is content of work well understood? How should this change?
- What is the most effective organizational structure below the CTO? Does it change with modality?
- Best practices to identify, grow and develop the CTOs of the future?
- What are our key learnings from our experience as CTOs?

Cynthia Pussinen
Former Chief Technical Officer
Spark Therapeutics, Inc.

Michael Kamarck
BioPharma Advisor & Board Member

ROOM 1 CHAIR

Allogene THERAPEUTICS

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

Dr. Judith Koliwer
Principal Consultant, Cell & Gene Therapy
Körber Pharma Software

9:50 - 10:25 am

BREAKOUT ROOM 1
STRATEGIC MANUFACTURING

Moderna: The Rise of mRNA Vaccines – CMC Operations During a Once-in-a-Lifetime Pandemic

- Our journey from a "platform" to a "multi-product" company
- How we achieved the seemingly impossible
- What we learned along the way
- Where we are today and where the journey takes us next

Tara Jones
SVP, North America Operations
Moderna

9:50 - 10:25 am

BREAKOUT ROOM 2
QUALITY

The Quality Equation

- Do you want to ensure that you never have a surprise regulatory inspection outcome?
- The equation incorporates all you need to assess the status of your site and is even better for companies with networks of sites.
- Data integrity, quality culture, process capability, management commitment and Quality Management Systems are all assessed to produce actionable data whether you are overseeing a CMO or operate your own network of sites.

Brandon Varnau
Head, Industrial Affairs Specialty Care
Global Business Unit Quality Operations
Sanofi

9:50 - 10:25 am

BREAKOUT ROOM 3
CELL & GENE THERAPY

Lyell's Manufacturing Journey - Building Capacity and Capabilities to Support Multiple Cell Therapy Programs

- Overview of Lyell science, technologies and platforms
- Developing a manufacturing strategy to control supply, enable scale and deliver multiple modalities
- Establishing electronic systems and digital ways of working from the start
- Building Lean principles and execution discipline into the organization early
- Delivering on the vision and strategy including lessons learned

Stephen Hill
Chief Operating Officer
Lyell Immunopharma

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

10:45 - 11:15 am **INTERACTIVE THINK TANKS**

INTERACTIVE THINK TANKS

During the Day Two Morning Networking Break there will be three different 'Interactive Think Tank' areas set up in the Exhibition Hall.

These are informal and unmoderated networking opportunities for like-minded attendees to get together in small groups to brainstorm and discuss issues of common interest. Icebreaking questions and topics of possible conversation will be provided but are by no means mandatory.

TOPIC 1
Digital Transformation Tactics & Strategies

TOPIC 2
Talent Attraction, Training, & Retention

TOPIC 3
CMO/CDMO Challenges

11:20 - 11:55 am

BREAKOUT ROOM 1
STRATEGIC MANUFACTURING

"Applying Lessons Learned from Covid 19 for Future Pandemic Preparedness"!

Given the experiences of Covid 19 Pandemic Response, we are even more aware of the need to be ready for what lies ahead with emerging and existing infectious diseases. Covid 19 continues to be a problem with evolving variants, Flu season ahead is anticipated to be worst in years, and we're learning about new or resurfacing infectious disease outbreaks around the world on a daily basis. Therefore, Pandemic Preparedness is more important now than ever. This presentation will share the key CMC lessons learned from the past two years that can be applied to Pandemic Preparedness – with focus on Manufacturing Processes, Partnerships and People!

Aine Hanly
Chief Technology Officer
Vir Biotechnology

11:20 - 11:55 am

BREAKOUT ROOM 2
QUALITY

Progressing Towards Labs-of-the-Future…TODAY!

Are you currently designing your Quality Control Labs-of-the-Future? If not, there's no better time to start than the present! Learn how Eli Lilly and Company is advancing towards Labs-of-the-Future, through strategic initiatives associated with an integrated Digital Plant program. Areas of global focus and investment include:

- QC Operational Excellence
- Next Generation Informatics Solutions
- Process Analytical Technology
- Lab Automation and Robotics
- New Facility Considerations

Mark Butchko
Associate VP Global Quality Laboratories
Eli Lilly

11:20 - 11:55 am

BREAKOUT ROOM 3
CELL & GENE THERAPY

Industrialization of CAR-T Therapies – Autologous vs Allogeneic: Common and Uncommon Hurdles

- Industry evolution at a glance
- Donor Variability, the greatest source of variability for cell therapies. Thoughts on characterizing and accommodating this variability
- Process considerations for Autologous CAR and the importance of a good data ecosystem to provide insight and understanding to this highly complex therapeutic modality
- Brief introduction to Kyverna

Karen Walker
Chief Technology Officer
Kyverna Therapeutics

12:00 - 12:35 pm

Technical Operations Strategies in an Uncertain Market

- State of the current market and impact on manufacturing cell and gene therapies
- Key factors to consider when scaling up a facility for advanced medicines
- Make vs. Buy and the advantages and challenges of both solutions given the current market

WORKSHOP
BREAKOUT ROOM 1

Moderator:

PROJECT FARMA
A PRECISION FOR MEDICINE COMPANY

Adam Pfeiffer
VP of Strategy
Project Farma

Panelist:

PROJECT FARMA
A PRECISION FOR MEDICINE COMPANY

Tony Khoury
EVP
Project Farma

BIONTECH

Marc Wolfgang
VP, Technical Operations
BioNTech

TCR² THERAPEUTICS

Peter Olagunju
Chief Technical Officer
TCR² Therapeutics

12:00 - 12:35 pm

Establishing a 'Culture of Data' in Pharma Manufacturing

Pharmaceutical manufacturers have worked diligently and successfully to foster a 'culture of quality', resulting in fewer overall regulatory citations year over year since 2010. How can better data management and analytics impact not only quality but process improvement and efficiency gains as well?

- What trends are driving the need to move towards both managing and using data better?
- The 'culture of data' starts with changing old ways of working. What steps do biopharma manufacturers need to take to initiate their transformation?
- How can manufacturers use manufacturing process data to quickly and proactively improve outcomes?

WORKSHOP
BREAKOUT ROOM 2

aizon

pwc

Vishaka Rajaram
Director, Pharmaceutical and Life Sciences Practice
PWC

12:00 - 12:35 pm

Emerson Real-Time Modeling System in Takeda's Los Angeles Plasma Fractionation Facility

- Expected benefits of integrated scheduling and modeling
- Building the model
- Integrating the model with various systems
- Switching to a new scheduling software in manufacturing

WORKSHOP BREAKOUT ROOM 3

EMERSON

Takeda

Sean Ganley
AGILE Champion III
Takeda

12:35 - 1:35 pm

Executive Lunch

Sponsored By: Sharp

12:35 - 1:35 pm

LUNCH-AND-LEARN ROUNDTABLE DISCUSSIONS

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

Building the Facility of the Future

AMGEN

Jim Weidner
Executive Director of Engineering
Amgen

Bringing Automation and Innovation During Early Stage of Process Development

Beam THERAPEUTICS

Manmohan Singh
Chief Technology Officer
Beam Therapeutics

How Can We Make Cell Therapy Potency Assays as Effective and Robust as Small Molecule Testing?

IOVANCE BIOTHERAPEUTICS

Parinaz Rajaii
Director, Quality Operations
Iovance Biotherapeutics

Discussing A Risk Based QA Approach in a Virtual Company

mirum

Vinita P. Kumar
SVP, Quality
Mirum Pharmaceuticals, Inc.

Building Quality in Small Clinical Stage Biotech Companies

NGMBio

Claus Weisemann
VP Quality
NGM Biopharmaceuticals

Thinking Outside the Box: Manufacturing Challenges and Solutions for Novel Modalities

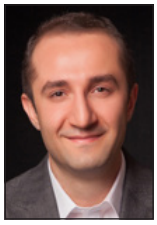
NOVOME BIOTECHNOLOGIES

Tariq Warsi
VP of Technical Operations
Novome Biotechnologies

Phase Appropriate Quality Considerations in a Changing Regulatory Environment

Dave Geoghegan
Head of Quality
Spark Therapeutics

Bringing the Digital Revolution to Gene Therapy Process Development and Scale-Up



Pouria Motevalian
Director Process Development
Thermo Fisher Scientific

Building an Agile Supply Chain for the Future

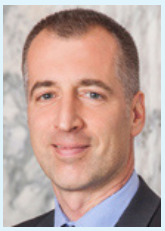
Pratik Ahuja
VP, Supply Chain
Urovant Sciences

1:35 - 2:10 pm

BREAKOUT ROOM 1
STRATEGIC MANUFACTURING

Global Talent Trends in Pharma and Biotech Manufacturing

- The accelerating generational gap in senior Manufacturing talent
- Is Biotech Manufacturing a company-level or an industry-level challenge?
- A proposed solution: launching the "TechOps Leadership Accelerator"



Pascal Bécotte
Managing Director
Russell Reynolds Associates

Shannon Knott
Executive Director
Russel Reynolds Associates

1:35 - 2:10 pm

BREAKOUT ROOM 3
CELL & GENE THERAPY

FLEXible GMP Manufacturing –A Case Study by ElevateBio

- Understand the significance of closed, automated and scalable instrumentation.
- Learn how Cytiva's FlexFactory™ is a viable solution for the "capacity crunch."
- Learn more about Chronicle™ Automation Software and how it can help digitally transform your operations.
- Discover lessons learned and key recommendations for capacity expansion projects.

Michael Paglia
Chief Operational Officer, BaseCamp
ElevateBio

2:15 - 3:15 pm

Panel: Looking Backwards, Looking Forwards: Maximizing Our Impact on the Future of Medicine

The past few years has seen a migration of talent and technology from traditional biopharmaceutical manufacturing to ATMP manufacturing:

- How has this changed the CMC ecosystem, and are we overbuilding capacity again?
- Avoiding the dangers of fragmentation. How should we better communicate, collaborate, and consolidate our best ideas so we all succeed?
- Discussing the reasons to set up a new company today, and imagining how our business ecosystem will continue to grow and evolve
- Debating which production platforms will best suit the newer modalities
- Exploring the next steps for existing platforms like mAbs: How do we efficiently serve giant markets such as Alzheimer's indications, for example?
- Striking the balance between pandemic and personalized medicine as we look to the future

ALTOS™

Ann Lee-Karlon
Chief Operating Officer
Altos Labs

GRAPHITE BIO

Jerry Cacia
Chief Technical Officer
Graphite Bio

RESILIENCE

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

Michael Kamarck
BioPharma Advisor & Board Member

3:15 - 3:20 pm

Chair's Closing Remarks

Allogene THERAPEUTICS

Alison Moore
Chief Technology Officer
Allogene Therapeutics