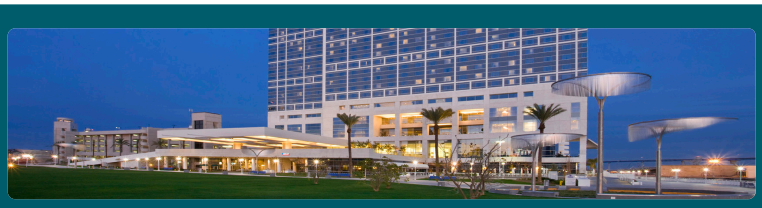
AGENDA

BIOMANUFACTURING WORLD SUMMIT
BMWS23
November 14-16, 2023 | San Diego, CA



Hilton San Diego Bayfront

NOVEMBER 14, 2023

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

AGENDA

5:00 pm - 6:00 pm

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

- Is talent and workforce development in our industry changing? If so how and why?
- What are the most important new technologies in biomanufacturing today?
- What current factors are affecting speed of development and efficient manufacturing?
- What Regulatory progress has been made and what future opportunities exist?
- How can we improve the access of biologic medicines?

Moderator:

Alison Moore
CMC Executive

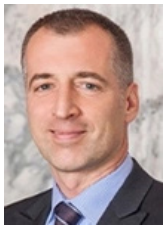
Panelists: Allogene Therapeutics

Tim Moore
EVP, Chief Technical Officer
Allogene Therapeutics

BAYER

Wolfram Carius
EVP Pharmaceuticals
Bayer AG

Russell Reynolds Associates



Dr. Pascal Bécotte
Managing Director
Russell Reynolds Associates

Sana Biotechnology

Snehal Patel
SVP, Head Technical Operations
Sana Biotechnology

6:00 pm - 7:00 pm

AGENDA

6:00 pm - 7:00 pm

Welcome Day Food Station

Sponsored By: Boehringer Ingelheim

6:30 pm

NOVEMBER 15, 2023

7:00 am - 7:45 am

Registration and Breakfast

Sponsored By: FLUOR®

7:45 am - 7:50 am

Opening Remarks and Important Announcements

7:50 am - 8:00 am

Chair's Welcome Address

Alison Moore
CMC Executive

AGENDA

8:00 am - 8:35 am

Manufacturing Strategies for Sustainable Global Growth: Building a Global Sustainable Supply Operation for the Future Leveraging Digital and Innovation

- Building a sustainable global supply operation for the future while navigating increased complexity, including growth in products and modalities and evolving needs of patients
- Focusing on expanding production capacity, enhancing operational efficiency, and accelerating the development and delivery of life-saving medicines and vaccines
- Exploring and implementing new manufacturing technologies such as continuous manufacturing, advanced analytics, and automation to streamline production processes and improve product quality and consistency
- Decarbonizing supply chains while ensuring they remain resilient and agile for a healthier society for patients and society

Per Alfredsson
SVP, Global Biologics Operations
AstraZeneca and President AstraZeneca AB
AstraZeneca

8:35 am - 9:10 am

Industrialization Challenges for ATMPs: Achilles' Heel AND Opportunity

- The field of ATMPs is evolving at a rapid pace while industrialization challenges are limiting access to these potentially curative treatments
- Managing complex supply chains will make the difference
- Digital solutions and innovating in key areas to reduce cost of manufacture are major enablers to drive access

Ralf Altenburger
Global Head, Cell and Gene Therapy, Genentech/Roche
Roche

ROOM 1 CHAIR

Alison Moore
CMC Executive

ROOM 2 CHAIR

Jack Garvey
CEO/ Managing Partner
Compliance Architects LLC

ROOM 3 CHAIR

Judith Koliwer, PhD
Sr. Industry Advisor and Principal Consultant Advanced Therapies
Körber Business Area Pharma

AGENDA

9:15 am - 9:50 am

BREAKOUT ROOM 1
STRATEGIC MANUFACTURING

Building Flexible, Scalable and Sustainable Cell Therapy Manufacturing Network to Serve Patients

- Balancing demand and capacity for personalized medicines
- Optimizing speed, cost and quality
- Embracing Innovation
- Enabling Horizontal Collaboration

NOVARTIS | Reimagining Medicine

Robert Zamboldi
Site Head – US Cell & Gene Therapy, Morris Plains
Novartis

9:15 am - 9:50 am

BREAKOUT ROOM 2
QUALITY

Leveraging Enterprise Connectivity to Make CMC Regulatory and Quality a Competitive Advantage at Merck

- How we are working to position the Regulatory CMC and Quality organizations to best support the evolving R&D pipeline and commercial Manufacturing objectives
- Preparing for complex new modalities and emerging technologies, insights from our recent pipeline filings
- Leveraging ICHQ12 and Reliance to better manage post-approval change
- Simplifying key Quality and Regulatory business processes through cross-functional prioritization, 'OneTeam' collaboration and digital experimentation - case studies and learnings

MERCK

Jennifer McCafferty
SVP, CMC-Regulatory and Quality
Merck

9:15 am - 9:50 am

BREAKOUT ROOM 3
CELL & GENE THERAPY

Gene Tuning: Expanding the Reach of Biomedicine

- Cell and Gene Therapies (CGT) have revolutionized the era of biomedicine.
- Advances in biotechnology and increased understanding from functional genome annotation and gene regulation are enabling gene tuning as therapeutic approach.
- What is gene tuning?
- Use cases demonstrating the unique value of gene tuning

TUNE THERAPEUTICS

Heidi Zhang
EVP, Head of Technical Operations
Tune Therapeutics, Inc.

AGENDA

9:55 am - 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

Empowering Innovation: Enhancing CDMO Capabilities for Collaborative Success

- Addressing the challenges of outsourced manufacturing as biopharma companies aim to enter global markets through capacity expansion and seek strong partnerships
- Highlighting the significance of planned growth to meet industry demand and Samsung Biologics' proactive growth strategy to synergize for success through CDMO collaboration
- A CDMO's Perspective: Strategizing for the future through diversification and portfolio augmentation, with a core focus on the development of an expanded range of therapies while concurrently bolstering capacity

SAMSUNG BIOLOGICS

Kevin Sharp
SVP, Head of Samsung Biologics America Sales
Samsung Biologics

11:40 am - 12:15 pm

WORKSHOP
BREAKOUT ROOM 2

Small But Mighty: How Digital Technology Can Support Small Batch Manufacturing of mRNA Therapeutics

mRNA manufacturing offers great benefits and potential for infectious diseases and personalized medicines due to the advantages in flexibility, cost, and speed of development, but there are still challenges to overcome to fully realize the potential, especially when addressing small batch manufacturing. Considering manufacturability and scale-up from the beginning will help to deliver process efficiency and scalability along the spectrum of mRNA products. In this presentation, we'll discuss how digital technology can help accelerate therapeutic development and strategies to adopt a paper free approach at all stages of development.

- Small and flexible manufacturing allows for optimized solutions for personalized therapeutics and small batch manufacturing
- Digital technology can support mRNA therapeutics by helping to accelerate batch release and improve compliance
- The hidden costs of paper

cytiva

Katarina Stenklo
Enterprise End-to End Solutions Leader
Cytiva

AGENDA

11:40 am - 12:15 pm

WORKSHOP

BREAKOUT ROOM 3

Process Optimization with Digital Solutions: A Holistic Approach for Data Management and Analysis in Cell and Gene Therapy

- Biophorum's publication on best practice for patient traceability
- Best practice implementation of electronic batch records for cell and gene therapy
- Holistic process model of cell-based therapy
- Iterative approach for the digitization of a cell and gene therapy process

Judith Koliwer, PhD
Sr. Industry Advisor and Principal Consultant Advanced Therapies
Körber Business Area Pharma

12:20 pm - 12:55 pm

BREAKOUT ROOM 1
STRATEGIC MANUFACTURING

We are What We Eat: Biological Modalities and Challenges at Takeda

- Takeda started as a company in health care in 1781 with a sole focus on the Japanese market. Takeda acquired expertise in small molecule development, semi-synthetics and live virus vaccines
- In the 21st Century, Takeda reset its ambitions, seeking to become an international biopharmaceutical company. In the 2000's, Takeda expanded its offerings and markets by a series of acquisitions. There was no restriction on the modalities of acquired products
- A transformation of Takeda's R&D, plus a major acquisition of a company of equal size but very different product portfolio has led to Takeda having commercial products in many different biological modalities and even more modalities in play in research
- This talk will discuss the challenges that this variety of modalities has created for manufacturing and for CMC in research, along with strategies being adopted in those areas to address this spectrum of modalities

Michael Thien
Head & SVP, Pharmaceutical Sciences
Takeda Pharmaceuticals

12:20 pm - 12:55 pm

BREAKOUT ROOM 2
QUALITY

Strengthening our Industry: Intersection of Innovation, Customer Experience, and Proactive Resilience

- Enabling business growth through proactive resilience
- Managing risks related to the quality of our products and illicit trade to protect patients from potential harm
- Digital – How are we preparing our organizations for the future

Federico A Feldstein, JD
VP, Global Head of Supply Chain Quality
Johnson & Johnson Innovative Medicines

AGENDA

12:20 pm - 12:55 pm

BREAKOUT ROOM 3
CELL & GENE THERAPY

Towards Industrialization of Cell Therapy

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"

Jens Vogel
SVP & Global Head of Biotech
Bayer Pharmaceuticals

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

Sponsored By: RSM

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

Data Driving Manufacturing Robustness

Amy Doucette
Head of Business Operations – Automation Product Group Pharma
Applied Materials

How Does a True Global Manufacturing Network Bring Value to Patients and Your Organization?

Michael Kraich
VP of Global Project & Product Management
Boehringer Ingelheim Biopharmaceuticals GmbH

Establishing Reference Standards to Accelerate Therapeutic Development

Seshu Tyagarajan
Chief Technical and Development Officer
Candel Therapeutics

Transforming Pharmaceutical Manufacturing with Artificial Intelligence

Dr. Larry R. Fiegland
Discoverant Product Manager
Dassault Systèmes

AGENDA

Beyond Capacity & Capabilities: What Traits Should Biopharma Companies Look for When Partnering with CDMOs

Brad Wynja
VP of Business Development
INCOG BioPharma Services, Inc.

Giuseppe Mauro
VP, Head of Large Molecule Manufacturing
Incyte Biosciences Technical Operations Sarl

Enabling Reduced COGM Through Continuous Manufacturing: Flexible J.POD® Platform

Ben Castro
SVP Manufacturing Operations
Just – Evotec Biologics

How Are We Developing the Next Generation of Biopharma Leadership?

Eric Hacherl
Chief Operating Officer
Kyttaro Therapeutics

Strategic Levers and Risks in Manufacturing Capacity Network Design and Value Chain Execution

Kacey Fetcho-Phillips
AVP, Site Head
Merck

Balancing Efficiency and Resilience in a Global Supply Chain

Heather Erickson
VP, Supply Chain Management & Business Operations
Sangamo

Exploring Phase-Appropriate QA Oversight for Accelerating Gene Therapy Drug Development

Mike Nuzzolo
Head of Quality Operations
Spark Therapeutics

The Quality Culture Journey – How Do We Build It and Keep It Healthy So We Can Best Serve Our Patients

Georgeta Puscalau
Senior Vice President Quality
Tune Therapeutics, Inc.

AGENDA

1:55 pm - 2:30 pm

Panel: CDMOs as Critical Partners in the Biopharmaceutical Ecosystem. The Challenges and Trends of CDMO Industry in the Past, Present and Future.

- Analyzing How Contract Development and Manufacturing Organizations (CDMO's) have transformed over the years, from being merely service providers to becoming indispensable partners in the biopharmaceutical ecosystem.
- Examining the challenges CDMO's have faced in meeting the increasing demand for biopharmaceutical products and the strategies employed to overcome capacity limitations.
- Highlighting the importance of collaborative partnerships between biopharmaceutical companies and CDMO's in driving innovation and accelerating drug development timelines.
- Discussing the technical challenges faced by CDMO's in bioprocessing, such as scalability, process optimization, and future platform technology convergence.
- Exploring the role of CDMO's in supporting the development and manufacturing of complex personalized medicine (C&GT) and the challenges they face in this rapidly evolving field.
- Forecasting the future trends of the CDMO industry and identifying emerging opportunities and potential disruptions that will shape its trajectory in the coming years.

FUJIFILM Diosynth biotechnologies

Lars Petersen
President and CEO
FUJIFILM Diosynth Biotechnologies

RESILIENCE

Rahul Singhvi
Co-Founder & CEO
Resilience, Inc.

WuXi ADVANCED THERAPIES 药明生基 | 药明康德 WuXi AppTec

David Y. H. Chang
President and Chief Technology Officer
WuXi Advanced Therapies

2:35 pm - 3:10 pm

WORKSHOP
BREAKOUT ROOM 1

Panel: Technical Operation Strategies for Flexible Manufacturing

- How to decide when to scale internal manufacturing
- Advantages of flexible, phase-appropriate facility builds
- Operational readiness and a successful facility startup

Moderator:

PROJECT FARMA
A PRECISION FOR MEDICINE COMPANY

Adam Pfeiffer
VP
Project Farma

Panelists:

ARCELLX

Doug Alleavitch
VP Quality
Arcellx

PROJECT FARMA
A PRECISION FOR MEDICINE COMPANY

John Khoury
EVP
Project Farma

ThermoFisher SCIENTIFIC

Paul Jorjorian
VP Biologics
Thermo Fischer

AGENDA

2:35 pm - 3:10 pm

WORKSHOP
BREAKOUT ROOM 2

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

- 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™

Sarah Stevens, Ph.D.
President of Azzur Labs & Azzur Cleanrooms on Demand™
Azzur Group

2:35 pm - 3:10 pm

WORKSHOP
BREAKOUT ROOM 3

Deliver Products to Patients Faster with a Purpose-Built, No-Code MES Solution

- How to overcome the challenges that are slowing your manufacturing processes and ultimately get your products to patients sooner.
- How a modern, purpose-built, no-code MES solution can be deployed rapidly in your facility. Modern MES designed specifically for the bio manufacturing environment and maps easily to existing processes, with pick-up-and-use simplicity. Solutions are designed to solve the challenges faced by process engineers, manufacturing operators, plant managers, and quality assurance professionals.
- Real-world results that fellow life sciences manufacturers are achieving as a result of digitizing with a modern MES.

MasterControl™

Brian Curran
SVP Manufacturing Excellence Success
MasterControl, Inc.

3:15 pm - 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 pm - 5:05 pm

Accelerating the Pace of Progress for Innovative Biologic Products

- Highlight the importance of manufacturing technologies for innovative biologic products
- Discuss efforts to expedite development of products for small populations through increased use of accelerated approval
- Review efforts toward global regulatory convergence
- Summarize internal changes and external initiatives at FDA in support of expeditious product development

FDA

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

AGENDA

5:05 pm - 6:10 pm

Panel: Biotech Manufacturing Industrialization, Talent Development, and Leadership — A Tribute to Our Friend Mike Kamarck

Over the last few decades we have all witnessed the industrialization of biologics manufacturing, as well as continuous progress in complex medicines such as Cell and Gene Therapy. In this panel we will reflect on where we started, where we are now, and what our future holds. We dedicate this conversation to Mike Kamarck, an exceptional leader of our era whose legacy includes everything we plan to discuss:

- **Achievements** - What we did, and what we have learned from the rapid rise of biologics manufacturing industrialization
- **Encore** - Exploring what comes next in the industrialization for the complex medicines manufacturing so that curable medicines can be made upon approval for all patients
- **Reflections** - How leaders like Mike have championed the technology development, talent development, and industry-wide leadership beyond any one company
- **Winning Over Diseases** - Demonstrating the importance of technology, manufacturing, talent development and leadership as we march forward together
- **Carrying On** - Discussing how we will continue the mission Mike championed, and have fun with a contagious big smile as we do it

Alison Moore
CMC Executive

Wolfram Carius
EVP Pharmaceuticals
Bayer AG

Charles L. Cooney
Robert T. Haslam Professor of Chemical Engineering, Emeritus, and Faculty Director, Emeritus Deshpande Center for Technological Innovation
MIT (Massachusetts Institute of Technology)

Sanat Chattopadhyay
EVP, President, Merck Manufacturing Division
Merck

Mike McDermott
EVP, Chief Global Supply Officer
Pfizer

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

Brendan O'Callaghan
EVP, Manufacturing and Supply
Sanofi

Aine Hanly
Chief Technology Officer
Vir Biotechnology

Michael Kamarck
(In Memoriam)
BioPharma Advisor & Board of Directors:
Passage Bio, VaxCyte

AGENDA

6:10 pm - 6:15 pm **Chair's Closing Remarks**

Alison Moore
CMC Executive

6:15 pm

6:30 pm

7:15 pm

AGENDA

NOVEMBER 16, 2023

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

Sponsored By: FLUOR®

7:45 am - 8:20 am **The Integrated Development and Manufacturing Organization: The Future of Cell Therapy Manufacturing**

BREAKFAST WORKSHOP

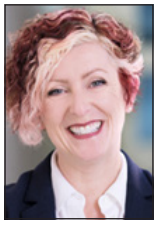
BREAKOUT ROOM 2

- Introducing the Integrated Development and Manufacturing Organization (IDMO)
- Integrating technology and manufacturing services to overcome manufacturing bottlenecks and meet global cell therapy patient demand
- Automating cell therapy manufacture to increase flexibility, decrease manufacturing costs, improve quality, and increase capacity
- Join the IDMO revolution

CELLARES

John Tomtishen
VP Operations
Cellares

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



Alison Moore
CMC Executive

AGENDA

8:35 am - 9:10 am

Strategies for Achieving Business Impact through Digital Transformation in Biopharmaceutical Manufacturing

- Recognize the Value of Production Data: The most valuable data in biopharmaceutical manufacturing comes from production itself. By leveraging this data, manufacturers can improve efficiency, reduce costs, and enhance quality.
- Identify the Right Goals and Outcomes: To ensure that the digital transformation has a significant impact, it is important to identify the right goals and outcomes. This involves setting clear targets and metrics that align with the overall business strategy.
- Create a Unified System: Biopharmaceutical manufacturers should connect disparate IT systems to create a unified whole. This will enable them to access and analyze data from across the organization, leading to better decision-making and improved operational efficiency.
- Build a Scalable Approach: To achieve sustainable digital transformation, biopharmaceutical manufacturers should adopt a step-by-step approach and start small to go big. This will enable them to build a scalable model that can be rolled out across the enterprise.

Stacey Ma
EVP, Pharmaceutical Development and Manufacturing
Gilead

9:10 am - 9:45 am

Our Journey in Next Generation Manufacturing: What We Can Achieve Together

- Where our organizations are heading as a community of pharmaceutical manufacturers
- Our current and future capabilities by geography, people, and technology
- Practical leadership approaches that empower us to tackle challenges and set ambitious goals for the future
- Next generation platforms that will change how we work and succeed
- Examples from Pfizer that illustrate these pursuits in action

Roberto Silveira
Global Technology & Engineering
Pfizer

ROOM 1 CHAIR

Alison Moore
CMC Executive

ROOM 2 CHAIR

Jack Garvey
CEO/ Managing Partner
Compliance Architects LLC

ROOM 3 CHAIR

Judith Koliwer, PhD
Sr. Industry Advisor and Principal Consultant Advanced Therapies
Körber Business Area Pharma

AGENDA

9:50 am - 10:25 am

BREAKOUT ROOM 1
STRATEGIC MANUFACTURING

A Vision for the Future of mRNA Technology: Moderna's Plans for the Future of mRNA Manufacturing & Expansion

- Development of mRNA Therapeutics: Moderna is advancing its mRNA platform technology to develop new therapeutics for a range of diseases, including cancer, rare genetic diseases, and autoimmune disorders.
- COVID-19 Vaccine Production: Moderna continues to support countries across the world with their vaccination campaigns against COVID-19, and remains the only company to have generated clinical data of its monovalent XBB.1.5 vaccine candidate showing an immune response against XBB sublineages XBB.1.5, XBB.1.16, and XBB.2.3.2, in addition to BA.2.86, EG.5 and FL.1.5.1 variants
- Manufacturing Capacity: Moderna is currently right-sizing its manufacturing footprint in line with the resizing of the COVID-19 vaccine market due to the move from a pandemic to an endemic market. Moderna expects additional capacity at its new mRNA manufacturing facilities in the UK, Canada, and Australia when completed in 2025.
- Research and Development: Moderna is investing in research and development to improve its mRNA technology and develop new therapeutic applications. The company also plans to collaborate with other researchers and organizations to accelerate the discovery of new treatments.
- Global Impact: Moderna's long-term goal is to revolutionize medicine by using mRNA technology to address unmet medical needs worldwide. The company plans to expand access to its therapies and vaccines globally, with a focus on developing countries and underserved populations.

moderna

Luis Mustafa Perez
VP Innovation & Operational Excellence
Moderna

9:50 am - 10:25 am

BREAKOUT ROOM 2
QUALITY

Quality Reborn – Redefining Education of Quality Business Leaders

It is time for Quality leaders to transition from a traditional compliance driven role to that of a Quality Business Leader making quality a competitive advantage for companies rather than seen as a cost. To become a successful Quality Business Leader requires mastering the following skills

- The craft of quality
- Decision making in challenging situations
- Employee engagement
- Strategic quality and compliance management
- Making quality operations a financial value add
- Internal and external global change leadership

KRONOS·BIO

Anders Vinther
SVP Pharmaceutical Development & Manufacturing
Kronos Bio

AGENDA

9:50 am - 10:25 am

BREAKOUT ROOM 3
CELL & GENE THERAPY

Unlocking the Power of Gene Therapy to Accelerate Healthcare Transformation

- The power and potential of gene therapy
- The paradigm shift yielding vast societal benefit
- Highly dynamic marketplace, with tailwinds and headwinds
- Overcoming key challenges, ranging from platform, to medical, commercial and manufacturing
- Introducing Spark's Gene Therapy Innovation Center: Roche's flagship COE for gene therapy manufacturing globally

Spark THERAPEUTICS

Chris Stevens
Chief Patient Supply Officer
Spark Therapeutics

10:25 am - 11:15 am

Pre-Arranged One-to-One Meetings

10:30 am – 10:50 am: Meeting Slot 8 / Networking
10:55 am – 11:15 am: Meeting Slot 9 / Networking

10:45 am - 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

AGENDA

10:45 am - 11:15 am **Focus Group**

Focus groups are informal moderated conversations among peers that occur during networking times outside the regularly scheduled conference agenda. There is no sign up. Delegates and speakers are welcome to opt into the focus group. The focus group will take place in the corner of the Exhibition Hall in a well-marked area that include a sound barrier. All participants will be provided with wireless headphones to ensure everything said can be heard over the background noise of the Exhibition Hall.

Transitioning an AAV Product from HEK Cells to Sf9 - What is the Value Proposition?

NIIMBL The National Institute for Innovation in Manufacturing Biopharmaceuticals

Eric Hacherl
Co-Lead, NIIMBL Viral Vector Program
NIIMBL

11:20 am - 11:55 am **Taking Commercial Cell Therapy Supply to the Next Level**

- Optimize global manufacturing processes to meet growing patient demand
- Discover the importance of having a global manufacturing network to successfully supply patients
- Understand key success factors to achieve a reliable, sustainable and best-in-class manufacturing success rate and turnaround time for rapid and reliable delivery
- Learn how automation will shape the future of scaling CAR T-cell therapy to reach more patients

Kite A GILEAD Company

Chris McDonald
SVP & Global Head of Technical Operations
Kite, a Gilead Company

12:00 pm - 12:35 pm

WORKSHOP
BREAKOUT ROOM 1

The Future of Medicine Will Cost Less and Move Faster Than We Ever Imagined

- Showcasing how enterprise-grade modular laboratories and related infrastructure that can be scaled and reconfigured as needed will fundamentally and radically change the price and timelines involved in developing the next generation of medicine
- Offering best practices and lessons learned about how to understand what you need, customize what you want, scale as you grow, and course-correct as you discover, all at a fraction of traditional costs
- Illustrating how this works based on real-world examples
- For more information, please enjoy this interview with Amrit Chaudhuri of SmartLabs, recorded at BMWS22.

SmartLabs

Amrit Chaudhuri
CEO/Cofounder
SmartLabs

AGENDA

12:00 pm - 12:35 pm

WORKSHOP
BREAKOUT ROOM 2

Unleashing the Potential: Leading the Future of Biologics Market Suppl

- Exploring how FUJIFILM Diosynth Biotechnologies is taking a leading role in transforming the biomanufacturing landscape through rapid expansions and a bold network strategy
- Highlighting cutting-edge strategies that enhance the efficiency and rapid scalability of production
- Case study: FUJIFILM Diosynth Biotechnologies rapid expansion journey unlike anything seen before in the market
- Focusing on people & culture: Implementing a modular cloning approach, keeping trust and delivery at the forefront, and not only rapidly scaling manufacturing capabilities across US and Europe, but also expanding to be able to flexibly meet clients' needs end to end – covering the entire value chain
- Prioritizing scaling responsibly both from a climate and a community perspective

FUJIFILM Diosynth biotechnologies

Dave Stewart
SVP, Operational and Process Technology, Large Scale Business Unit
FUJIFILM Diosynth Biotechnologies

12:00 pm - 12:35 pm

WORKSHOP
BREAKOUT ROOM 3

Opportunities and Challenges of GMP Manufacturing of RNA-LNPs

- Manufacturing considerations and adaptations to accelerate scale-up, increase workflow efficiency, and standardize GMP manufacturing processes for RNA vaccines and therapeutics
- How to improve operational flexibility to address novel molecules and expand targeted delivery to new applications beyond mRNA vaccine development
- Strategies to increase manufacturing capacity for different stages of clinical development and commercial manufacturing of RNA-LNP drug products

PRECISION NANOSYSTEMS now part of Cytiva

Martin Rabel
Sr. Field Application Scientist
Precision NanoSystems Inc.

12:34 pm - 1:35 pm

Executive Lunch

Sponsored By: RSM

AGENDA

12:35 pm - 1:35 pm **Themed Lunch 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:

CDMO Magic – Secrets for Managing Contract Partners for Favorable Outcomes

Greg Sukay
VP Manufacturing and Process Technologies
Arcutis Biotherapeutics

Approaches for Accelerating Biologics Development to Launch and Enabling Cycle Time Reduction

Vinod Bulusu
Executive Director, Head Global Biologics CMC Product Stewardship
AstraZeneca

Industry 4.0 and the Disruption of Biopharmaceutical Manufacturing Paradigms

John Tomtishen
VP Operations
Cellares

Finding the 'Sweet Spot', CMO and Internal Assets: Strategies to Meet Global Demand and Requirements in BioPharma

Shahid Rameez
Director, Global Vaccines and Biologics Commercialization
Merck

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

Tariq Warsi
VP of Technical Operations

Increasing Batch Performance: Leveraging Learnings From Biotech to Gene Therapy Manufacturing

Christine Sheaffer
Head of Manufacturing and Supply
Spark Therapeutics

Annex 1: Expectations, Challenges and Solutions from Publication to Implementation

Annette Hillebrand
Executive Director Global Regulatory Affairs CMC
Ultragenyx

Optimizing External Manufacturing Partnerships: Strategies for Successful Collaboration

Glen Campbell
Head of External Manufacturing
Vir Biotechnology

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

AGENDA

1:35 pm - 2:10 pm

BREAKOUT ROOM 1
STRATEGIC MANUFACTURING

Mission Possible: The Role of Manufacturing in Realizing the Potential of Cell Therapy

- CAR T cell therapies offer a differentiating capability to leverage the specificity of adaptive immunity to fight cancer and other immune-related diseases.
- Manufacturing is a key (if not the key) enabler to realize the potential of cell therapy to reach patients.
- Supply challenges associated with autologous CAR-T supply include scalability, evolving fundamental understanding of clinically relevant critical quality attributes, rapidly changing manufacturing technology and analytical platforms, unpredictable demand and limited availability of operational systems to manage a "make-to-order" business.
- Considerations to enable reliable, compliant supply today and in the future include understanding the needs of the patient, investment in fundamental product understanding, innovating in manufacturing and business processes, investing in people and the possibilities of supply chain design, technology selection, integration of discovery, development & supply and establishing strategic partnerships.

Bristol Myers Squibb™

Thomas Potgieter
SVP, Global Cell Therapy Development & Operations
Bristol-Myers Squibb

1:35 pm - 2:10 pm

BREAKOUT ROOM 2
QUALITY

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

ATARA BIO

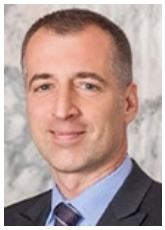
Amy Gamber
VP, Manufacturing
Atara Biotherapeutics

2:10 pm - 2:45 pm

Global Talent Trends in Pharma and Biotech Technical Operations

- The great reckoning – single-asset company valuation recalibrations reverse top talent trend and lead to unprecedented layoffs in the industry
- The generational gap continues to progress – leading only becomes more challenging
- Leaders in the healthcare industry indicate the greatest drop in leadership confidence across industries

Russell Reynolds ASSOCIATES



Dr. Pascal Bécotte
Managing Director
Russell Reynolds Associates

Russell Reynolds ASSOCIATES

Shannon Knott
Executive Director
Russell Reynolds Associates

AGENDA

2:45 pm - 2:50 pm **Chair's Closing Remarks**

Alison Moore
CMC Executive