BIOMANUFACTURING WORLD SUMMIT
BMWS20

November 16-17, 2020 | biomanworld.com

AGENDA

NOVEMBER 16, 2020

8:50 - 9:00 am

Co-Chairs' Welcome Address

Pat Yang
Chairman at ***Acepodia***
& Founding Board Director
at ***Sana Biotechnology***

Alison Moore
Chief Technology Officer
Allogene Therapeutics

9:00 - 9:30 am

Keynote: Reinventing a Biopharma Company for the 21st Century

- Bristol Myers Squibb is a company that has undergone an extensive transformation and as a result, has reinvented itself
- Once a company consisting of multiple and vastly different business units, it is now the largest diversified specialty global biopharma company
- Its mission and focus is to utilize innovation to advance the treatment of serious disease and significant unmet medical need
- This organizational evolution required substantial change for the product development and manufacturing arms of the company
- Technology, systems, processes, people and culture all needed to be re-evaluated through a "new lens"
- The presentation will cover this journey including approach, successes, lessons learned and what's next

Lou Schmukler
EVP and President,
Global Product Development & Supply
Bristol-Myers Squibb

9:35 - 10:05 am

COVID-19 MAbs at Pandemic Speed, Volumes and COGs

- Vir Biotech has discovered a neutralizing COVID-19 mAb to a unique, highly conserved Coronavirus spike sequence, high barrier to resistance and effector function
- We have partnered with numerous CDMOs and GSK to move from discovery to the clinic in approximately 6 months
- World-wide pandemic requirements for an efficacious neutralizing mAb may exceed 20 metric tons – challenging the capacity of industry manufacturing infrastructure

Michael Kamarck
Chief Technology Officer
Vir Biotechnology

ROOM 1 CHAIR

Pat Yang
Chairman at ***Acepodia***
& Founding Board Director
at ***Sana Biotechnology***

Alison Moore
Chief Technology Officer
Allogene Therapeutics

ROOM 2 CHAIR

ROOM 3 CHAIR

Mucahit Agirtmis
Manager of MES
Solutions for Cell
and Gene Therapy
Körber Pharma Software

10:10 - 10:40 am

BREAKOUT ROOM 1
STRATEGIC MANUFACTURING

A Bio-Manufacturing Transformation – Meeting the Needs of Patients and an Evolving Pipeline

- Discussing the challenge of supplying large patient populations: What makes sense now, and what does the future hold?
- How are cell-line improvements, fed-batch cell culture technology, and high-performance purification allowing our industry to increase output?
- Creating modular, scalable production facilities that will give our organizations the capacity to respond to changing global demand
- Illustrating the combination of process, plant, and operations using Sanofi's global facilities as a case study

Brendan O'Callaghan
SVP & Global Head
of Specialty Care IA
Sanofi

10:10 - 10:40 am

BREAKOUT ROOM 2
QUALITY

Building Quality into Development

- Establish key values and cultural philosophies as the foundation for building Quality into development
  - Proactively collaborate with other functional lines to establish respect and transparency
  - Make risk-based decisions rooted in scientific merit
  - Change the perception: Quality and innovation are NOT mutually exclusive
  - Put patients first through integrity, trust, and accountability
- Create roles and tools which help perpetuate those values and philosophies
  - Quality Product Lead role
  - Efficient team structures and clear expectations
  - Knowledge management tools
  - Change management structure

Shannon Holmes
Director, Product Development Quality
Biogen

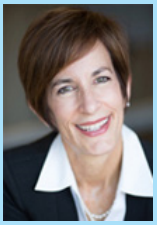
10:10 - 10:40 am

BREAKOUT ROOM 3
CELL & GENE THERAPY

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



Charlene Banard
Global Head of Technical Operations for Cell & Gene Therapy
Novartis

10:40 - 11:55 am

Pre-Arranged One-to-One Meetings

10:45 am – 11:05 am: Meeting Slot 1/Networking
11:10 am – 11:30 am: Meeting Slot 2/Networking
11:35 am – 11:55 am: Meeting Slot 3/Networking

12:00 - 12:30 pm

WORKSHOP
BREAKOUT ROOM 1

Building a Resilient Supply Chain and Robust Manufacturing Platform to Accelerate Cell and Gene Therapy Commercialization

- The downside to the strong growth in cell and gene therapies has intensified the need for viable, compliant solutions that can scale quickly to meet future needs
- In a recent BioPlan survey, over 50 percent of manufacturers expect to experience moderate to severe commercial scale capacity constraints over the next five years
- Regulatory complaint components of several cell and gene therapies are in limited supply and the gap will only widen as additional innovative therapies that rely on these components are approved
- We will discuss the unique needs of this evolving market and introduce our approach to manufacturing strategy that offers the flexibility and scalability needed to drive novel treatments to commercialization

AKRONBIOTECH

Ezequiel Zylberberg
VP of Product Development
Akron Biotechnology

cytiva

12:00 - 12:30 pm

WORKSHOP
BREAKOUT ROOM 2

Disrupting Quality Standards (or Beliefs) Through Digitalization

- The current state of digital transformation in life science
- How to disrupt the quality standards: Digital transformation roadmap and the situation ongoing at SBL
- Digital transformation's Value proposition: Improve quality, productivity, and for unparalleled client experience
- Samsung Biologics' P4 plan and vision: We're building the future

SAMSUNG BIOLOGICS

Sam MacHour
SVP & Chief Quality Officer
Samsung Biologics

George Siu
Part Leader
Samsung Biologics

12:00 - 12:30 pm

WORKSHOP
BREAKOUT ROOM 3

Transport Simulation Testing of Your Therapy: A Better Approach Than "Real World" Shipping Tests

- Accelerated, sequential testing (e.g., ASTM, ISTA) is no longer acceptable by the FDA for drug product testing
- Real-world testing cannot test the "worst-case" edges of your operating space
- Real-world testing in the post-COVID-19 world will be difficult and expensive

Gary Hutchinson
President
Modality Solutions

Dan Littlefield
Principal
Modality Solutions

MODALITY solutions™

12:30 - 1:30 pm

Lunch Break / Open Networking

1:30 - 2:00 pm

BREAKOUT ROOM 1
STRATEGIC MANUFACTURING

'Next' Generation Manufacturing: What Did We Learn and Where Are We Going?

- Discuss how today's pipeline and technologies are reshaping biomanufacturing
- Looking at the technologies that enable next generation manufacturing processes
- Review case studies and strategies for rapid manufacturing scale up for leading products
- Focus on the necessity of investing in people and robust strategies to support the workforce and culture
- Show opportunities that allow for successful navigation in the future of manufacturing, including leveraging legacy and culture as drivers of change

AMGEN

Arleen Paulino
SVP Global Manufacturing
Amgen

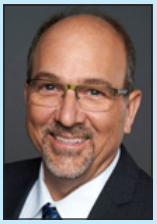
1:30 - 2:00 pm

BREAKOUT ROOM 2
QUALITY

Focused on the Cure: Leadership in Cell Therapy

- Extending our leadership in hematologic malignancies
- Advancing the frontier of cell therapy in solid tumors
- Enabling access and ensuring quality
- Leveraging the best technologies, research and operational drug development advances to accelerate a pipeline of disruptive platforms

Kite
A GILEAD Company



Prentice Curry
SVP, Quality and Compliance
Kite, A Gilead Company

1:30 - 2:00 pm

BREAKOUT ROOM 3
CELL & GENE THERAPY

CMC Complexities and Opportunities in Cell and Gene Therapy

- Discussing the unique technical, clinical, and manufacturing challenges involved in live modality therapies
- Seeking ways to reduce costs and improve patient access
- Learning from the experience of early adaptors and pioneers in the space
- Discussing the evolving FDA guidelines on live modality therapies: Can the industry do more to contribute to the future of our regulatory environment?

bluebirdbio

Susan Abu-Absi
SVP, Pharmaceutical Development & Technology
bluebird bio

2:05 - 2:35 pm

WORKSHOP
BREAKOUT ROOM 1

Group Therapy Session: How to Achieve Your Digital Vision in Biomanufacturing

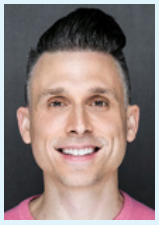
It's time to speak openly about the "ups and downs" of trying to roll out an industry 4.0 vision in large biopharma while ensuring the vision aligns to business outcomes. In this session, our speakers will unpack all the challenges and opportunities that come with operationalizing a digital vision in biomanufacturing.

The panel discussion will highlight Accenture's recent research on digital maturity in manufacturing operations across industries and focus on three key questions:

- How mature are manufacturers' digital operations capabilities?
- What are the associated investment requirements and expected return?
- What change and enablers are needed to successfully transform?

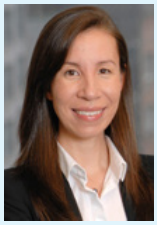
Hear from leaders on the front lines of achieving their industry 4.0 vision in large biopharma and ensuring that it aligns to business outcomes

Bristol Myers Squibb™



Derrick Fournier
Executive Director, Global Product Development and Supply Business Insights and Analytics
Bristol-Myers Squibb

accenture



Anne Marie O'Halloran
Supply Chain Global Lead-Life Sciences
Accenture

accenture

Barry Heavey
Life Sciences Industry X.0 Lead – Ireland
Accenture

2:05 - 2:35 pm

WORKSHOP
BREAKOUT ROOM 2

Improving Your Quality Systems with an Organizational Maturity Model

- What is OMM?
- Common obstacles that prevent organizations from having an OMM in place
- Why is it important to measure current organizational processes?
- Benefits of creating an OMM

PROPHARMA GROUP®

Eric Good
Director, Compliance
ProPharma Group

2:05 - 2:35 pm

Leveraging Manufacturing IT Systems to Boost Productivity, Scalability and Compliance in Autologous T-Cell Therapy

- Digital Solutions to Autologous Cell Therapy Manufacturing Challenges

WORKSHOP
BREAKOUT ROOM 3

Adaptimmune

John Lunger
Chief Patient Supply Officer
Adaptimmune

KÖRBER

Zinaid Dzinovic
Director Principal Consulting & Client Advisory
Körber Pharma Software

2:35 - 3:50 pm

Pre-Arranged One-to-One Meetings

2:40 pm – 3:00 pm: Meeting Slot 4/Networking
3:05 pm – 3:25 pm: Meeting Slot 5/Networking
3:30 pm – 3:50 pm: Meeting Slot 6/Networking

3:20 - 3:50 pm

Interactive Think Tanks

What Operations Performance Improvements Can We Take Forward to the Future Following Our Experiences Maintaining Supply During the COVID Pandemic?

How do we Create Strong Succession Plans for CMC/Tech Ops Leadership?

3:55 - 4:25 pm

Inter-Company Collaborations During the COVID-19 Pandemic — Thoughts About How We Work Better Together in the Future

Session details to be announced.

moderna™
messenger therapeutics

Juan Andres
Chief Technical Operations and Quality Officer
Moderna

4:25 - 4:35 pm

Co-Chairs' Closing Address

Acepodia

Sana Biotechnology

Pat Yang
Chairman at ***Acepodia***
& Founding Board Director at ***Sana Biotechnology***

Allogene THERAPEUTICS

Alison Moore
Chief Technology Officer
Allogene Therapeutics

NOVEMBER 17, 2020

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Alison Moore
Chief Technology Officer
Allogene Therapeutics

9:00 - 9:30 am

Fighting COVID-19 with Innovation – A Race Against Time

Session details to be announced.

Pam Cheng
EVP, President
Global Operations & IT
AstraZeneca

9:35 - 10:05 am

Accelerating Delivery of New Medicines

- Examining technologies, tools, and platforms to accelerate the pace of biopharmaceutical development
- How development velocity can affect clinical development and what we learn in this process
- Examining how acceleration impacts our quality, regulatory, and development functions. How do we all keep pace?
- Understanding how acceleration affects data monitoring and analytics throughout the product lifecycle
- Discussing what steps we as an industry will need to take together to make this the new normal

John Pinion
EVP Translational Sciences,
Chief Quality Operations Officer
Ultragenyx Pharmaceutical

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at ***Sana Biotechnology***

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Mucahit Agirtmis
Manager of MES
Solutions for Cell
and Gene Therapy
Körber Pharma Software

10:10 - 10:40 am

Reimagining Manufacturing Process Control For Cell and Gene Therapy; New Frontier in Personalized Medicines

BREAKOUT ROOM 1
STRATEGIC MANUFACTURING

- Describe what is unique about autologous CAR T manufacturing compared to Biologics and the implications of these differences to CMC
- Understanding patient material variability as a key consideration that guides manufacturing control strategy
- Describe innovative approaches to mitigate incoming patient material variability including adaptive manufacturing approaches based on differentiation state of cells.
- Describe the multiple complimentary levers (managing incoming variability, control strategy levers, validation and CPV and precision dosing)
- Lastly highlight the framework to monitor residual risk after integrating all of the control strategy elements

Bristol Myers Squibb™

Shishir Gadam
VP Cell Therapy Manufacturing Science and Technology
Bristol-Myers Squibb

10:10 - 10:40 am

SaudiVax Adapts During A Global Pandemic with a New Business Continuity Approach

BREAKOUT ROOM 2
QUALITY

- Global travel restrictions during the SARS COVID 19 pandemic have strained the ability of construction companies and equipment suppliers to meet our business plans
- SaudiVax will manufacturer monoclonal antibody therapies to combat infectious diseases and has firm plans for capacity expansion. To ensure quality, SaudiVax requires factory acceptance testing of the equipment from various vendors. Travel restrictions posed a threat to our ability to test and qualify the instruments and materials that had been purchased for our expansion
- As the digital connection network has proven to be essential during this pandemic, we sought a method to address our business continuity needs and effectively conduct remote factory acceptance testing

SVAX
Where Healthy Begins

Professor Mazen Hassanian
Managing Director
SaudiVax

10:10 - 10:40 am

From the Clinic to the Patient: Commercializing a First in Kind Allogeneic Stem Cell Therapy

BREAKOUT ROOM 2
CELL & GENE THERAPY

- Discussing the manufacturing, supply chain and operational challenges involved in developing novel therapies
- Comparing and contrasting these issues to traditional biologics, vaccines and cell therapies
- How can manufacturers leverage Industry 4.0 solutions to deliver innovative medicines to patients
- Offering real-world working examples of a rollout of these new tools and practices
- Discussing Takeda's journey to take Alofisel from development to market as a novel therapy

Takeda

Eric Hahn
SVP, Head Biologics Operating Unit
Takeda

10:40 - 11:55 am

Pre-Arranged One-to-One Meetings

10:45 am – 11:05 am: Meeting Slot 7/Networking
11:10 am – 11:30 am: Meeting Slot 8/Networking
11:35 am – 11:55 am: Meeting Slot 9/Networking

10:45 - 11:15 am **Interactive Think Tanks**

Considerations for Post Phase 1 Timing of New Technology Deployment: Pre-BLA or Post BLA?

What Strategies can be Used to Try to Stay Ahead of CMC Activities when Approaching BLA in Cell and Gene Therapy?

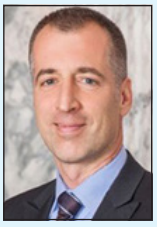
12:00 - 12:30 pm

WORKSHOP
BREAKOUT ROOM 1

The World has Changed: How to Adjust Your Leadership and Talent Strategy During an Unforeseen Crisis

- What impact is the pandemic having on Biotech company's end-to-end supply chains?
- How have organization's talent strategy changed and adapted in this context?
- Leading through a crisis: a "stop, start, continue" analysis of your leadership framework

Russell Reynolds ASSOCIATES



Pascal Bécotte
Co-Leader, Corporate Officers Sector (Global Functions) & Global Leader, Operations & Supply Chain Practice
Russell Reynolds Associates

12:00 - 12:30 pm

WORKSHOP
BREAKOUT ROOM 2

Industry 4.0 and The Total Cost of Quality: The Bi-Modal Challenge Facing Our Industry Today

- Meeting the needs and sophistication of today's life science industry
- Managing the opposing dynamics of lowering costs whilst enabling innovation
- Gaining key insight for your organization that will deliver the superior performance your patients are relying on
- Embracing digital transformation to ensure product quality, safety, efficacy, continuity of supply and compliance

Sparta Systems

Stephen McCarthy
VP, Digital Innovation
Sparta Systems

12:00 - 12:30 pm

WORKSHOP
BREAKOUT ROOM 3

Practical Implementation of Innovative and Scalable Technologies to Accelerate Biologics Development and Commercialization: A CDMO Perspective

- Challenges associated with development and scale-up of therapeutic (mAbs, recombinant proteins) and regenerative (gene and gene-modified cell therapy) biologics
- How new and innovative technologies such as Thermo Fisher's 5K DynaDrive bioreactor, cross divisional collaboration centers, and best in class manufacturing capabilities can help alleviate those challenges

ThermoFisher SCIENTIFIC

Paul Jorjorian
VP & General Manager, Biologics
Thermo Fisher Scientific

12:30 - 1:30 pm

Lunch Break / Open Networking

1:30 - 2:00 pm

BREAKOUT ROOM 1
STRATEGIC MANUFACTURING

Paving the Way for Successful Industrialization of Cell and Gene Therapies

- Cell & Gene Therapies promise to revolutionize medicine and may enable curative approaches for hard to treat diseases
- Limitations in first generation technology, CMC capabilities and capacities are bottlenecks in bringing those products to patients on a global scale
- Bayer's approach is to apply open innovation and external partnering in discovery & product innovation, while leveraging our core strengths in advanced manufacturing of difficult to make biologics
- Successful industrialization requires vision, leadership, diverse talent, the right organizational set-up and the right culture.
- Examples of Bayer's technological approaches, including process integration, intensification, automation and digitalization will be shown that will form the basis for creating our next generation cell and gene manufacturing platforms

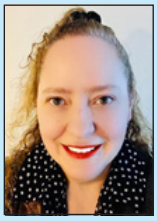
Jens Vogel
SVP & Global Head of Biotech
Bayer Pharmaceuticals

1:30 - 2:00 pm

BREAKOUT ROOM 2
QUALITY

Developing a World-Class Quality Management and Compliance System

- **Quality System:** Developing a quality system infrastructure to ensure compliance
- **Quality & Compliance Focus:** Ensuring a strong quality and compliance focus with CMOs, partners and suppliers
- **Audits:** Navigating the challenges of auditing CMOs during a pandemic
- **Quality Mindset:** Placing quality and compliance as the core strength of your organization and the industry



Kim Burson
Head of Quality Assurance and Quality Control
Denali Therapeutics

1:30 - 2:00 pm

BREAKOUT ROOM 3
CELL & GENE THERAPY

Challenges and Opportunities in Analytical Development for Cell and Gene Therapies

- With no standardized methods in analytical development of cell and gene therapies, we must define our own best practices
- Looking back: with the evolution and industrialization of analytical development in biologics over the past 20 years: what did we learn, how can we leverage it?
- Looking forward: with the speed of evolution of the field, high cost of analytical development, and need for greater efficiency begs the question: where do we need to be and how do we get there?

Stacey Ma
EVP Technical Operations
Sana Biotechnology

2:05 - 2:35 pm

Panel: Looking at the Big Picture: Where is Our Industry Going, and How Should We Get There?

- Debating the merits of nimble and flexible facilities versus manufacturing battleships
- Preparing your pilot plants and manufacturing facilities to move forward with Phase II-III approvals
- Forecasting requirements for optimizing manufacturing equipment, facilities and partners to increase speed to market
- Achieving business goals to better manage times of product and economic uncertainty
- Putting theory into practice: Implementing key metrics to improve manufacturing flexibility

Derek Adams
Chief Technology and Manufacturing Officer
bluebird bio

Greg Russotti
Chief Technology Officer
Century Therapeutics

Jerry Cacia
SVP, Head Global Technical Development
Genentech

2:40 - 3:10 pm

New Therapeutic Modalities and Moore's Law in Biopharmaceutical Manufacturing

- Why new therapeutic modalities? We are going up the central dogma of molecular biology
- What are some of the unique challenges and opportunities in commercializing new modalities?
- Offering lessons learned from the first generation of new therapies. How will their example inform what we can expect? What can we learn from the semiconductor industry?
- Moore's Law in action for biomanufacturing

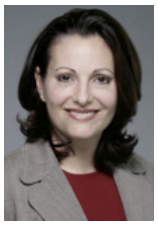
Hari Pujar
Operating Partner
Flagship Pioneering

3:15 - 3:45 pm

Panel: The Past, Present and Future of the Global Bio-Pharma Supply Chain

- How our "new normal" is affecting our critical materials procurement and how do we adapt for the future?
- Examining how the proposed nationalization of our supply chains will affect risk management and operations planning
- What does post-COVID19 Supply Chain robustness look like?
- How do novel modalities (mRNA, Cell & Gene Therapy) with already existing supply chain challenges cope with these new global constraints?
  - How will high volume ultra cold chain products affect existing specialized ultra cold chain logistics?
- Seismic shifts and emerging fault lines create lasting affects, what are they and how do they shape our industry in the years to come?

Craig Kennedy
SVP Global Supply Chain Management
Merck



LeAnn Pipkins
VP Global Supply Chain
Gilead Sciences

Stephen Hardt
VP, Supply Chain and External Manufacturing
Allogene Therapeutics

Som Chattopadhyay
VP Global Supply Chain
Amgen

3:45 - 3:55 pm **Co-Chairs' Closing Address**

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