MONDAY, SEPTEMBER 23 – **PRE-CONFERENCE WORKSHOPS**

8:00 **Continental Breakfast**

8:45

WORKSHOP A: A Blueprint for Success — The Role of Medical Affairs in Ensuring a Successful Product Launch

Across the core launch phases, medical affairs teams play a critical role in preparing the market for a successful product launch. Developing a compliant, strategic launch plan through high-impact scientific activities that harmonize all levels of your medical and commercial groups is crucial for a successful product launch.

- Learn how early commercial and new product planning teams determine the needs of the marketplace, lay the foundation, and develop the marketing plans ahead of a launch
- Determine how to build a value proposition for different types of drugs in particular spaces
- Understand how medical affairs manages the drug development hand-off from the clinical research team
- Examine best practices for managing key pre-launch activities in anticipation of market introduction
- Discuss the role of field medical in identifying key thought leaders, understanding their awareness, and developing a plan of action to educate and engage these key stakeholders

Matthew D. Bryant, Pharm.D., *Deputy Director, Data Generation and Observational Studies,* **BAYER**

Tony Russell, *Senior Director, Product Strategy and Commercial Planning,* **THERAVANCE BIOPHARMA**

**This session contains a 30-minute networking break*

WORKSHOP B: Ensure Compliant Communications During Scientific Exchange and Off-Label Data Dissemination

Regulatory bodies recognize the value of truthful and non-misleading scientific or medical publications on unapproved new uses of a product. However, the major challenges with off-label communications are being able to provide accurate scientific data and protecting the patient, all while extending the market for a particular product.

- Explore the distinction between solicited and unsolicited queries and discuss regulatory expectations for medical affairs teams
- Clarify how to provide scientific research and medical findings that are clearly non-promotional
- Develop tools and techniques to provide ethical, accurate and balanced off-label data while adding patient value in a compliant manner

**This session contains a 30-minute networking break*

11:45 **Workshop A Concludes** | **Workshop B Concludes**

12:00 **Luncheon**

1:00

WORKSHOP C: In Pursuit of Evolving Medical Training — Blending Scientific Content With Communication Skills

In our dynamic industry, excellence in medical training can provide a competitive advantage for MSLs as they engage with health care practitioners. Developing a rigorous and engaging medical training plan enhances MSL performance, making the MSLs a true partner with providers. In this workshop, learn about different ways to engage your field team in scientific content and communication/presentation skills (and perhaps have a little fun during your medical training).

- Learn techniques to blend scientific content training with communication skills, including journal clubs, post-conference training, debates, and HCP engagement
- Discuss ways to onboard field team members and ensure field readiness
- Explore ways to prepare for a product launch and to ensure the MSLs are confident and capable of field excellence
- Challenge your communication skills with an activity to emphasize the importance of being able to communicate effectively

Shannon Colton, Ph.D., *Director, U.S. Medical Training,* **EMD SERONO**

**These sessions contains a 30-minute networking break*

WORKSHOP D: Establish an Integrated Approach to Managing Medical Information and Medical Communications to Leverage Insights and Deliver Value to Patients

In the age of empowered consumers, medical affairs groups can play a central role in informing data needs and ensuring the delivery of relevant medical information and impactful communications that address the needs of patients.

- Cultivate synergies in scientific communications and medical information services to provide useful resources to patients and healthcare professionals
- Centralize scientific content creation for improved quality, speed, and reduced cost
- Identify the need for resource development and align communication resources across field and internal medical affairs

**This sessions contains a 30-minute networking break*

4:00 **Workshop C Concludes** | **Workshop D Concludes**

TUESDAY, SEPTEMBER 24, 2019 | **MAIN CONFERENCE, DAY ONE**

7:30 **Main Conference Registration and Continental Breakfast**

8:30 **Chairperson's Opening Remarks**

8:45 **Interpret FDA Guidance: How the Agency May Use Data to Support Regulatory Decision-Making**

- Consider opportunities and challenges for generating industry-wide standards
- Improve value communication and promotional activities by adopting a real-world evidence-based communication strategy that is supported by a regulatory framework
- Learn how to face real-world evidence challenges through an operational and regulatory perspective

Nneka Onwudiwe, Pharm.D., Ph.D., MBA, *Founder and Chief Executive Officer,* **PHARMACOECONOMICS CONSULTANTS OF AMERICA (PECA) LLC**

9:30 **Panel: Explore the Evolving Regulatory and Payer Landscape and the Use and Acceptance of Real-World Evidence for Product Approval**

- Gain an understanding of regulatory and payer expectations and requirements for RWE
- Consider how to conduct clinical trials that show value and generate enough evidence to back them up
- Highlight new ways of real-world data generation (digital technology, machine learning, etc.)

Jefferson Tea, *Vice President, Medical and Scientific Affairs,* **TAKEDA PHARMACEUTICALS**

10:15 **Leverage Online Discussion Platforms for Optimal Stakeholder Engagement**

- Identify the logistical and resource barriers to domestic and global stakeholder engagement
- Learn about innovative communication solutions that leading organizations utilize to overcome these challenges
- Discuss how to use these solutions to deliver improved engagement outcomes while maintaining regulatory compliance

Michael Kirby, *Vice President, Business Partnerships,* **WITHIN3**

10:45 **Networking Break**

MEDICAL AFFAIRS EXECUTIVE STRATEGY

11:30 **Track Chair Opening Remarks**

11:45 **A Framework to Help Take Your Organization From Data Collection to Insights**
- Understand the framework behind insights collection: From national security to understanding what your teenagers are really up to
- Develop insight collection tactics to match your organization's needs
- Hear how to turn data into actionable Insights

Blake Mobley, Ph.D., *Chief Information Officer,* **SAMUMED**
Mirta Grifman, Ph.D., *Senior Director, Medical Affairs,* **SAMUMED**

12:30 **Luncheon**

1:30 **The Benefits of Early Medical Affairs Involvement in Clinical Trials to Identify Protocol Challanges and Drive Patient Recruitment**
- Explore the formation of a new medical affairs function called Investigator Science Liaisons (ISLs) that focuses on deep scientific communication with investigators early on during clinical trials
- Bring scientific expertise regarding current treatment practice, profile physician practices, needs and preferences
- Identify protocol challenges by delivering real-time insights from the investigators and improve under-recruitment and site selection
- Understand the advantages of early engagement with leading experts to develop honest and transparent relationships and keep physician's interest in future collaborations

Natalia Denisova, *Vice President, Head of Medical Affairs,* **MPHAR**

2:15 **The Key Elements of Building a Real-World Evidence (RWE) Generation Group**
- Review what RWE and observational studies are and examine the different categories under this umbrella
- Understand what real clinical effectiveness is in the real world and what real impact is on patients and the healthcare system outside of a clinical setting
- Hear how to determine evidence gaps from a clinical and market access perspective, and bridge these gaps with what payers are expecting
- Build a best-in-class field medical team that can be well versed real-world data and evidence and understand the value proposition for payers

Jefferson Tea, *Vice President, Medical and Scientific Affairs,* **TAKEDA PHARMACEUTICALS**

3:00 **Networking Break**

3:30 **Establish the Value of Medical Affairs to Ensure Proactive Collaboration and Alignment With Functional Partners**
- Discuss how to bridge the gap when working a highly matrixed organization between preclinical, clinical operations, and medical affairs
- Develop a culture of collaboration with open communications within cross-functional teams to allow for efficient channel management and rapid bidirectional information flow
- Consider the types of personality traits that can be beneficial when building out a new team
- Explore how to proactively manage your team's career and continue their development

Johan Baeck, *Vice President, Clinical Development and Medical Affairs,* **JOUNCE THERAPEUTICS**

4:15 **Prioritize Investigator-Initiated Research to Inform Your Organization's Development Strategy and Generate Evidence for Registration Trials**
- Discuss the importance of investigator-initiated trials in a product's lifecycle strategy, while remaining compliant with regulatory requirements
- Understand how investigator-initiated research can identify new areas of treatment and help inform your development organization on target areas they should be focusing clinical trials
- Hear case examples of IITs providing key data and the shortest path for registration

Jose Ricardo Perez, *Executive Medical Director,* **EXELIXIS**

5:00 **Cocktail Reception**

6:00 **Day One Concludes**

MSL BEST PRACTICES

Track Chair Opening Remarks

Medical Affairs and Patient Advocacy – Where Do They Meet?
- Gain an overview of the overall global strategy to roll out patient-centric programs
- Identify opportunities to partner with patient advocacy groups and determine who is the best partner for your company
- Leverage these partnerships to understand what is best for the patient and don't miss the opportunity to measure endpoints and outcomes important to key external stakeholders
- Work with compliance partners to create innovative, patient-centric programs
- Measure the performance and success of patient centricity

Heather S. Ambrose, *Director, Acute Care Field Medical and Patient Advocacy,* **BTG INTERNATIONAL**

Panel: Intersection of Medical Affairs and Patient Advocacy
- Explore the overlap between medical affairs and patient advocacy at various companies
- Understand how field medical can drive partnerships with patient advocacy
- Discuss how field medical is uniquely positioned to create multi-stakeholder value

Sagar Shah, Pharm.D., *Senior Director and Head, Field Medical Affairs,* **AKCEA THERAPEUTICS**
Carol Hoang, Pharm.D., MBA, *Vice President, Medical Affairs,* **ADVERUM BIOTECHNOLOGIES**

Launch Excellence: Preparing a Field Medical Team for an Upcoming Launch — Label Training and Certification
- Describe a training plan that addresses both scientific content and communication skills to prepare a field team for launch
- Review a process for evaluating field team members to ensure launch readiness and to identify areas of development
- Highlight the importance of establishing a culture of trust and learning to enable support from leadership and the medical affairs team

Shannon Colton, Ph.D., *Director, U.S. Medical Training,* **EMD SERONO**

Effective Management of Field-Based and Remote Personnel: Fundamentals and Nuance
- Build a culture of trust from afar with transparent communications and reminding teams of shared purpose and goals
- Track and manage accountability, productivity, and priorities for your team across different geographies
- Give teams a sense of "shared competence" and encourage them to utilize each other as resources

Kate Pietrovito, *Senior Director, Medical Affairs Operations, Biocompatibles,* **BTG**

Panel: Remote Leadership Challenges — Creating Field Team Harmonization
- Identify barriers to creating a high-performing field team
- Address common challenges faced by field medical leaders when managing remote teams
- Discuss innovative approaches to measuring the value of your remote personnel

Sagar Shah, Pharm.D., *Senior Director and Head, Field Medical Affairs,* **AKCEA THERAPEUTICS**
Kate Pietrovito, *Senior Director, Medical Affairs Operations, Biocompatibles,* **BTG**

	MEDICAL AFFAIRS EXECUTIVE STRATEGY	MSL BEST PRACTICES
8:30	**Continental Breakfast**	
9:15	**Track Chair Recap of Day One**	**Track Chair Recap of Day One**
9:30	**Fit-to-Purpose: Establishing Medical Affairs in a Start-up Environment** → Discuss key considerations when designing and growing a medical affairs organization in a small-company environment → Compare and contrast medical affairs responsibilities in a small-company or start-up environment vs. larger or more established organizations → Delineate emerging roles of medical affairs in the rare disease space, with a focus on gene and cell therapy **Leslie Meltzer, Ph.D.,** *Vice President, Medical Affairs,* ORCHARD THERAPEUTICS	**Streamline Efficiencies and Improve Techniques to Build and Run Advisory Boards** → Learn how to manage your brand by prioritizing markets and considering their similarities and differences → Discuss key areas of strategic planning necessary to make decisions on the scope and reach of your advisory boards → Explore the tactical implementation of advisory board management before, during and after each meeting → Review the involvement of key internal and external decision makers necessary to optimize the advisory board **Scott McConnell, Pharm.D.,** *Scientific Affairs Consultant,* KALEIDO BIOSCIENCES
10:45	**Key Questions to Ask and Common Pitfalls/Blindspots to Avoid When Developing a Medical Plan** → Explore the needs of the organization and when to build certain functions based on where you are in your life cycle → Hear how to coordinate across functional areas to avoid misalignment and confusing strategies with tactics → Ensure accountability and built-in temperature checks to monitor progress and/or course-correct when necessary **Jodi Smith, Ph.D.,** *Medical Director,* EMD SERONO	**The Role of Medical Affairs in the Digital Evolution of Medicine** → Consider the current healthcare landscape and where we are headed → Discuss what role medical affairs groups should play → Review examples of what has and has not worked → Understand what's necessary to be successful with digital projects **Roy Palmer, Ph.D.,** *Global Medical Innovation and Effectiveness Lead,* PFIZER
11:00	**Networking Break**	
11:30	**Optimize your Communication Model With Regional Affiliates to Leverage Existing Resources During Launches** → Review a case example of leveraging an existing franchise to launch a new product in a rare disease space → Have the affiliates play a bigger role and co-develop materials to achieve a resource-minimal launch → Learn from past launches to create a streamlined model for preparing for market introduction **Cristina Costantino, Ph.D., MBA,** *Senior Global Scientific Director,* GENENTECH	**Implement and Utilize KPIs and Metrics to Demonstrate the Value of Field Medical** → Consider the actual value of KOL/thought leader interactions in different settings (congresses vs. offsite meetings, etc.) → Determine which interaction and activity provides more quality and leads to stronger relationships → Explore how to incorporate measures indicative of the quality of an activity, especially those that result in actions from KOLs **Matthew J. Maneen, Ph.D.,** *Senior Director and Head of U.S. Field Medical,* AVANIR PHARMACEUTICALS
12:15	**Luncheon**	
1:15	**Best Practices for Managing Medical Affairs Activities When Collaborating With Alliance Partners** → Examine the various motivations that drive strategic collaborations and partnerships between companies in today's healthcare environment → Consider the potential cultural differences that may exist between biotechs and big pharma or U.S. and ex-U.S. companies and how to ensure a successful partnership → Understand the importance of establishing a model to manage medical affairs when working with a strategic partner → Mitigate the risks of opening new regions and territories in partnerships or out-licensing scenarios **Diana Stefani-Hunyady, M.D., MBA, BCMAS**	**PANEL: The Establishment of Internal Firewalls to Avoid Compliance Violations Between Commercial and Medical Affairs Teams** → Assess why compliance and overregulation are concerning issues for medical affairs leadership, as evidenced by recent surveys → Discuss the use of firewalls and the challenges they present for MSLs and sales teams in their communication with therapeutic area experts → Determine how intense a firewall should be to allow for efficient communication while simultaneously maintaining compliance **Scott McConnell, Pharm.D.,** *Scientific Affairs Consultant,* KALEIDO BIOSCIENCES **Ross Goldstein,** *Director, Medical Affairs,* RETROPHIN
2:00	**Track Chair Closing Remarks**	**Track Chair Closing Remarks**
2:15	**Conference Concludes**	