2nd Biosimilar Market Access and Commercialization Strategies Summit

Determine Effective Implementation Methods to Navigate Through Challenges and Sustain Success When Bringing Biosimilars to Market

September 17-18, 2018
Revere Hotel Boston Common | Boston, MA

FEATURED SPEAKERS

Jay Brown, *Sr. Director Outpatient Pharmacy Services,* **NOVANT HEALTH, INC**

Niraj Chhaya, *Risk Management, Biosimilars,* **BOEHRINGER INGELHEIM LIMITED**

Mona Chitre, *Vice President of Pharmacy,* **EXCELLUS BLUECROSS BLUESHIELD**

Christopher Colburn, *Executive Director, Payers & Trade,* **COHERUS BIOSCIENCES**

Ruediger Jankowsky, *Managing Director,* **CINFA BIOTECH**

Divya Chadha Manek, *Head, Business Development,* **NIHR**

Bruce Leicher, *Senior Vice President and General Counsel,* **MOMENTA PHARMACEUTICALS**

Top Reasons to Attend

- **DISCOVER** past, current and future regulatory standards to develop Biosimilars and bringing them to the market in an efficient manner at a low cost
- **EXPLORE** best practices for the commercial structure of a biosimilar from strategy to execution
- **INVESTIGATE** the primary disparities between biosimilar and comparability
- **MEASURE** the lack of interchangeability with the reference drugs
- **APPRECIATE** the significance in creating partnerships to successfully establish biosimilar products
- **EXPLORE** the challenges of obtaining patents to advance the biosimilar product at a quick rate and a low cost
- **JUSTIFY** success strategies from organizations such as Pfizer, Amgen, Boehringer Ingelheim, Mylan and more

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CHAIR

Re-Evaluate Your Marketing Strategies Based on Competition, Risk Analysis and Mitigation

- Pinpoint efficiencies in developmental costs and timelines
- Identify the importance of traceability and accuracy in biosimilar product development
- Combat the challenges associated with patient access

Nacer Hedroug, *Associate Director Validation and Tech Transfer,* **WOCKHARDT LTD.**

CASE STUDY: Overcoming the Global Challenges of Biosimilar Development

- Address global challenges associated with development and commercialization of a mid-size player
- Examine the advantages tailored clinical study design
- Recognize the importance of consistency of the biosimilar concept to reduce time and budget

Ruediger Jankowsky, *Managing Director,* **CINFA BIOTECH**

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2nd Biosimilar Market Access and Commercialization Strategies Summit

Determine Effective Implementation Methods to Navigate Through Challenges and Sustain Success When Bringing Biosimilars to Market

Dear Colleague,

With only a few biosimilar drugs currently on the market, there is a major opportunity to take advantage of accessing the marketplace ahead of your competition. There are many obstacles sponsor organizations need to take into account before development, accessing the marketplace, and achieving market success. The **2nd Biosimilar Market Access and Commercialization Strategies Summit** will uncover best practices in order to overcome these difficulties and improve ROI.

It is necessary to understand effective implementation strategies countries around the world that have had success when bringing biosimilars to market. As the development process continues to advance, it is critical to distinguish the major issues surrounding approval pathways to methodically access the marketplace at a reasonable price.

With the FDA playing a pivotal role in the approval process, you will have the opportunity to hear from industry experts to meet safety, purity, and potency standards in order to advance biosimilars into the marketplace. This will be a great opportunity to gain key insights to evaluate evolving regulations, analyze optimal pricing models, accelerate market access strategies, and execute strategic decisions to mitigate risk and build for commercial success. Also designated lunches and networking breaks will enhance the exchange of knowledge and foster future business partnerships.

I look forward to welcoming you to Boston this September!

Sincerely,

Michael Martinez

Michael Martinez | Conference Production Director
ExL Events, a division of Questex, LLC

VENUE INFORMATION

Revere Hotel Boston Common
200 Stuart St / Boston, MA 02116

To make reservations, please call 617-457-2683 and request the negotiated rate for **ExL's September Meetings**. You may also make reservations online using the following weblink:https://bit.ly/2H3wgAD. The group rate is available until **August 27, 2018**. Please book your room early, as rooms available at this rate are limited.

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WHO SHOULD ATTEND

This conference is designed for representatives from pharmaceutical, medical device and biotechnology companies with responsibilities in the following areas:

- Biosimilars
- Biologics/Biotechnology/Biogenerics
- Biopharmaceuticals/Biotherapeutics
- Market Access Commercialization
- Drug Safety and Risk Management
- Marketing and Sales
- Strategic/Corporate Planning
- Compliance/Regulatory
- Pricing and Reimbursement
- HEOR and Outcomes Research
- Legal Affairs
- Intellectual Property
- Medical Affairs
- Corporate Affairs
- Manufacturing/Bioprocesses
- Pharmacovigilance
- Clinical Affairs/Operations/Development Process
- Control and Analytical Technologies
- Regulatory Affairs
- Medical Science Liaisons
- R&D
- Quality Control/Assurance

This conference is also of interest to:

- CROs/CMOs/CMDOs
- Law Firms
- API Manufacturers
- Distributors
- Consulting Companies
- Market Access Service Providers
- Licensing Services
- Distribution and Logistics Services
- Packaging and Labeling Companies
- Preclinical/Nonclinical/Analytical Development Research Organizations

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Day One – **Monday, September 17, 2018**

8:00 Registration and Continental Breakfast

9:00 **Chairperson's Opening Remarks**

Nacer Hedroug, *Associate Director Validation and Tech Transfer,* **WOCKHARDT LTD.**

9:15 **Overcoming the Global Challenges of Biosimilar Development**

CASE STUDY

- Address global challenges associated with development and commercialization of a mid-size player
- Understand how to leverage market access through a strong local presence
- Examine the advantages of the crossover design and the two-stage design for clinical studies
- Recognize the importance of consistency of the biosimilar concept to reduce time and budget

Ruediger Jankowsky, *Managing Director,* **CINFA BIOTECH**

10:00 **Overview of a Preferred Strategic Approach When Bringing Biosimilars to Market**

- Identify specific factors when successfully accessing the marketplace
- Justify partnerships to overcome difficulties during implementation
- Determine the level of physician-provider success when dealing with patient uptake

Christopher Colburn, *Executive Director, Payers & Trade,* **COHERUS BIOSCIENCES**

Mona Chitre, *Vice President of Pharmacy,* **EXCELLUS BLUECROSS**

10:45 Networking Break

11:15 **The Role of Biosimilar Pharmacovigilance Regulations**

- Understand the different approaches between the EU and U.S.
- Explore how to best utilize immunogenicity, interchangeability, and traceability
- Appreciate the risk management approach to successfully implement an effective market strategy

Dr. Niraj Chhaya, *Risk Management, Biosimilars,* **BOEHRINGER INGELHEIM**

12:00 Luncheon

1:00 **Key Global Regulatory Considerations for Biosimilars**

- Recognize the impact regulatory challenges have in the pharmaceutical industry
- Review specific guidance documents for further justifications to access the market efficiently
- Outline the future of biosimilar regulations and how extrapolation and interchangeability will be measured

1:45 **Optimize Pricing Strategies to Gain a Better Market Position**

- Identify specific pricing strategies to compete at a high level and sustain market success
- Discuss price expectations to ensure sustainability and increase the efficiency of care delivery
- Gain insight into Europe's mandatory price cut and how they are limiting the market for biosimilars

Jay Brown, *Senior Director, Outpatient Pharmacy Support Services,* **NOVANT HEALTH**

2:30 Networking Break

3:00 **Manage Payer and Provider Considerations for Market Entry**

PANEL

- Evaluate specific opportunities to optimize market success through payer and provider collaboration
- Consider the economic factors for cost-effectiveness to create an improved understanding of biosimilars in clinical practice
- Enhance education and understanding surrounding reimbursement

Sarfaraz Niazi, *Adjunct Professor, Department of Biopharmaceutical Sciences,* **UNIVERSITY OF ILLINOIS AT CHICAGO, COLLEGE OF PHARMACY**

3:45 **Navigate the Patent Dance and Other Legal Hurdles to Successfully Progress Biosimilars to the Market**

- Recognize the regulatory pathway for biosimilar products entering the market
- Construct a strategic approach when maneuvering through the "patent dance"
- Determine the finest methodologies and ethical issues to prepare for litigation under BPCIA

Joanna Brougher, *Adjunct Professor,* **CORNELL LAW SCHOOL**

4:30 End of Day One

Day Two – **Tuesday, September 18, 2018**

8:00 Continental Breakfast

9:00 **Chairperson's Recap of Day One**

Nacer Hedroug, *Associate Director Validation and Tech Transfer,* **WOCKHARDT LTD.**

9:15 **The Interchangeability Guidance, Recent Developments and Options for Seeking Approval of Interchangeable Biologics**

- Overview of the FDA interchangeability guidance, its implementation, and impact other regulatory guidelines
- Discuss recent industry developments and activities
- Understand differences of the Biosimilar and Interchangeable Biologics Approval Pathway
- Consider implications of interchangeability on naming, reimbursement, and substitution

Bruce Leicher, *Sr. Vice President and General Counsel,* **MOMENTA PHARMACEUTICALS, INC.**

10:00 **Recognize Specific Obstacles to the Adoption of Biosimilars**

- Discuss the Biosimilar Paradox: Higher out-of-pocket costs for biosimilars versus branded Medicare Part D drugs
- Outline strategic methods to prepare for when the coverage gap closes in 2020
- Navigate through the Biosimilar Rebate Trap and how it has played out in 2018

Aaron Hakim, *Researcher,* **YALE UNIVERSITY SCHOOL OF MEDICINE**

10:45 Networking Break

11:15 **Initiate Biosimilar Medicine Trials in the NHS**

— CASE STUDY —

- Implement strategic solutions to unique challenges
- Adopt the network approach to site selection
- Increase clinical confidence through education

Divya Chadha Manek, *Head, Business Development,* **NIHR**

12:00 Luncheon

1:00 **Re-Evaluate Your Marketing Strategies Based on Competition, Risk Analysis and Mitigation**

- Pinpoint efficiencies in developmental costs and timelines
- Identify the importance of traceability and accuracy in biosimilar product development
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Nacer Hedroug, *Associate Director Validation and Tech Transfer,* **WOCKHARDT LTD.**

1:45 **Discuss the Challenges When Obtaining Approval and Sustaining Market Success**

- Outline the barriers related to biosimilar research and development for market entry
- Diversify your product and strategy to compete in a highly competitive market
- Consider certain developmental aspects in order to create a successful marketing strategy

Joseph P. Fuhr, Ph.D., *Adjunct Faculty College of Population Health and Professor Emeritus Economics,* **WIDENER UNIVERSITY**

2:30 **Summit Closing Remarks**

Nacer Hedroug, *Associate Director Validation and Tech Transfer,* **WOCKHARDT LTD.**

2:45 Summit Concludes

"Very rich knowledge sharing amongst audience and panelists."

—Director, **BRISTOL-MYERS SQUIBB**

"Exceeded my expectations through networking, quality sessions, and applicability to current work."

—Executive Director, **WINDTREE THERAPEUTICS**

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