



Biosimilar Market Access and Commercialization Strategies Summit

Date : Sep 18, 2017 - 12:30 PM - Sep 19, 03:30 PM

Event URL : <http://www.nyeeventslist.com/events/biosimilar-market-access-and-commercialization-strategies-summit-aug-2017>

Organizer : ExL Events

Venue : The Westin Boston Waterfront

Location : 425 Summer Street,
Boston, MA, US, ZIP: 02210

The FDA's approval of the first wave of biosimilars cleared the way for manufacturers to make lower-cost versions of expensive biologic drugs, saving patients money and improving access to important medications. There is a significant market opportunity ahead for biosimilar drugmakers; by 2020, leading biologic medicines worth more than \$80 billion global annual sales will lose their patent protections, and biosimilars is the largest area for potential growth in the biotech sector. But with great rewards, there are also great risks that must be considered. In contrast to Europe, this is still an uncharted territory for the US market, and barriers to market access are not as low as they seem to be. From FDA approval to pricing and marketing strategies, there are risks and financial uncertainties. Therefore, the industry needs to know how to best address those challenges and optimize the biosimilar launch process.

Whether you are exploring your chances of tapping into the competitive biosimilars marketplace or are an expert in the field, the Biosimilar Market Access and Commercialization Strategies Summit will provide detailed presentations, intensive case studies and collaborative panel discussions relevant to your interests. Our talented faculty will address everything from navigating evolving regulations, analyzing optimal pricing models, accelerating market access strategies, and executing strategic decisions to mitigate risk and build for commercial success. In addition, designated lunches and networking breaks will enhance the exchange of knowledge and foster future business partnerships.

Featured Speakers Include:



Bruce Leicher
Senior Vice President and
General Counsel
MOMENTA
PHARMACEUTICALS



Chrys Kokino
Head Global Biologics
Commercial
MYLAN



Rakesh Dixit
Vice President, R&D, Global
Head, Biologics Safety
Assessment
MEDIMMUNE,
ASTRAZENECA GROUP



Ambrose Carrejo, Pharm.D.
National Pharmaceutical
Contracting and Strategies
Leader
KAISER PERMANENTE



Ashish Dugar
Officer & Vice President,
Commercial Development
INTRA-CELLULAR
THERAPIES



Molly Burich
Associate Director Public
Policy
BOEHRINGER INGELHEIM

Top Five Reasons to Attend

1. Explore factors to consider before developing biosimilars — improve your chances on the road to approval and commercial success
2. Hear best practices and case studies for a successful biosimilar product strategy from its conception to execution
3. Stay up to date with FDA guidances and other regulatory guidelines and join the debate on nonproprietary naming of biological and biosimilar products
4. Navigate biosimilar policies, regulations and compliance issues under the new administration
5. Network with leaders in the industry and get tips on how to manage payer and provider considerations for market entry, engage with patients, and stay competitive

Who Should Attend

This conference is designed for biotech professionals responsible for:

- Biosimilars
- Biologics/Biotechnology/Biogenics
- Biopharmaceuticals/Biotherapeutics
- Market Access Commercialization
- Marketing and Sales
- Strategic/Corporate Planning
- Pricing and Reimbursement
- HEOR and Outcomes Research
- Legal Affairs
- Intellectual Property
- Medical Affairs
- Manufacturing/Bioprocesses
- Clinical Affairs/Operations/Development
- Regulatory Affairs
- Medical Science Liaisons
- R&D
- Quality Control/Assurance

This event is also of interest to:

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

Day One

Monday, September 18

PRE-CONFERENCE WORKSHOP

8:15AM – 9:00AM

[Registration and Continental Breakfast for Workshop Participants](#)

9:00AM – 12:00PM

[WORKSHOP: UNCOVER MARKET ACCESS OF BIOSIMILARS IN THE U.S. MARKET](#)

While the biosimilar market continues to develop, much remains unanswered to ensure the commercial success of biosimilars in the United States. It is essential for manufacturers and product innovators to understand the approval pathways and familiarize themselves with the major issues surrounding market access and evaluation of biosimilars.

This workshop will help stakeholders identify key issues related to the U.S. biosimilar landscape and review effective strategies for market access.

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Commercialization of Biosimilars: Navigating the Crossroads Between Business Development, Product Development, and Strategic Portfolio Management

- Analyze the issues, challenges and impacts of market access unknowns for biosimilars in the U.S. market
- Learn best practices for when to start/update market analysis for a new biosimilar program
- Implement data–driven rationale for biosimilar pipeline
- Discuss common pitfalls and realistic timelines in designing a biosimilar program

Pricing and Naming Considerations for Biosimilar Pipelines

- Review the topics to consider when developing biosimilar pricing strategies
- Examine the current dialog over biosimilar naming

Kristi Sarno, Senior Consultant, Latham BioPharm Group; Former Director Business Development, PFENEX, INC.

There will be a half–hour networking break at 10:00.

12:00PM – 12:30PM

[Luncheon for Workshop Participants](#)

MAIN CONFERENCE

12:30PM – 1:00PM

[Main Conference Registration](#)

1:00PM – 1:45PM

[Chairperson's Welcome And Opening Remarks](#)

John Coelho, Global Medical Strategy Leader, MERCK

1:45PM – 2:30PM

[KEYNOTE: UNCOVER EMERGING TRENDS AND THE FUTURE OF BIOSIMILAR DRUG MARKET IN THE UNITED STATES](#)

Chrys Kokino, Head Global Biologics Commercial, MYLAN

2:30PM – 3:15PM

[ANALYZE THE BIOSIMILARS PIPELINE AND THE U.S. MARKET EVOLUTION](#)

Ashish Dugar, Officer & Vice-President, Commercial Development, INTRA-CELLULAR THERAPIES

3:15PM – 3:45PM

[Networking Break](#)

3:45PM – 4:30PM

[PANEL: REVIEW REGULATORY STRATEGIES AND INTERACT EFFECTIVELY WITH THE FDA](#)

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

Jennifer Horonjeff, Founder, Savvy Cooperative; Officer, Patient-Centered Outcomes Research, Columbia University Medical Center; Member of the Arthritis Advisory Committee and Consumer Representative, FDA

4:30PM – 5:15PM

[Economics Impacts of Biosimilars](#)

Joseph P. Fuhr, Adjunct Faculty, THOMAS JEFFERSON UNIVERSITY COLLEGE OF POPULATION HEALTH; Professor Emeritus of Economics, Widener University

5:15PM –

[Day One - Closing Remarks](#)

Call our call center at the number below or email [marilyn.turner\(a\)nyeeventslist.com](mailto:marilyn.turner(a)nyeeventslist.com) for registrations or additional information about this event!

Day Two

Tuesday, September 19

8:15AM – 9:00AM

[Registration and Continental Breakfast](#)

9:00AM – 9:15AM

[Chairperson's Recap of Day One](#)

John Coelho, Global Medical Strategy Leader, MERCK

9:15AM – 10:00AM

[THE INTERCHANGEABILITY GUIDANCE AND THE OPPORTUNITY AND EFFICIENT APPROVAL OF INTERCHANGEABLE BIOLOGICS](#)

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

10:00AM – 10:45AM

[CASE STUDY: KAISER PERMANENTE'S BIOSIMILAR EXPERIENCE](#)

**Ambrose Carrejo, Pharm.D., National Pharmaceutical Contracting and Strategies Leader,
KAISER PERMANENTE**

10:45AM – 11:15AM

[Networking Break](#)

11:15AM – 12:00PM

[BENCHMARK COMPLEX FACTORS TO DECIDE BETWEEN BIOBETTER VERSUS
BIOSIMILAR DEVELOPMENT OPTIONS](#)

**Rakesh Dixit, Vice President, R&D, Global Head, Biologics Safety Assessment,
MEDIMMUNE, ASTRAZENECA GROUP**

12:00PM – 12:45PM

[REVIEW THE REGULATORY IMPACT OF BIOSIMILAR MARKET ENTRY: HOW GUIDANCE
AND LEGISLATION IMPACTS APPROACH TO MARKET ENTRY](#)

**Patrick Lucy, PFENEX Interim CEO, President and Secretary, and Chief Business Officer,
PFENEX**

12:45PM – 1:45PM

[Luncheon](#)

1:45PM – 2:30PM

[DISCUSS REIMBURSEMENT CONSIDERATIONS FOR BIOSIMILARS](#)

Molly Burich, Associate Director Public Policy, BOEHRINGER INGELHEIM

2:30PM – 3:15PM

[UNDERSTAND THE IMPORTANCE OF PATIENT-CENTERED RESEARCH IN BIOSIMILAR
DRUG DEVELOPMENT](#)

Jennifer Horonjeff, Founder, Savvy Cooperative; Officer, Patient-Centered Outcomes
Research, Columbia University Medical Center; Member of the Arthritis Advisory Committee and
Consumer Representative, FDA

3:15PM –

[Day Two – Summit Closing Remarks](#)

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Event Categories : BUSINESS & MANAGEMENT CONFERENCES,