
Join over 600 life science executives at the
CLINICAL BUSINESS EXPO
The Business of Biosimilars event is now the
BUSINESS OF BIOSIMILARS & BIOBETTERS
Discover Commercialization Opportunities in the US and Abroad through In-Depth Analysis of Scientific and Business Development Considerations
LEARN FROM 30+ INDUSTRY EXPERTS AS THEY SHARE THEIR INSIGHTS ON ISSUES THAT MATTER MOST
Understand the Regulatory and Legal Implications that may Affect your Biosimilar Profitability
Create Strategies to Ensure Commercialization Success
Leverage New Manufacturing Processes to Increase Profit
Delve into Scientific Considerations including Establishing Similarity, Defining Bioequalivance and Interchangeability and Assess Immunogenicity to Preserve Biosimilar Integrity
NEW FOR 2011
Lessons Learned from Regional Spotlights from around the World
Specialized Tracks for Development and Commercialization Considerations
4 Highly Focused Workshops
Roundtable Discussions on Global Harmonization
September 19-21, 2011 Seaport World Trade Center Boston, MA
www.biosimilarsevent.com

The Business of Biosimilars event is now the

Business of Biosimilars & Biobetters

Dear Colleague:

Biosimilars are expected to be one of the fastest growing industries around the world:

- The global biosimilar market is expected to grow from $243 million in 2010 to **$3.7 billion** in 2015 *(Datamonitor, 2011)*
- More than 30 branded **biologics worth $51 billion will lose patent exclusivity by 2015** *(Datamonitor, 2011)*
- **Biological pharmaceuticals are expected to grow** from 39% of global pharmaceutical sales in 2008 to 75% of global pharmaceutical sales in 2014
- Due to how costly ($100 million, on average) and lengthy (up to 8 years) it is to develop a biosimilar, **now is the time to invest in biosimilars and develop your business strategy**

This year, The Business of Biosimilars event is expanding to the **Business of Biosimilars and Biobetters** in order to better address the needs of our audience and reflect the changes in the biopharmaceutical industry. Due to the lack of regulatory guidance within the US and the ongoing debate about the anticipated value of commercializing biosimilars in the US and abroad, we have decided to expand the scope of our meeting to enable pharmaceutical and biotech companies to discover global biosimilar and biobetter commercialization opportunities through in depth analysis of scientific and business development considerations.

Now in its third year, the Business of Biosimilars and Biobetters event returns with a more global approach.

- Grow your profit potential by learning from industry experts on how they developed and commercialized biosimilars in the US, Europe and Asia
- Navigate legal and regulatory requirements in different countries to prepare you for biosimilar success around the world
- Compare and contrast market differences through regional-specific case studies to evaluate which countries offer you the best opportunities
- Learn advanced scientific strategies to streamline biosimilar and biobetter development through sessions focused on proving comparability, bioequivalence and interchangeability; preclinical and clinical testing, manufacturing methods and more

We are proud to bring you this leading event, and look forward to personally welcoming you in Boston.

Sincerely,

Sarah Gordon
Program Director, Biopharmaceutical & Healthcare Division
INSTITUTE FOR INTERNATIONAL RESEARCH

Danya Burakoff
Conference Director, Biopharmaceutical & Healthcare Division
INSTITUTE FOR INTERNATIONAL RESEARCH

CLINICAL BUSINESS EXPO

6 Events. 1 Exhibit Hall. Incomparable Networking Opportunities

This event is part of the Clinical Business Expo. IIR's Clinical Business Expo is the host location and home to 6 exclusive and successful conferences all related to clinical business to deliver the latest technical, operational and scientific approaches for clinical development including:

Special Thanks to our Distinguished Advisory Board

MARK BOWDITCH
Patent Attorney
Sandoz

GILLIAN CANNON
MBA, PhD
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BRIAN HARVEY
Vice President of Regulatory Affairs
Sanofi-Aventis

BRUCE LEICHER
Senior Vice President and General Counsel
Momenta Pharmaceuticals Inc.

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IP Director and Counsel
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SUZANNE M. SENSABAUGH
MS, MBA
Founder & Member
HartmannWillner LLC

GILLIAN WOOLLETT
MD
Chief Scientist
Engel & Novitt

Who You Will Meet

The audience will be comprised of CEOs, Presidents, Directors and Managers of **biotech and pharmaceutical** companies with titles in the following areas:

- Regulatory Affairs & Quality Assurance
- Scientific Affairs & Medical Affairs
- Legal Counsel, IP/Patent Litigation
- Clinical Operations
- Business Development & Business Operations
- Strategic Sourcing
- Marketing & Sales

This event may also be of interest to:

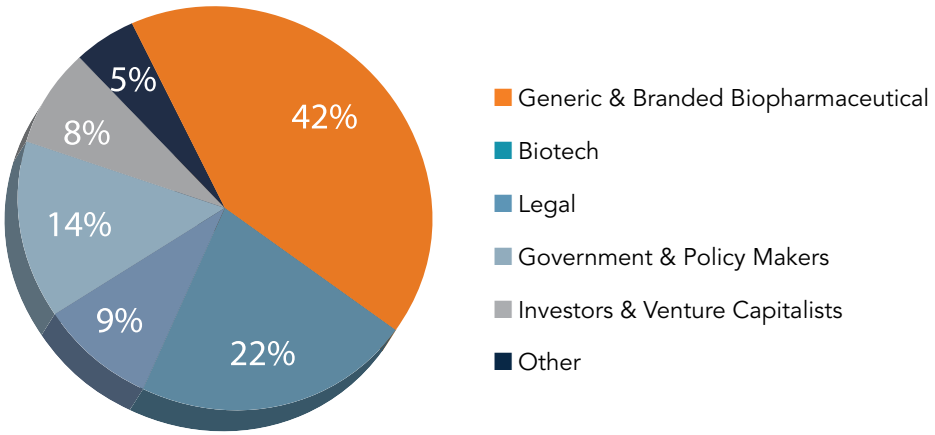
- Law Firms
- Policy Makers
- Government
- Investors & Venture Capitalists

Global Spotlight

Last year's event included speakers and attendees from the United States, the UK, India, Japan, Korea, Hungary, the Netherlands and Switzerland.

This year promises to have an even greater global perspective.

Audience Profile by Industry



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Business of Biosimilars

Read the Blog:
futurebiopharma.blogspot.com

Biologics coming off patent in the next couple years:

2012
Enbrel

2013
Epogen/ Procrit
Avonex
Neupogen
Humalog
Rebif
Byetta

2014
Remicade
NovoLog

2015
Neulasta
Rituxan
Lantus
Herceptin
Synagis
PegIntron

2016
Aranesp
Humira

2017
Avastin
Pegasys

Advanced Strategies to Overcome Scientific Challenges and Streamline Biosimilar Development

This symposium is designed for established professionals in the biosimilar and/or biobetter industry. It is also for professionals who work at companies that are beginning to break into the industry, or are interested in potentially breaking into the industry. Attendees should have a strong understanding of biosimilars and biologics.

7:30 *Symposium registration*

8:30 **Improve Higher-Order Structure Comparability Studies**

One of the biggest differences between biosimilars and traditional generics is overcoming the challenge of establishing structural comparability between your biosimilar and the originator.

- Identify challenges in matching biosimilars to originator products
- Determine suitable techniques and standards for measuring comparability
- Examine what structural differences are compatible with the concept of highly similar when there are no clinically meaningful differences

Curtis Meuse, *Research Chemist,* **National Institute of Standards and Technology (NIST)**

9:15 **Regulate Immunogenicity to Decrease Unwanted Responses and Ensure Patient Safety**

Immunogenic responses can be caused by everything from molecular structure and product impurities to patients' immune systems. It is hard to protect against unwanted responses, since even small manufacturing changes can produce large responses.

- Create strong molecular structures and protect against impurities to protect against negative responses
- Create an action plan to identify ways to overcome unwanted responses
- Learn the standards regulatory bodies employ to ensure patient safety

Magdalena Leszczyniecka, PhD, *Chief Executive Officer,* **STC Biologics Inc.**

10:00 **Improve Cell Line Development**

Biosimilar cell line development needs to produce a recombinant protein similar to the originator's based on QbD, which can be costly and time consuming.

- Identify strategies to minimize contamination and lower impurity levels
- Engineer expression vectors and cell lines to aid in development of an effective cell line producing product

S. Thippeswamy, MD, *President and CEO,* **Dr. Swamy's Lab**

10:30 *Networking Break*

11:00 **Streamline Testing During the Early Stages of Biosimilar Development**

The typical biosimilar takes approximately eight years to get to market, and the first steps include studies done in the lab, then animal studies. Streamline the process in order to work more efficiently and ensure timely development.

- Identify assays that need to be taken into consideration for comparability in reactivity
- Test toxicology to ensure safety
- Discuss regulatory requirements for animal testing

Zheru Zhang, PhD, *Vice President of Research and Development,* **Celltrion**

11:45 **Determine Clinical Trials Necessary for Biosimilar Development**

Advanced clinical trials are the longest and most expensive aspect of bringing a biosimilar to market, and also the most important to proving effectiveness and safety. Develop an effective strategy to ensure your biosimilar is ready to be released into the marketplace.

12:30 *Networking Luncheon*

1:30 **Case Study TBD**

2:30 *Networking Break*

3:00 **Identify New Tools That Aid in Biosimilar Development**

As demand for biosimilar drugs continues to grow, companies are creating new ways to increase the efficiency of biosimilar development.

- Analyze the costs and benefits associated with new products
- Weigh the risks and rewards of disposable bioreactors, including disposal regulations by region
- Identify new technologies that are on the horizon

3:45 **Guided Discussion**

If Technological Advances in Manufacturing Create a Better Version of the Originator, Is the Product Still a Biosimilar?

Magdalena Leszczyniecka, PhD, *Chief Executive Officer,* **STC Biologics Inc.**

4:30 *Full Day Symposium Closes*

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MORNING WORKSHOP I

8:30 *Morning Workshop Begins*

Create or Re-Assess your Emerging Market Strategy

This workshop is for Business Development, Regulatory Affairs, Strategic Sourcing and Quality Assurance professionals in the biosimilar, biobetter and biologic biopharmaceutical industries, as well as biotech industry that are currently in or looking to break into emerging markets.

Views on developed and emerging markets vary: some companies prefer to start in emerging markets then move into a developed market, whereas others start in a developed market then commercialize in an emerging market. Explore biosimilar and biosimilar-like products opportunities in markets where the originator drug is not available. This workshop evaluates the risks and rewards of biosimilar development in both marketplaces.

- Create a strategy to determine which marketplace is best for your biosimilar
- Understand the potential benefits of releasing a biosimilar product when the originator is not available
- Weigh the financial rewards and risks of starting in one market with the intention to move to another market

Richard Dicicco, *Chairman,* **Harvest Moon Pharmaceuticals USA, Inc**

10:30-11:00 *Networking Break* 12:30 *Networking Luncheon* 1:30 *Afternoon Workshops Begin*

1:30 AFTERNOON WORKSHOP II

Biosimilar IP Protection and Patent Litigation Strategies for Development in the US and Abroad

This workshop is designed for those who are concerned with regulatory and legal affairs, legal counsel and IP/Patent litigation within biosimilar and originator biopharmaceutical and biotech companies.

This workshop explores the new patent litigation process from both biosimilar and originator points of view and provides you with an understanding of biosimilar patent protection. Differentiate the legal implications of utilizing an abbreviated Section 351(k) biologics application under the new approval pathway or a full BLA. Learn how to keep your originator product safe while pursuing biosimilars in other areas. Hear aggressive strategies your company can employ to prepare for legal disputes in advance.

- Weigh the risk/reward options for using a Section 351(k) application vs. a full BLA
- Identify strategies for IP protection of biosimilar products
- Consider strategies for IP protection of originator products subject to biosimilar applicant challenge
- Review the new patent litigation process associated with the 351(k) application pathway
- Secure the appropriate exclusivity period for interchangeable biologics

Bruce A. Leicher, *Senior Vice President and General Counsel,* **Momenta Pharmaceuticals, Inc.**
D. Christopher Ohly, *Partner,* **Schiff Hardin LLP**
Janis K. Fraser, Ph.D, *Principal,* **Fish & Richardson**

1:30 AFTERNOON WORKSHOP III

Biosimilar Commercialization Primer from Compliant Market to Consumer Acceptance

This workshop is for professionals in commercial affairs, marketing, and sales and brand development within the biosimilar industry.

Although the R&D of biosimilars is important, successful commercialization your drug is how you make a profit. Create a long-term strategy to introduce your biosimilar to the marketplace and position it as a safe and cost-efficient alternative to the originator.

- Utilize creative labeling and naming strategies to increase visibility while maintaining regulatory compliance
- Construct a profitable pricing strategy
- Create a marketing strategy to make providers, patients and payers more comfortable with your biosimilar
- Evaluate key stakeholders' concerns when prescribing biosimilars in terms of patient safety and explore the potential problems that pharmacists may face in regards to interchangeability

Peter J. Pitts, *President,* **Center for Medicine in the Public Interest**
Kristie C. Kuhl, JD, *Senior Vice President,* **Makovsky**
Steven E. Goldberg, MD, MBA, *VP & Chief of Medical Affairs,* **Express Scripts**

2:30-3:00 *Networking Break* 4:30 *Workshops Conclude*

7:45 *Main Conference Registration*

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

Magdalena Leszczyniecka, PhD, *Chief Executive Officer,* **STC Biologics Inc.**

8:45 **Main Street Outlook**

Current Trends and Outlook of the Biosimilar Market around the World

Recap biosimilar growth over the past year, and learn which markets are prepared for the biggest growth, broken down by therapeutics and geographic locations. Explore which critical considerations need to be taken into account for strategic decision-making in biosimilar development.

Gillian Woollett, *Chief Scientist,* **Engel & Novitt**

9:15 **Wall Street Outlook**

Analyzing the Biosimilar Financial Opportunity

With more than $51 billion worth of biologics sales coming off patent between 2011 and 2015 and life expectancy is growing, biosimilars are expected to grow faster than most other drug categories. However, biosimilars are extremely expensive to create and it is a market yet to be realized.

- Learn which therapeutics generally have the highest profit potential
- Discuss which biologics are best posed for biosimilar development
- Recognize the challenges and uncertainties associated with the biosimilar industry
- Identify key players in the biosimilar marketplace

Priscilla Huang, *Finance Lead,* **Merck Bioventures**

9:45 **Investor Outlook**

Examine Biosimilar Development from an Investor Point of View to Better Position your Biosimilar or Biobetter

Listen as investors discuss what factors they consider when selecting which biosimilar development program they should fund.

- Overcome barriers to securing funding
- Listen as investors spell out what they're looking for in biosimilars
- Make your biosimilar stand out in the current biosimilar or biologic landscape

Moderator: Priscilla Huang, *Finance Lead,* **Merck Bioventures**

10:30 *Networking Break in* CLINICAL BUSINESS EXPO *Exhibit Hall*

11:00 **Regulatory Update of FDA Considerations on Biosimilars**

Hear the FDA's key considerations from the forum they held in November of 2010, and learn the tentative timeline on pending legislative and regulatory decisions including the abbreviated pathway.

- Understand the impact changes to the Healthcare Reform may have on the abbreviated pathway
- Learn how the FDA defines interchangeability and sameness
- Discuss mAbs from the FDA's perspective

Suzanne Sensabaugh, MS, MBA, *Founder and Member,* **HartmannWillner LLC**

11:45 **Implementation of Single Use Technologies in the Manufacture of Biosimilars**

New technologies in single use technologies allow developers to increase operational efficiency by enabling consistent unit operations development, process optimization, technology transfer and process scale-up.

- Review the current status of single use technology from a market perspective
- Identify the challenges facing single use technology, and how these differ by region and regulatory authority
- Review the benefits of single use technologies and explain the implications for the future of manufacturing

Edward-Graham Brown, *Vice President, Strategic Marketing, Process Solutions Business Unit,* **EMD Millipore**

12:30 *Strolling Luncheon in* CLINICAL BUSINESS EXPO *Exhibit Hall*

1:45 **Regional Spotlight**

Biosimilar Development in India

The biosimilar market in India is growing rapidly—in 2008 it was worth approximately $200 million and is expected to reach $580 million by 2012. Analyze how the marketplace is expected to evolve, and the IP and tax implications of bringing biosimilars to market in India. Hear about anticipated regulatory modifications in the Central Drugs Standard Control Organization.

- Learn the process for biosimilar approval in India
- Identify opportunities for Indian drugs to move into more highly regulated markets
- Analyze regional-specific opportunities for developing and commercializing biosimilars

Subir Basak, PhD, MBA, *Chief Executive Officer,* **Celestial Biologicals,** *Chief Commercial Officer,* **Intas Biopharmaceuticals**

2:30 **The US Abbreviated Pathway: The Good, the Bad and the Undefined**

In November 2010, the FDA held a forum where pharma, biotech, biosimilar and patient advocacy groups could express their concerns and suggestions for the creation of a biosimilar pathway. Based on that discussion, some companies have publicly declared that they are planning on using this pathway whereas other companies are staunchly against it.

- Hear both sides of the heated debate on the value of the abbreviated pathway
- Determine if the abbreviated pathway is best for your biosimilar

Moderator: Bruce A. Leicher, *Senior Vice President and General Counsel,* **Momenta Pharmaceuticals, Inc.**

Brian E. Harvey, MD, PhD, *Vice President U.S. Regulatory Policy,* **Sanofi-Aventis**

Steven E. Goldberg, MD, MBA, *VP & Chief of Medical Affairs,* **Express Scripts**

3:15 *Networking Break in* CLINICAL BUSINESS EXPO *Exhibit Hall*

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	Development Considerations	Commercialization Considerations
	This track is designed for individuals focused on the **technical and scientific** considerations of biosimilar or biobetter development.	This track is designed for individuals focused on the **marketing and commercialization** considerations of biosimilar or biobetter development.
4:00	**Understand the Biological, Chemical and Clinical Considerations when Establishing Similarity** • Define similarity from varying points of view • Identify different biological, chemical and clinical markers when establishing similarity • Anticipate immunogenic responses to avoid negative clinical consequences	**Anticipate Sales and Marketing Costs Associated with Biosimilar Product Launch** • Understand the cost of utilizing a sales force to inform prescribers about your drug • Examine factors that must be considered to best brand your biosimilar • Discuss the implications of INN criteria when naming products Gillian Cannon, MBA, PhD, *Commercial Head,* **Merck Bioventures**
4:30	**Define Bioequivalence and Interchangeability** • Decrease divergent product drift over time: slight drift in the makeup of the biosimilar and slight drift in the makeup of the reference can lead to significant product differences despite earlier demonstration of equivalence • Discuss how reference standards vary by country Charles Di Liberti, *President,* **Montclair Bioequivalence Services, LLC**	**Discuss Pricing, Payment and Reimbursement Strategies and challenges for Biosimilar Commercialization** • Calculate how to competitively price your biosimilar • Learn what health plans identify as "must-haves" for adding a medication to their formulary • Determine the impact payment and reimbursement has on drug distribution
5:00	**Immunogenicity Assessment while Preserving Desired Structural and Functional Aspects of the Biosimilar** • Determine where to best test immunogenicity within the preclinical or clinical stages with a look into regional regulatory guidance • Explore the analytical tools that best identify immunogenicity	**Prepare for Potential Traceability and Labeling Problems in Biosimilar Commercialization** • Hear why originator manufacturers are concerned about traceability • Understand the legal implications of patients' medications being traced to the wrong source • Develop an emergency strategy for if another medication is traced back to your company

5:30 **Networking Reception**

Networking Reception in CLINICAL BUSINESS EXPO *Exhibit Hall*

"The subject of biosimilars is complex, multifaceted, and of critical importance to the future of healthcare. I think that Business of Biosimilars 2010 covered the issues well, and was very informative. In my opinion, Business of Biosimilars and Biobetters 2011 is shaping up to be an even richer program."

—Charlie DiLiberti, President, Montclair Bioequivalence Services, LLC

7:30 **Roundtable Discussions**

Does a Global Biosimilar Opportunity Even Exist?

Since regulatory, legal, clinical and brand development obstacles vary by region, would it even be possible to create a global biosimilar product?

Sign up on-site for one of these facilitated discussions and take advantage of the opportunity to discuss this question from one of the following points of view:

Topic I: Impact of Regulatory Differences

Topic II: Varying Legal Perspectives

Topic III: Differing Clinical Requirements

Topic IV: Brand Development & Cultural Differences

8:45 **Chairperson's Day 1 Recap**

Kevin Whelan, *Director of Biologics Policy,* **Pfizer**

9:00 **Increase Profitability by Considering New Biosimilar Manufacturing Processes**

In biosimilars, it's often said that the process makes the product, and often the process is costly and lengthy. Learn ways to reduce costs and improve cell lines by utilizing new manufacturing processes.

- Discuss the technical criteria needed to demonstrate biocomparability
- Analyze the scientific considerations that need to be taken into account for manufacturing to maintain purity levels
- Discuss ways to lower the costs associated with product manufacturing

Crawford Brown, PhD, *Chief Executive Officer,* **Eden Biodesign,** *a member of* **The Watson Group**

M.S. Mahadevan, *Director, Strategic Marketing, Process Solutions Business Unit,* **EMD Millipore**

9:30 **Regional Spotlight**

Lessons Learned from Biosimilar Development in the Established European Marketplace

European countries are furthest ahead in biosimilar development, with Germany and the UK leading the way. Hear from a biosimilar developer who has a product that has been on the market for a number of years.

- Estimate the effect a growing marketplace will have on biosimilar pricing strategies
- Discuss the long term benefits of creating biosimilars in a highly regulated market, including the opportunity to easily move to less-regulated marketplaces
- Analyze regional-specific opportunities for commercializing biosimilars

Samuele Butera, *Vice President of US Biopharmaceutical Operating Unit,* **Sandoz USA** *(invited)*

10:15 *Networking Break in* CLINICAL BUSINESS EXPO *Exhibit Hall*

11:00 **Overcome IP Barriers to Biosimilar Development and Commercialization**

Patent Law attempts to strike a fair balance between providing monopolies for patentable inventions and enabling free competition. Both originator and biosimilar companies are critically interested in patents, with a view toward (often global) product profitability.

- Understand IP barriers to biosimilar market entry and learn how to navigate a way through those IP barriers in the US and other high-profit countries
- Consider IP issues relevant to the introduction of biosimilar in the global marketplace including how to avoid, address and mitigate against patent infringement risks
- Secure patent protection for your biosimilar and protect your company from any patent "surprises" when launching your biosimilar

Naomi Pearce, *IP Director and Counsel,* **Hospira**

11:45 **Regional Spotlight**

Biosimilar Opportunities within the US

People in the US spend more on pharmaceuticals than anywhere else in the world, so it comes as no surprise that the US is going to be a huge market for biosimilars, especially with the number of biologics coming off patent by 2015.

- Discuss the current regulatory climate, and how biosimilars fit into PPACA
- Understand how consumer, pharmacist and physician perceptions in the US will shape the marketplace

Kevin Whelan, *Director of Biologics Policy,* **Pfizer**

12:30 *Networking Luncheon*

POST CONFERENCE INTENSIVE

Continue the discussion with this 90-minute intensive focused on biosimilar oncology opportunities. This optional session is included in your event registration.

1:30-3:00 **Delve into Oncology Money-Making Opportunities**

Consisting of approximately 35% of the potential biosimilars market, oncology is likely to be one of the most profitable therapies, and US oncologists have stated that they will adopt biosimilars faster than those in Europe. Identify the originator oncology drugs that have patents expiring and understand the biosimilar growth opportunities in this rapidly growing therapeutic area.

Shefali Kakar, PhD, *Clinical Pharmacology, Oncology Business Unit,* **Novartis Pharmaceuticals Corporation**

3:00 *Conclusion of Business of Biosimilars & Biobetters Conference. See You Next Year!*

15 REASONS TO ATTEND THIS YEAR'S BUSINESS OF BIOSIMILARS AND BIOBETTERS

1. Customize the event to best meet your needs through intensive workshops, specialized tracks and focused roundtable discussions
2. Gain global insight as speakers from around the world speak on the biosimilar issues that have the greatest effect on their profitability
3. Decide if the Abbreviated Pathway or a full BLA is most beneficial to your organization when you hear from both sides of the debate
4. Learn best practices from companies that have developed biosimilars in different regions around the world
5. Optimize efficiency by utilizing new technologies and new manufacturing processes
6. Network with peers at this event, and exchange ideas with five other co-located events that create the Clinical Business Expo
7. Learn branding strategies to ensure consumers are comfortable with your biosimilar
8. Take your biosimilar from preclinical to commercialization with sessions that provide you with the tools for biosimilar success
9. Position your biosimilar to secure funding from investors
10. Identify future opportunities in biosimilar development and commercialization
11. Discuss if a biosimilar global marketplace exists through guided roundtable discussions
12. Ensure your biosimilar is safe for consumers through preclinical and clinical testing, and pharmacovigilance studies
13. Define strategies for a successful product launch through effective sales and marketing strategies
14. Identify strategies to establish similarity, bioequivalence, interchangeability
15. Develop a strong pricing strategy to ensure profitability and physician and patient interest

COMPANIES THAT HAVE BENEFITED FROM THE BUSINESS OF BIOSIMILARS & BIOBETTERS IN THE PAST

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2011 Distinguished Speaker Faculty

Subir Basak, PhD, MBA, *Chief Executive Officer, Celestial Biologicals, Chief Commercial Officer,* **Intas Biopharmaceuticals**

Mark Bowditch, *Patent Attorney,* **Sandoz**

Crawford Brown, PhD, Chief Executive Officer, **Eden Biodesign,** *a member of* **The Watson Group**

Edward-Graham Brown, *Vice President, Strategic Marketing, Process Solutions Business Unit,* **EMD Millipore**

Gillian Cannon, MBA, PhD, *Commercial Head,* **Merck Bioventures**

Richard Dicicco, *Chairman,* **Harvest Moon Pharmaceuticals USA, Inc.**

Charles Di Liberti, *President,* **Montclair Bioequivalence Services, LLC**

Janis K. Fraser, Ph.D, *Principal,* **Fish & Richardson**

Steven E. Goldberg, MD, MBA, *VP & Chief of Medical Affairs,* **Express Scripts**

Brian Harvey, *Vice President of Regulatory Affairs,* **Sanofi-Aventis**

Priscilla Huang, *Finance Lead,* **Merck Bioventures**

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Bruce Leicher, *Senior Vice President and General Counsel,* **Momenta Pharmaceuticals Inc.**

Magdalena Leszczyniecka, PhD, MBA, *President and CEO,* **STC Biologics**

M.S. Mahadevan, *Director, Strategic Marketing, Process Solutions Business Unit,* **EMD Millipore**

Curtis Meuse, *Research Chemist,* **National Institute of Standards and Technology (NIST)**

D. Christopher Ohly, *Partner,* **Schiff Hardin LLP**

Naomi Pearce, *IP Director and Counsel,* **Hospira**

Peter J. Pitts, *President,* **Center for Medicine in the Public Interest**

Suzanne M. Sensabaugh, MS, MBA, *Founder & Member,* **HartmannWillner LLC**

S. Thippeswamy, MD, *President and CEO,* **Dr. Swamy's Lab**

Kevin Whelan, *Director of Biologics Policy,* **Pfizer**

Gillian Woollett, MD, *Chief Scientist,* **Engel & Novitt**

Zheru Zhang, PhD, *Vice President of Research and Development,* **Celltrion**

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Reach the Business of Biosimilars Audience

The Business of Biosimilars event offers you an excellent opportunity to showcase your products and/or services in front of key decision-makers. Morning and afternoon breaks are designed to ensure maximum networking opportunities. Maximize your 2011 marketing dollars by sponsoring a luncheon or breakfast.

To learn more about marketing opportunities, please call **Michael Vidoni, Business Development Manager at 646-895-7479** or **mvidoni@iirusa.com.**

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register@iirusa.com

WEB
www.biosimilarsevent.com

FEES

Including luncheons and refreshments, your investment for attending the 3rd Annual Business of Biosimilars and Biobetters is:

REGISTER	Before 6/24/2011	Before 7/29/2011	Before 8/26/2011	After 8/26/2011
Conference + CBE Exhibit Hall	$1,695	$1,795	$1,895	$2,195
Conference + 1 Pre-Event AM or PM Workshop + CBE Exhibit Hall	$2,095	$2,195	$2,295	$2,595
Conference + 2 Pre-Event Workshops or Symposium + CBE Exhibit Hall	$2,395	$2,495	$2595	$2,895

It's a fact – attendees of a conference walk away with the most value when they experience it with a peer– there is just too much information available for one person to capture it all. Therefore, no longer are group discount structures restricted only to those groups registering from the same company. We recognize and respect that colleagues and peers span companies, disciplines, communities and peer groups. As a result, we are pleased to offer the most cost effective pricing possible in order to accommodate and promote cross-company collaboration. We're also aware of the need to send groups to multiple events and so, as long as they are within the II R Pharmaceutical/Healthcare portfolio – we are pleased to extend a group discount that can be applied across different events.

- Bring one peer (group of 2 in total) – receive 20% off standard and onsite pricing
- Bring two peers – (group of 3 total) – Receive 25% off standard and onsite pricing
- Bring three peers or more – Call Aloycia Bellillie at 646-616-7625

**All registrations must take place at the same time for discount structures to apply*

ADDITIONAL DISCOUNT OPPORTUNITIES

- I am from a company that is speaking at Business of Biosimilars and Biobetters and qualify for 25% off the standard rate
- I am from a company that is sponsoring the Business of Biosimilars and Biobetters and qualify for 25% off the standard rate
- I am a Government, Non-Profit or Academic Professional and qualify for 30% off the standard rate

** All discounts are off the standard and onsite fees. No two discounts can be combined. Please note that early registration discounts may be a better value than some of the discount opportunities here, so please register today.*

PAYMENT

Payment is due within 30 days of registering. If registering within 30 days of the event, payment is due immediately. You may pay by check, VISA, MasterCard, Discover, Diner's Club or American Express. Please make all checks payable to the "Institute for International Research, Inc." and write the name of the delegate(s) and our reference number P1686 on the face of the check. If payment has not been received prior to registration the morning of the conference, a credit card hold will be required.

DATES & VENUE

September 19-21, 2011
Seaport Hotel and World Trade Center Boston
1 Seaport Lane
Boston, MA 02210
(800) 440-3318

HOTEL ACCOMMODATIONS

Attendees requiring guest room accommodations should call (617) 385-4212 and request the negotiated group rate of $269 + tax/night for "IIR attendees". The negotiated rate will be available until August 25, 2011.

CANCELLATION POLICY

If you need to make any changes or have any questions, please feel free to contact us via email at *register@iirusa.com*. Cancellations must be in writing and must be received by IIR prior to 10 business days before the start of the event. Upon receipt of a timely cancellation notice, IIR will issue a credit voucher for the full amount of your payment, which may be applied towards registration fees at any future IIR event held within 6 months after issuance (the "Expiration Date").

All credit vouchers shall automatically expire on the Expiration Date and shall thereupon become void. In lieu of issuance of a credit voucher, at your request, IIR will issue a refund less a $795 processing fee per registration. Registrants are advised that no credit vouchers or refunds will be issued for cancellations received less than ten business days prior to start of the event, including cancellations due to weather or other causes beyond the Registrant's control. IIR therefore recommends that registrants allow for unexpected delays in making travel plans. Substitutions are welcome at any time. If for any reason IIR decides to cancel this conference, IIR accepts no responsibility for covering airfare, hotel or other costs incurred by registrants, including delegates, sponsors, speakers and guests.

EVENT DOCUMENTATION ORDER

If you are unable to attend the program, or would simply like to order additional sets of documentation for your colleagues, they are available for $495 per set. The documentation is a compilation of the speaker presentations including overheads, power point presentations, articles and charts. The documentation is available online two weeks after the event takes place. Credit Card Payments Only. All speakers and topics listed are confirmed as of press time. When substitutions must be made due to speaker cancellations, IIR makes every effort to find a replacement of equal caliber to present the scheduled topic.

DRESS CODE

Casual and comfortable attire is suggested. We recommend bringing a sweater, as the conference room may be cool.

Any disabled individual desiring auxiliary aid for this conference should notify IIR at least 3 weeks prior to the conference in writing, by faxing to 212.661.6045.

INCORRECT MAILING INFORMATION

If you are receiving multiple mailings, have updated information, or would like to be removed from our database, please contact our database department at 212.661.3876 or fax 212.661.3014.

PRESS

Press permission must be obtained prior to the event and is dependent upon speakers' approval. The press may not quote speakers or delegates unless they have obtained their approval in writing. For press inquiries please contact Allison Nilsen at *arigels@iirusa.com.*

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BUSINESS OF BIOSIMILARS & BIOBETTERS

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