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biosimilars INDIA 2010

TWO-DAY STRATEGIC CONFERENCE

30 SEPTEMBER – 1 OCTOBER 2010

Le Royal Méridien Mumbai, India

Gain In-Depth Guidance on:

Regulation
Understanding the impact of WHO guidelines in respect to Indian and European regulatory frameworks

Commercialisation
Evaluating the market opportunities, international partnerships and profitable outsourcing models

Research and Development
Overcoming the cloning, fermentation and purification complexities to maximise yield and commercial viability

Manufacturing
Achieving effective collaboration of R&D, process development and manufacturing functions

Cold Chain Management
Leveraging the latest cold chain distribution systems to ensure quality throughout the chain

Innovation Strategies
Exploring the viability of biobetters and biosuperiors

Outstanding Contributions from:

MK Sahib
Director Biotechnology
Wockhardt

Steffen Denzinger
Associate Director PC-SR
Global Applied Technology
Performance & Life Science Chemicals
Merck KGaA

Rustam Modi
Chief Scientific Officer, Director Quality Assurance
Intas Biopharmaceuticals

VK Vinayak
Vice President Research and Development
Panacea Biotec

Sanjay Singh
CEO
Gennova Biopharmaceuticals

Vikram Paradkar
Vice President Biotechnology
Reliance Life Sciences

Vijay Kshirsagar
Executive Vice President, Corporate Quality Assurance and Regulatory Affairs
Unichem Laboratories

Anand Kumar
Associate Vice President, Quality
Wockhardt

Gopal Dasika
Vice President, Biotechnology
Unichem Laboratories

Narasimham Jammi
Head Biotechnology
Shasun Chemicals and Drugs

Subir Basak
CEO
Celestial Biologicals

Aruna R Khare
Principal Scientist, Incharge, Bioassay and Immunoassay Laboratory
USV

UC Banerjee
Professor & Head Department of Pharmaceutical Technology, Biotechnology
NIPER

Samir Sangitrao
Head Regulatory Affairs
Intas Biopharmaceuticals

Vishwanath B Malkar
Head Regulatory and Quality
Reliance Life Sciences

Krishnamohan B
General Manager Operations, Biotech Division
Lupin Pharmaceuticals

Hareesh Parandhaman
Head Business Development, Biotechnology
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CONFERENCE DAY ONE - Thursday 30 September 2010

09:00 **Registration and refreshments**

10:00 **Opening remarks from the chair - Biosimilar development, opportunities and challenges**
MK Sahib, Director Biotechnology
Wockhardt

Gaining Regulatory Approval

10:20 **Clarifying the biosimilars regulatory position in India and identifying strategies for gaining speedy market authorisation for new products**
- Mapping out the current biosimilars regulatory approval process and identifying gaps and bottlenecks in the framework
- Understanding the regulatory requirements around:
  - Clinical trials
  - Comparative analysis
  - Documentation
- Establishing the correct form and volume of data required to ensure a timely approval process
- Setting out realistic timelines for R&D, product development and commercialisation of biosimilars
- Updating on how the guidelines are evolving with input from the industry

Vishwanath B Malkar, Head Regulatory and Quality
Reliance Life Sciences

11:00 **Adapting to stringent European regulations to ensure the timely and successful commercialisation of products in western markets**
- Evaluating the key challenges of gaining biosimilars regulatory approvals in Europe
- Establishing the range and level of clinical trials required to achieve approvals
- Determining the depth of comparative analysis required
- Understanding the documentation complexities for European approvals

Partha Ghosh, Director, Service Lead, Early Stage Development, Europe
Parexel Consulting

11:40 **Morning refreshments**

12:10 **Understanding the latest WHO guidelines for developing and commercialising biosimilars in emerging markets**
- Clarifying the evolving WHO guidelines for biosimilars development and commercialisation
- Effectively interworking WHO guidelines with the Indian regulatory framework
- Establishing timelines for implementing the combined framework
- Consulting with industry to ensure a holistic, in-depth and clear set of guidelines for implementation ease
- Balancing the need for in-depth clinical trials with cost control of the end product

Vijay Kshirsagar, Executive Vice President, Corporate Quality Assurance and Regulatory Affairs
Unichem Laboratories

Commercialisation of Biosimilars

12:50 **Evaluating the biosimilars market opportunity across the semi-regulated countries and determining the pharmacopeial requirements**
- Assessing the commercial opportunities for biosimilars in semi-regulated markets
- Overcoming barriers to market entry and driving rapid take-up through robust and locally oriented marketing strategies
- Evaluating the regulatory framework and identifying effective ways of navigating these
- Managing the effects of frequently changing market and regulatory environments
- Evaluating the need for and path towards harmonisation of regulatory regimes and agency requirements across the semi-regulated markets
- Understanding regulatory and pharmacopeial expectations from analytics and monographs
- Analysing future requirements and initiatives needed for driving growth of Indian pharma industry

Samir Sangitrao, Head Regulatory Affairs
Intas Biopharmaceuticals

13:30 **Lunch and networking**

14:30 **Optimising your biosimilars commercialisation strategy to ensure rapid market take-up and healthy profit margins**
- Assessing the different commercial opportunities for biosimilars in India
- Overcoming barriers to market entry and ensuring rapid take up of the product
- Developing and understanding the 4P strategy for biosimilars
- Identifying case study benchmarks for biosimilars

Subir Basak, CEO
Celestial Biologicals

15:10 **Striking win-win international partnerships to drive the effective development and commercialisation of biosimilars**
- Identifying the key criteria for selecting and securing international partnerships for biosimilars product development and commercialisation
- Ensuring effective due diligence procedures to ensure a robust partnership from the outset
- Evaluating the benefits and pitfalls of various partnership approaches:
  - Joint ventures
  - Strategic alliances
  - Plain vanilla
- Setting up effective contracts to protect your interests whilst allowing flexibility to upgrade with ease
- Identifying the optimal partnership model to fuel high quality clinical trials

Hareesh Parandhaman, Head Business Development, Biotechnology
Lupin Pharmaceuticals

15:50 **Afternoon refreshments**

16:20 **Developing an outsourcing model that will deliver cost-effective and high quality biosimilars products**
- Comparing the benefits of in-house versus outsourced models for R&D, process development and manufacturing
- Assessing the capabilities of CRAMS in India and how facilities must develop to meet the needs of biosimilars product manufacturers
- Learning from experiences with outsourcing of biosimilars R&D, process development and manufacturing in Europe
- Identifying the key success criteria for selecting outsourcing partners
- Evaluating the economic case and balancing with the need to retain control over the product development process

Speaker to be confirmed

17:00 **Biobetters & biosuperiors - paving the way for lucrative longer term opportunities**
- Defining biobetters and biosuperiors and the additional studies required for achieving regulatory approvals
- Assessing the IPR issues affecting biobetters and biosuperiors
- Reviewing experiences with commercialised biobetters and biosuperiors to date
- Assessing the technical complexities of developing these products
- Building the business case for investing in biobetters and biosuperiors

Steffen Denzinger, Associate Director PC-SR Global Applied Technology Performance & Life Science Chemicals
Merck KGaA

17:40 **Roundtable Discussions** - an opportunity to join in with facilitated group discussions around the key issues raised during the course of the day. Come armed with your live challenges and take away practical implementable solutions.

18:30 **Close of conference day one**

Panelists at a previous UBM conference in India

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CONFERENCE DAY TWO - Friday 1 October 2010

09:00 **Registration and refreshments**

10:00 **Opening remarks from the chair**

R&D and Process Development

10:10 **Overcoming challenges in the cloning and fermentation process to maximise yield and ensure the commercial viability of biosimilars**

- Managing the technical complexities around the cloning process:
  - Instability
  - Immunogenicity
  - Screening of clones
- Developing the optimal fermentation environment to ensure maximum output
- Establishing the optimal parameters for scaling up
- Evaluating a range of low-cost, high-performance equipment to ensure the flexibility of the fermentation process

Gopal Dasika, Vice President, Biotechnology
Unichem Laboratories

10:50 **Addressing downstream process challenges through advanced purification techniques to meet pharmacopic requirements**

- Evaluating a range of downstream processes to achieve effective purification
- Analysing the benefits of chromatographic techniques for managing the bioactivity of large and complex molecules
- Assessing folding and re-folding techniques for achieving purification
- Leveraging cost-effective equipment and technologies to optimise yield and ensure safety

UC Banerjee, Professor & Head Department of Pharmaceutical Technology, Biotechnology
NIPER
Narasimham Jammi, Head Biotechnology
Shasun Chemicals and Drugs

11:30 **Morning refreshments**

12:00 **Identifying advanced techniques for addressing immunogenicity issues in biosimilars**

- Understanding the level of immunogenicity analysis required for regulatory approval
- Assessing the value and reliability of existing test data for informing your biosimilars product development
- Identifying opportunities for reducing timescales on delivering robust immunogenicity profiles
- Determining the key criteria for selecting highly qualified laboratories for immunogenicity testing
- Managing the costs of delivering high quality test data

Aruna R Khare, Principal Scientist, Incharge, Bioassay and Immunoassay Laboratory
USV

12:40 **Running advanced comparability studies to deliver cost-effective biosimilars**

- Assessing the challenges of matching biosimilars to the innovator product in terms of quality and structural and physical characterisation
- Determining the best quality testing procedure for establishing safety of the profile in pre-clinical studies
- Evaluating various sensitivity techniques to deal with safety and immunogenicity issues
- Understanding the level of expertise required to assess minor variations
- Assessing advanced technical equipment for ensuring quality and cost-efficiency

Sanjay Singh, CEO
Gennova Biopharmaceuticals

13:20 **Lunch and networking**

14:30 **Working with complex monoclonal antibodies to deliver commercially viable biosimilars to the market**

- Overview of the similarities and differences between monoclonal and non-monoclonal antibodies
- Increasing the yield through effective cloning and fermentation techniques
- Overcoming the purification and stabilisation challenges
- Working with the structural differences in laboratories and their impact on clinical development
- Taking advantage of the benefits of fully humanised monoclonal antibodies

VK Vinayak, Vice President Research and Development
Panacea Biotec

15:10 **Developing a scaling-up process that protects product quality whilst ensuring cost-efficiency**

- Establishing the appropriate parameters for fermentation kinetics to optimise productivity levels
- Understanding the impact of scaling up on process and product related impurities
- Dealing with issues related to quality and physical verification of equipment
- Ensuring compliance with sophisticated PLC standards for quality control and productivity

Vikram Paradkar, Vice President Biotechnology
Reliance Life Sciences

15:50 **Afternoon refreshments**

16:20 **Achieving comparability of biosimilars to the innovator product - quality considerations**

- Considerations for selection of the reference innovator product
- Selecting the right analytical methods
- Identifying an appropriate laboratory for testing - assessing all the success factors
- Creating the right documentation including expert opinion

Anand Kumar, Associate Vice President, Quality
Wockhardt

Manufacturing and Distribution

17:00 **Establishing the cGMP facility requirements for cost-effective, large-scale biosimilars production**

- Ensuring effective collaboration of the manufacturing function with R&D and process development
- Delivering on the parameters as recommended by the pilot:
  - Designing capacity
  - Initial flow filtration level
  - TMP cross flow
- Embedding an efficient process for scaling up whilst protecting the stability and quality of the product
- Integrating flexibility into the manufacturing process to support different biological products
- Eliminating process variations and managing the effects of deviation in the most cost-efficient manner

Krishnamohan B, General Manager Operations, Biotech Division
Lupin Pharmaceuticals

17:40 **Understanding the cold chain management requirements for the storage and distribution of biosimilars**

- Assessing the cold chain management needs of biosimilars as compared with other biological products
- Examining the latest innovations in dedicated cold chain and distribution services
- Overcoming the challenges of continuous monitoring of in-transit biological products
- Finding a cost-effective means of dealing with power cuts and other cold chain barriers
- Developing effective processes to ensure compliance with end-to-end cold chain culture
- Assessing state-of-the-art equipment for cold chain management of biosimilars

Rustam Modi, Chief Scientific Officer, Director Quality Assurance
Intas Biopharmaceuticals

18:20 **Close of conference**

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"The global biosimilars market is expected to be worth $19.4 billion by 2014, growing at a CAGR of 89.1% from 2009 to 2014. The early commercialisation and high absorption rate of biosimilars products made Asia the dominant market in 2008 with 34.1% share of the global biosimilars product market." Markets and Markets

5 Great Reasons to Attend

- **Understand the latest WHO guidelines** and how they will interwork with the Indian regulatory framework
- **Gain in-depth insights** into the R&D and process development complexities
- **Optimise your biosimilars commercialisation strategy** and explore best partnership and outsourcing models
- **Explore longer term opportunities** with biobetters and biosuperiors
- **Ensure cost-effective manufacturing and distribution** strategies

Who Should Attend?

This conference has been designed specifically for VPs, Directors, GMs and Heads of: Biologics, Biotechnology, R&D, Process Development, Formulations, Analysis and Testing, Regulation, and Product Development from:

- Biopharma Manufacturers
- Biotechnology Manufacturers
- Generic Pharma Manufacturers
- Innovator Pharma Manufacturers
- Equipment Suppliers
- Ingredient & Material Suppliers
- Analytical Laboratories
- CRAMS

JUST SOME OF THE ATTENDEES AT BIOSIMILARS INDIA 2009:

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INTAS BIOPHARMACEUTICALS
JOHNSON & JOHNSON
LUPIN PHARMACEUTICALS (BIOTECH)
MERCK & CO
PANACEA BIOTEC
PIRAMAL HEALTHCARE
RELIANCE LIFE SCIENCES
SANOFI-SYNTHELAB (INDIA)
SUN PHARMACEUTICALS
IPCA LABORATORIES
SHASUN CHEMICALS AND DRUGS
TAKEDA
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Delegates at a previous UBM conference in India

Feedback from delegates at our Biosimilars 2009 conference

"Very good speaker selection, one of the best organised conferences in India, providing a very affordable and fruitful platform for networking"
Manjula Das, Chief Scientific Officer, Abexome Biosciences

"Very valuable to hear from speakers with up-to-the minute information. Especially impressed with the participation and questions raised"
Bina Ramani, CEO, NCE LifeSciences

"Biosimilars are the new stream to be explored. Such conferences are critical to understanding the future approach and making successful submissions"
Anita S Ghagare, Senior Manager Regulatory Affairs, Unichem Laboratories

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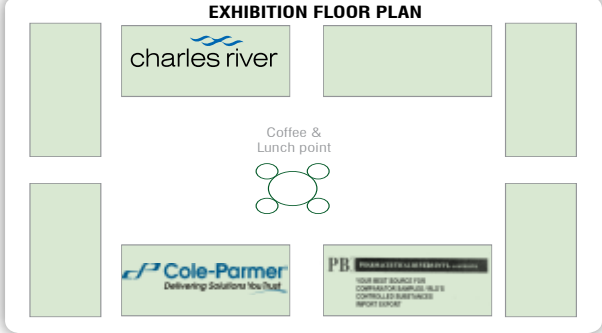

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biosimilars
INDIA 2010

"The 'Made-in-India' biosimilars market (domestic plus export) was worth around $200 million in 2008, and is expected to more than double to reach around $580 million by 2012" (Biospectrum)

Dear Colleague,

CPhI Conferences is delighted to announce its **2nd Annual Biosimilars India 2010** conference. Building on the success of our 2009 conference, we bring you a revised and refreshed agenda that deep dives into the most timely R&D, manufacturing and regulatory challenges facing the biosimilars industry today!

There is no denying that the global biosimilars opportunity for Indian manufacturers and allied industries is enormous. However, to take full advantage of the rewards that await, you must be fully equipped and aligned to tackle the technical, commercial and regulatory challenges today.

Attend this intensive two-day strategic conference and prepare to take your biosimilars strategy to the next level. Just some of the issues that will be tackled at this conference include:

- **Regulatory Developments** – understand the impact of local and international regulatory scenarios and the implications for your biosimilars strategy
- **R&D and Process Development** – gain in-depth guidance on advanced cloning, fermentation and purification processes and their scale-up, to ensure the quality and safety of your biosimilars
- **Manufacturing and Distribution** – take advantage of cost-effective cGMP facilities and cold- chain management for volume production and distribution of biosimilars
- **Commercialisation** – pricing, partnerships and outsourcing strategies to drive the early profitability of your biosimilars business
- **Biobetters and Biosuperiors** – pave the way today to reap the longer term rewards of the biologics market in India

We have assembled an outstanding line-up of industry leading speakers including senior representatives of: **Merck KGaA, Intas Biopharmaceuticals, Wockhardt, Panacea Biotec, Lupin Pharmaceuticals, Gennova Biopharmaceuticals, Reliance Life Sciences, USV, Shasun Chemicals and Drugs, Unichem Laboratories,** plus many more…

Don't delay! Call us today to secure your place at the only Biosimilars conference focused on the opportunities and challenges of the Indian market specifically!

I look forward to seeing you at the event in September.

Best wishes,

Niyoti Trivedi Vyas
Programme Manager
CPhI Conferences

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