

**IIHMR UNIVERSITY, JAIPUR**  
**EVENT OUTCOME REPORT**  
**Master Class Episode 44**

“Master Class Episode 44”
<b>Topic:</b> - “Exploring the Opportunities and Challenges of Biosimilar in the World”
<b>Date:</b> 19 <sup>th</sup> January 2022 from 04.00 PM to 05:00 PM
<b>Venue:</b> - IIHMR University, Jaipur
<b>Speaker:</b> -Mr. Ashish Mukherjee, VP Global Market Access, Biocon Biologics Ltd, Bangalore
<b>Number of participants:</b> - 86
<b>Introduction:</b> - This session featured: Mr. Ashish Mukherjee, VP Global Market Access, Biocon Biologics Ltd, Bangalore, India. The event was moderated by Dr. Saurabh Banerjee, Dean - SPM, IIHMR University, Jaipur and the Student coordinator is Ms. Chaitali Dilip Desale MBA PM Batch 12.
<p><b>Objective:</b></p> <p>A clear and professional objective statement for “Exploring the Opportunities and Challenges of Biosimilars in the World”:</p> <p>"To examine the global landscape of biosimilars by identifying key opportunities for expanding access to affordable biologic therapies, while analysing the regulatory, clinical, and market challenges that impact their adoption and integration into healthcare systems."</p>
<p><b>Salient Novel Points Covered:</b></p> <p>Salient Novel Points:</p> <p>Global Market Expansion Trends</p> <ul style="list-style-type: none"> <li>• Emerging economies are becoming key growth zones for biosimilars, driven by increasing demand for affordable biologics.</li> </ul> <p>Evolving Regulatory Harmonization</p> <ul style="list-style-type: none"> <li>• New efforts by global regulatory bodies (e.g., WHO, EMA, FDA) to standardize approval pathways are reducing market entry barriers.</li> </ul> <p>Next-Generation Biosimilars (Bio betters)</p> <ul style="list-style-type: none"> <li>• Innovation beyond mere imitation is creating improved versions of reference biologics, blurring the line between biosimilars and novel biologics.</li> </ul> <p>Cost Reduction with Real-World Evidence (RWE)</p> <ul style="list-style-type: none"> <li>• Use of real-world data is demonstrating long-term safety and efficacy, increasing prescriber confidence and payer support.</li> </ul> <p>Policy-Driven Market Access</p> <ul style="list-style-type: none"> <li>• Strategic government policies (e.g., incentivizing substitution) are accelerating uptake in certain regions, especially in Europe and Asia.</li> </ul>

## Supply Chain Localization Post-COVID

- The pandemic highlighted the need for regional manufacturing hubs, influencing biosimilar production and distribution models.

### **Role:**

#### Role of Exploring the Opportunities and Challenges of Biosimilars in the World

"To provide a comprehensive understanding of the evolving biosimilar landscape by identifying the potential for increased healthcare access, affordability, and innovation, while also addressing critical regulatory, clinical, and market-based barriers that influence their global development, acceptance, and integration into health systems.

This exploration serves multiple roles:

- Information Policy and Regulation
- Guides Industry Strategy
- Supports Healthcare System Planning
- Promotes Patient Access and Equity
- Strengthens Stakeholder Engagement

### **Challenges and Opportunities:**

#### Opportunities

##### Global Awareness & Policy Influence

- Insights from this exploration can guide policymakers in creating supportive regulatory environments.

##### Healthcare Cost Reduction Insights

- Identifying how biosimilars can lower costs helps healthcare systems and insurance providers manage budgets.

##### Market Development Strategies

- Provides pharmaceutical companies with data to develop biosimilars in underserved regions.

##### Strengthened International Collaboration

- Encourages cooperation between countries on regulatory harmonization, R&D, and knowledge exchange.

#### Challenges

##### Data Gaps and Regional Disparities

- Inconsistent availability of market data and clinical outcomes across countries can limit the scope of analysis.

##### Complex Regulatory Landscape

- Diverse and evolving regulatory requirements make comparative analysis difficult.

##### Intellectual Property & Legal Barriers

- Patent laws and exclusivity rights vary globally, complicating exploration of market entry strategies.

##### Stakeholder Resistance and Misinformation

- Understanding and addressing biases among healthcare providers and patients can be

difficult.

### **Q &A and Interactive Discussion:**

Here's a comprehensive plan for an Interactive Discussion session on "*Exploring the Opportunities and Challenges of Biosimilars in the World*," including engaging questions and suggested answers to guide meaningful dialogue among participants.

#### **Introduction (3–5 minutes)**

- Briefly define biosimilars.
- State the goal: To explore both the global potential and barriers to biosimilar development, acceptance, and implementation.

#### **Opportunities Section**

Q2: What are the key benefits biosimilars can offer to global healthcare systems?

Suggested Answers:

- Reduced cost of biologic treatment
- Improved access in low- and middle-income countries
- Increased treatment options for patients
- Market competition leading to innovation

#### **Future Scope:**

Policy & Regulatory Evolution

Innovation in Biosimilar Development

Expansion into New Therapeutic Areas


Enhanced Market Penetration & Global Access



Strengthened Pharmacovigilance and Post-Market Surveillance

Economic and Policy Research

Sustainability and Ethical Impact

## Exploring the Opportunities and Challenges of Biosimilars

 Wednesday, Jan 19, 2022

 04:00 PM - 05:00 PM (INDIA) 



**SPEAKER**

**Mr. Ashis Mukherjee**  
VP Global Market Access,  
Biosim Biologics Ltd. Bangalore



**MODERATOR**

**Dr. Saurabh Banerjee**  
Dean SPM  
IIHMR University, Jaipur



**STUDENT  
COORDINATOR**

**Ms. Chaitali Dilip Desale**  
BBA-PH, Batch 12,  
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