

# 3<sup>rd</sup> International Conference and Exhibition on **Biowaivers, Biologics & Biosimilars**

October 27-29, 2014 Hyderabad International Convention Centre, Hyderabad, India

## **Intas-Merck Millipore: Partnership in biosimilars development strategy for emerging markets**

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The development of biosimilars for emerging markets faces many challenges, including abbreviated process development timelines, and cost pressures to develop robust manufacturing processes which enable passing cost savings on to the patient. Intas is a leading Biotech company from India with 8 biosimilar products launched in emerging markets and a product registered in Europe. The company has a pipeline of over 10 biosimilar molecules at various stages in development. Intas's goal is to develop cost effective and robust biosimilars processes to serve the global market. This presentation describes Intas's goals and challenges in biosimilars development and manufacturing, and their partnership with Merck Millipore. Data will be presented on affinity, cation and anion exchange chromatography development, as well as depth filtration as a replacement to centrifugation. This collaboration helped to overcome challenges such as minimizing process development time, reducing capital investment, and creating cost effective and scalable manufacturing operations. Future collaborative work will also be presented. The case study focuses on:

- The challenges of developing cost effective biosimilars for emerging markets
- Process development of downstream unit operations
- The value proposition of partnership

### **Biography**

Jennifer Campbell is the Director WorldWide Biosimilars Market for Process Solutions at Merck Millipore. She has 20 years of industry experience, including research and development, assay development, process development, cGMP manufacturing, and technical consulting. She has 2 scientific Master's degrees and an MBA, and she has published in the fields of animal research, biopharmaceutical validation, viral clearance, and biosimilars development.

Harish Shandilya is heading Biocharacterization of therapeutic proteins at INTAS Biopharmaceuticals Ltd., Ahmedabad. He is working with INTAS for last 7 years now. Prior to this assignment, he has developed clones for many biotherapeutic proteins. He is a molecular biologist by training and has worked at various prestigious institutions in India and abroad. He did his Postdoctoral work at Vanderbilt University Medical Center, Nashville, USA. Before joining Intas, he was associated with University of Pittsburgh, USA. He has done his PhD degree (1999) from India. He has published more than 20 research papers in reputed journals. He has experience of coordinating multiple Biosimilar product development programs for domestic and regulated market projects.

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