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One and a Half-day In-person Seminar:

Biosimilars Analytical Characterization and Comparability Studies

By: **Nanda Subbarao**, Senior Consultant, Biologics Consulting Group

Location: April 4-5 | San Diego, CA

SPEAKER

Nanda Subbarao, Senior Consultant, Biologics Consulting Group

Dr. Subbarao received her Ph.D. in Bio-organic Chemistry from the Indian Institute of Technology, Bombay, India. Her hands-on industrial experience covers stability and laboratory cGMP systems for both biologics and conventional drugs. She has extensive experience in evaluation of analytical methods and method validation for products ranging from pre-clinical to clinical and commercial phases.

She is an ASQ Certified Quality Auditor with expertise in setup of cGMP/GLP complaint Quality Systems for laboratory and stability programs as well as upgrade of existing Quality Systems for products during development and in commercial phase. She is currently a Senior Consultant with the Biologics Consulting Group specializing in Analytical, Stability, CMC and GLP/GMP Quality Systems. She serves on the American Association of Pharmaceutical Sciences, Stability Focus team Steering Committee and is the current Regulatory Sciences Lead for National Biotechnology Conference Programming Committee.

LEARNING OBJECTIVES

This workshop will provide the audience with:

- An overview of the current status of Global Biosimilar Guidance with a focus on the Analytical Package required for a Biosimilar product.
- The Analytical comparability studies currently required for comparison of the Reference Product with the Biosimilar will be discussed.
- The Analytical methods and specifications required for both comparability studies and lot release and stability studies will be addressed.

COURSE DESCRIPTION

Analytical Strategy is a critical element of Biosimilar product development plan. A comprehensive Analytical package which meets current regulatory expectations will minimize the amount of clinical studies and therefore control costs of the Biosimilar development program.

This is a rapidly evolving topic and the industry needs to keep up with the current expectations. The draft Revision1 of the EU Biosimilar Quality guidance was issued in May 2012 and is currently open for comments. The FDA guidance on Quality Considerations in Demonstrating Biosimilarity To a Reference Protein Product is expected this year. Other regions of the world continue to publish Biosimilar Guidance and their revisions and several scientific publications which present the industry point of view have been published recently.

AGENDA

DAY ONE — Thursday, April 4, 2013

8:30 AM - 9:30 AM	Introduction and overview of the Global Biosimilar guidances
9:30 AM - 10:30 AM	The Reference Product
10:30 AM - 10:45 AM	**Break**
10:45 AM - 12:00 Noon	The Biosimilar Comparability study overview
12:00 Noon - 1:00 PM	**Lunch**
1:00 PM - 3:00 PM	Analytical methods required in a Biosimilar Comparability study
3:00 PM - 3:15 PM	**Break**
3:15 PM - 5:00 PM	Analytical methods required in a Biosimilar Comparability study

DAY TWO — Friday, April 5, 2013

8:30 AM - 9:30 AM	Specification setting for Biosimilars
9:30 AM - 10:00 AM	Break
10:00 AM - 12:00 Noon	Lot release and Stability testing of Biosimilars

WHO WILL BENEFIT

- R&D chemists, supervisors and managers
- Regulatory Affairs personnel
- QC chemists, supervisors and managers
- QA Managers and personnel

Registration Form

GROUP REGISTRATIONS

Send Your Team for Maximum Benefit Get your team up to speed!

2 Attendees	-	Get 10% off
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Seminar Topic: Biosimilars Analytical Characterization and Comparability Studies

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Attendee 3			
Attendee 4			

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