

Biosimilars

Manufacturing and Sourcing Dynamics

Wednesday, December 2, 2009

10:30 am - 4:00 pm

Hilton Hotel, Parsippany, NJ

Presented by the
Education Committee of

DCAT

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Program Summary

With healthcare reform in the forefront of the daily news, one of the largest opportunities for new entries is in the field of biosimilars/follow-on biologics. Many companies have announced a strategy to develop follow-on biologics, seemingly entering the generic side of biologics, as well as alliances between manufacturing and generic companies.

Attend this unique DCAT program to learn more about biosimilars:

- Market overview and opportunities
- Development and manufacturing dynamics
- Regulatory approval
- Technologies for active ingredients and formulations

Who Should Attend:

Pharmaceutical/Biotech and Chemical industry professionals involved in:

- Sourcing
- Sales & marketing
- Business development

Schedule

10:30 am	Registration begins
11:00 am - 12:00 pm	Program Sessions
12:00 pm - 1:00 pm	Buffet Luncheon for registrants
1:00 pm - 4:00 pm	Program Sessions

INDUSTRY TOPICS

11:00 am

A Biologics Primer: Application to Biosimilars

Speaker: Carl Lawton, Ph.D., Director, Massachusetts Biomanufacturing Center, University of Massachusetts, Lowell

This session will trace the history of biologics from 1902 and the passage of the US Biologics Control Act 1902 until the present. Biosimilars/follow-on biologics have generated much interest for the potential of lowering health care costs. We will examine production methods used to make biologics and the analytical tools available to characterize their structures. A considered discussion about the manufacture of biologics, with immunological implications, will allow for an examination of potential cost lowering or potential pitfalls. The differences between generic small molecules and complex biologics will be discussed.

11:30 am

The Challenges of Demonstrating Comparability of Biosimilar Products

Speaker: Patricia Seymour, Senior Consultant, BioProcessTechnology Consultants, Inc.

Despite the current economic woes in the Western world, the economies of China, India, Russia, and Brazil are forecasted to grow substantially compared to the rest of the developed world. With this growth will come an increasing demand for better healthcare, including biologic drugs. These market opportunities along with the soon to open US market for biosimilars, also known as follow-on biologics, represent a tremendous opportunity for global growth of the biosimilars industry. The challenge will be for companies to develop appropriate global strategies to enable them to sell their product in all of the major markets, not just niche markets. A key component of any biosimilar development strategy must include the demonstration of comparability to the innovator reference product. This session will provide a detailed review of the important CMC issues of cell line development, process development, analytical methods development, and manufacturing that must be addressed in developing a biosimilar product and demonstrating its comparability with the innovator reference. The session will conclude with a discussion of different CMC strategies that companies are taking to enter and succeed in the biosimilar market. *Continued on page 2*

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Go to www.dcat.org to register and view the speakers' bios. • 1

1:00 pm

Biologic API Manufacturing: Early to End Stages

Speaker: Erik Hoglund, Director of Manufacturing, Lonza, Inc.

Given the increasing focus on the growing biosimilars industry, the existing biologics manufacturing industry faces many new challenges in its efforts for continued success. This session will provide an overview of mammalian cell fermentation from development to commercialization as well as focus on the challenges faced by the large scale manufacturing companies that are competing against new markets or biosimilar products. These companies will be forced to improve or change practices on many fronts. Areas such as process optimization, global harmonization, customer focus, and operational excellence will all be addressed.

1:30 pm

Challenges and Innovations in Downstream Processing and Purification of Biologics

Speaker: Margit Holzer, Ph.D., R&D and Technology Director, Novasep

The biosimilars market is predicted to be worth \$19.4B by 2014 with a CAGR of 89% (2009 – 2014). In Europe, biosimilar development has gained headway thanks to the progress made in registration requirements by health regulatory bodies; these improvements have helped define ways to evaluate comparability of biopharmaceuticals. Advances in analytical characterization methods have also helped to promote the development of biosimilars. The presentation will focus on novel downstream technologies and analytical methods for biosimilars, which can also help to reduce production costs.

2:30 pm

Contract Manufacturing in the "new" Pharma Supply Chain

Speaker: Hans Engels, President, DSM Pharmaceuticals Inc.

This session will review the main aspects of the challenges of the increasingly complex pharma/biopharm supply chain with regards to secondary manufacturing of biotech APIs (a.k.a. large molecules). This will include an analysis of the main success factors, like compliance vs. quality, (total) cost, supply chain management, operating working capital and security of supply. Various options to supply the worldwide market and their impact on the main success factors will be discussed.

DCAT The Drug, Chemical and Associated Technologies Association

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1-800-640-DCAT (3228)

The Drug, Chemical & Associated Technologies Association (DCAT) is the premier business development association in the pharmaceutical, chemical, nutritional and related industries. It offers a diverse range of services, programs, and activities designed to support the business development objectives of its membership.

3:00 pm

Evolving Regulations: Differences between a Requirement for an ANDA for Small Molecules vs. Biosimilars, and Review of CMC Regulations

Speaker: Gillian R. Woollett, MA, DPhil, Chief Scientist, Engel & Novitt, LLP

The US Congress, as part of health care reform, is considering proposals to create a new regulatory pathway for biosimilars.

These will be biologics that refer to a previously-licensed biologic approved under the PHS Act, just as a generic drug today refers to a previously-approved brand drug under the FD&C Act. However, the generally greater complexity of biologics has led to the emergence of legislative proposals that have more extensive regulatory expectations for the future biosimilar sponsors than apply to today's ANDA sponsors. These requirements will be discussed in terms of any final legislation enacted, and also in terms of the expectations for FDA interpretation, as well as how the sponsors of all biologics (both brand and biosimilar) will likely respond. To the extent appropriate, lessons learned from Europe and other major markets will also be reviewed.

3:30 pm

Roundtable Discussion

Registration and Fees:

The program registration fee is **\$229** for DCAT member company representatives and **\$459** for non-members. Lunch and refreshments are included. To register, visit www.dcat.org.

Event Sponsorship

Sponsorships for this program are available. Sponsors will be provided with appropriate recognition for their valued support. For more information on sponsorships, please contact the DCAT office at 1-800-640-DCAT (3228).

Directions to Hotel

The program will be held at the Parsippany Hilton Hotel at the following address: **1 Hilton Court Rt. 10
Parsippany, NJ 07054
Ph: (973) 267-7373**

From New York City take Rt. 80 West to Rte 287 South. Go 2 miles to exit 39B. Take Rte 10 West. Go 1/2 mile and turn right on Dryden Way. Make first left onto Campus Drive and first left onto Hilton Court.

From NY State take NY Thruway to Rte 287 South and continue as above.

From South Jersey take NJ Turnpike to exit for Rte 287 North. Follow to exit 39, Rte 10 West and continue as above.

From Western Pennsylvania take Rte 80 East to Rte 287 South and continue as above.

