

Coming in May

# SPECIAL REGULATORY PROGRAMS

Presented by

**UCSC Extension in Silicon Valley  
and Biologics Consulting Group**

## FDA REGULATION OF BIOTECHNOLOGY AND BIOLOGICS PRODUCTS: FROM IND TO BLA

X400.040 NATSC (1.5 quarter units) 15.0 Hours CA BRN/LVN Credit

The regulatory process for biological products differs significantly from that used for drugs and medical devices, and requires specific expertise based on the unique biochemical nature of the products. This two-day workshop, led by former FDA officials, provides a unique opportunity for biotechnology industry professionals to gain insight into the expectations and policies of FDA's Center for Biological Evaluation and Research (CBER) as well as how to interact productively with the agency.

**Day one** provides a detailed look at the IND process as it applies to biologic products, including the timing, structure and content of pre-IND meetings, and reviews currently acceptable IND formats. The content, format, and post-approval considerations of INDs are covered in depth.

**Day two** conducts a thorough review of the Biologics License Application (BLA) process including the information necessary for successful BLA planning and filing. GMP, GCP, and GLP requirements are reviewed including validation issues, biosearch monitoring inspections, and pre-approval inspections.

This course also reviews the requirements of combination products using a biological product. This course is designed for bioscience industry professionals with a basic understanding of the drug development process.

*Prerequisite(s):* Familiarity with the drug development process, gained through professional experience and/or formal course work.

JAMES G. KENIMER, Ph.D.

Guest Speakers:

RONALD MARCHESANI.

CARL ANDERSON.

See back page for instructor biographies.

### General Information

**Location:** UCSC Extension, 10420 Bubb Rd., Cupertino.

**Dates:** 2 meetings: Thursday–Friday, 8:30 am–5 pm, May 8–9.

**Fee:** \$700 (\$630 through Apr. 24).

**21339-001 (use course-section number to enroll)**

For more information, visit [www.ucsc-extension.edu/bcgbio](http://www.ucsc-extension.edu/bcgbio).

## MEDICAL DEVICES AND THE FDA: AN INSIDER'S PERSPECTIVE

X400.042 NATSC (0.5 quarter unit) 5.0 Hours CA BRN/LVN Credit

Understanding when and how to communicate directly with the FDA is crucial in speeding a medical device application to market. This special workshop takes you step-by-step through the maze of the medical device pre-approval process and highlights how to effectively communicate with FDA decision makers throughout. Explore important features of a high-quality pre-IDE submission, the most common reasons for IDE disapproval, and determine when a panel meeting is necessary. Through the use of real-world case studies, the course discusses what really matters to FDA in determining 510(k) versus a PMA, clinical study considerations, and the unique focus of FDA medical device Bioresearch Monitoring Inspections. This workshop will include a discussion of combination products including jurisdictional issues and common problems to avoid.

The lead instructor is a past medical reviewer at the FDA Center for Devices and Radiological Health and was an agency leader in developing the multicenter review practices for evaluating drug-eluting stents and other combination products.

*Prerequisite(s):* Familiarity with the pathway of medical devices to market. Completion of "Regulation of Medical Devices and Diagnostics," "Medical Devices: Regulatory Strategies and Marketing Pathways," or equivalent experience.

STUART PORTNOY, M.D.

CARL ANDERSON.

See back page for instructor biographies.

### General Information

**Location:** UCSC Extension, 10420 Bubb Rd., Cupertino.

**Dates:** Saturday, 8:30 am–5 pm, May 10.

**Fee:** \$435 (\$391.50 through Apr. 26).

**21340-001 (use course-section number to enroll)**

For more information, visit [www.ucsc-extension.edu/bcgdevices](http://www.ucsc-extension.edu/bcgdevices).



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## INSTRUCTOR BIOGRAPHIES

**JAMES G. KENIMER, Ph.D.**, is the founder and president of the Biologics Consulting Group, Inc. (BCG). Prior to founding BCG, Dr. Kenimer spent more than 15 years at the Food and Drug Administration as researcher, laboratory chief, and inspector.

**RONALD MARCHESANI** is head of West Coast Operations for the Biologics Consulting Group, Inc. Mr. Marchesani has over 29 years of biologics and biopharmaceutical industry experience in GMP quality systems, GMP compliance audits, GMP oversight of contract manufacturers, biodefense vaccines, regulatory compliance and GMP training. Prior to joining BCG, he held various senior quality managerial positions with ID Biomedical/ Shire Biologics, Acambis, Immulogic Pharmaceutical, and Genzyme. He most recently was senior director for Corporate GMP Compliance at Genentech.

**CARL ANDERSON** is a senior consultant at Biologics Consulting Group. Mr. Anderson has more than 17 years of experience with the FDA, where he conducted inspections of clinical investigators, institutional review boards (IRBs), GLP laboratories, and sponsors of clinical research in the U.S. and abroad.

**STUART PORTNOY, M.D.**, is a senior consultant in medical devices at Biologics Consulting Group. Dr. Portnoy has expertise in regulatory strategy for medical technologies, and product development for drug/device and biologic/device combination products. He assists clients with strategy and development of preclinical testing, and designing clinical protocols and drafting other documents that comply with FDA regulations and expectations. Dr. Portnoy served as a medical officer and clinical reviewer at FDA's Center for Devices and Radiological Health (CDRH) and was most recently a medical device consultant for PharmaNet.

## ENROLLMENT FORM

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**FDA Regulation of Biotechnology and Biologics Products: From IND to BLA**

Cupertino, May 8–9, \$700, **21339-001**

Early Enrollment Fee: \$630 through April 24, 2008.

**Medical Devices and the FDA: An Insider's Perspective**

Cupertino, May 10, \$435, **21340-001**

Early Enrollment Fee: \$391.50 through April 26, 2008.

Enclosed is a check for \$ \_\_\_\_\_. All fees must be paid at the time of enrollment. Make checks payable to Regents, University of California.

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