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BCG Welcomes:

CALLEY HERZOG

Calley comes to BCG with over 8 years experience in various technical engineering roles, including 3 years experience as a Biomedical reviewer at FDA in the Office of Device Evaluation, Division of General, Restorative and Neurological Devices, General Surgery Devices Branch. At FDA, Calley was involved in the review process for 510(k)s, IDEs and as lead reviewer for PMAs. Calley's combination of industry and FDA experience positions her to provide clients with a specialized understanding of regulatory processes and the challenges they may encounter when interacting with the agency.

Read Announcement

<http://www.biologicsconsulting.com/announcements/html/herzogannouncement.html>

See Curriculum Vitae

<http://www.biologicsconsulting.com/cvfiles/html/herzog.html>

IAN MILLETT, PhD, RAC

Dr. Millett was previously a Medical Device Fellow with the FDA. During his tenure, he drove the reevaluation of the agency's oversight of software containing devices. His other accomplishments include panel discussions, review of HDE devices and the review of point-of-care devices. Working within OIVD at both the 510k and PMA level, Ian brings a strong IVD background to BCG's clients. In industry, Dr. Millett directed the regulatory efforts for a broad portfolio of products including stem cell therapies, sterilization, and drug-eluting stents. Ian will utilize his broad technical and regulatory expertise to assist clients with developing market-specific and global regulatory strategies for bringing medical devices and combination products to market quickly.

Read Announcement

<http://www.biologicsconsulting.com/announcements/html/millettannouncement.html>>

See Curriculum Vitae

<http://www.biologicsconsulting.com/cvfiles/html/millett.html>

JOSEPH FRATANTONI, MD

Dr. Fratantoni is a clinical and research hematologist by training and brings over 30 years of experience in biologics research, development and regulation, with 18 of those years at the Center for Biologics Evaluation and Research (CBER) of the U.S. Food and Drug Administration (FDA). In his final four years at CBER/FDA, he was Director of the Division of Hematology. After leaving CBER in 1996, he was a consultant, specializing in blood and blood-related products, until 1999 when he joined MaxCyte, Inc in Gaithersburg, MD as Vice President, Medical Affairs and Clinical Development. While with MaxCyte he managed the clinical and regulatory aspects of development of a cell-loading technology for use with clinical cell and gene therapy.

Read Announcement

<http://www.biologicsconsulting.com/announcements/html/fratantoniannouncement.html>

See Curriculum Vitae

<http://www.biologicsconsulting.com/cvfiles/html/fratantoni.html>

BCG Welcomes Affiliates

MICHAEL VANDERZWAN, PH.D.

Michael Vander Zwan, Ph.D., a 30-year pharmaceutical industry expert in quality management and GMP compliance, is now an affiliate of BCG. His career spans both API and drug product development, regulatory approvals and commercial operations in the USA and abroad. In such roles as Vice President for QA and Compliance at Celgene Corp and at Pharmacia, and as Head of Global Quality for Roche in Switzerland and as Executive Director at Merck and Co., Inc, he played a leading role in these areas:

- developing, validating, and gaining regulatory approval to launch new products,
- implementing and improving companywide GMP compliance programs,
- designing and building new QC/QA organizations and improving operational performance of existing ones,
- gaining prompt regulatory approval for new plants,
- coaching, mentoring and developing new quality leaders,
- solving product quality and process quality problems.

Dr. Vander Zwan is adept at helping organizations build long-lasting, GMP-compliant programs, as well as resolving short-term compliance issues. He helps companies in all technical and quality aspects of new drug development, CMC preparation and preparing for regulatory pre-approval inspections. He knows how to scientifically investigate process and product quality problems, identify root causes and determine permanent corrective actions

STEVE GUTMAN, M.D.

Dr. Gutman is a board certified pathologist with over seventeen years of experience as a regulatory scientist at FDA and more than a decade of experience as Chief of the Clinical Laboratory at the Buffalo VA Medical Center. At the FDA he was a founding member and first director of the Office of In Vitro Diagnostic Devices, a unique office in the Center for Devices and Radiological Health which integrates premarket, compliance and patient safety oversight of laboratory tests. He represented FDA on the Clinical Laboratory Improvement Amendment Committee (CLIAC), the Secretary's Advisory Committee on Genomics, Health and Society (SACGHS), and on the executive committee for the US technical advisory committee to the International Standards Organization Technical Committee for laboratory tests (ISO-TC 212). At FDA he helped develop transparent standardized review processes for diagnostic devices, worked to formulate new policy in drug-diagnostic co-development, and participated in patient safety initiatives to better capture real world use of laboratory tests. He has special interests in diagnostic reasoning, method development and design, patient safety and risk communication, and personalized health care.

Contact BCG President, Jim Kenimer, Ph.D., jkenimer@bcg-usa.com if interested in Dr. Vander Zwan or Dr. Gutmans's services

Case Studies

article by: Michael Trapani, MS, MBA, Senior Consultant at BCG

Biologics Consulting Group, Inc. (BCG) is a team of consultants who provide regulatory and product development advice on the development and regulatory approval processes of biological, drug and medical device products. Often, our clients require strategic advice and assistance in making important investment decision or in addressing complex regulatory compliance challenges. The case studies described below show a sampling of the consulting services we offer.

Case # 1

Challenge:

A client (private equity company) planned to make an investment in several monoclonal antibodies drugs under clinical development in the treatment of various cancers. The company wanted a regulatory assessment of the probability of FDA approval for each of these drugs to help them estimate the potential returns and/or opportunity costs associated with their investments.

Solution:

Our regulatory assessments included a review of current FDA guidance for the approval of new drugs in the treatment of cancers; published information from FDA on the approval of similar

drugs and treatment indications; information gathered from advisory committee meetings published research information on the approvals of new biological drugs in oncology over the past two decades; and FDA mechanisms for granting fast track designation , priority review and or other opportunities for enabling an expedited pathway for drug approval.. This extensive review and assessment was performed over a two-week period to meet the client's timeline.

Case # 2

Challenge:

A client (specialty biopharma company) planned to make an acquisition of a company's approved products, intellectual properties and manufacturing facilities. The company was financing the acquisition through private investments and needed to ensure that the proposed purchase price was fair and justified based on the regulatory approval and compliance status of the company's key products.

Solution:

A regulatory assessment was performed to determine whether there were ongoing or potential regulatory compliance issues related to maintaining the approval of the marketed biologic products in the US. The assessment included a review of correspondence between the company and FDA, NDA/BLA submissions, and the results of recent FDA inspections. This extensive review and assessment was performed within a few weeks so that the client could secure financing and submit its offer.

Case # 3

Challenge:

A client had experienced recent FDA compliance issues associated with manufacturing testing and release of the several marketed in-vitro biologic products currently licensed by FDA. The company had recently undergone a merger with a larger company and found themselves with remaining staff that were either relatively new or inexperienced.

Solution:

A GMP audit and assessment was performed to identify and address gaps in the quality, laboratory and manufacturing systems. Based on the results of the audit, we provided assistance in developing and writing policies and procedures and implementing a corrective action program so that the compliance issues could be addressed and resolved.

Case # 4

Challenge:

A client company was preparing a BLA submission of the therapeutic monoclonal antibody for the treatment of autoimmune diseases. The company had recently undergone internal GLP and GCP audits identifying gaps in their operations, processes and procedures for archiving and retrieving research reports and supporting data.

Solution:

A gap assessment including process mapping was performed for archiving and retrieving reports, records and supporting data. A project team was subsequently assembled to implement improvements and to prepare the company for an upcoming FDA bioresearch monitoring inspection.

Case # 5**Challenge:**

A not for profit company, currently performing clinical research in the treatment of HIV and population control studies recognized that they needed to be trained on current FDA requirements for the manufacturing and testing of drugs products currently in Phases I and II clinical development.

Solution:

A one-day training sessions of current FDA requirements and expectation for manufacturing and testing of test materials used in clinical research was developed and presented to the company's research staff. The presentation was prepared so that the company could reuse the training materials as refresher training for new employees who may join the company in the future.

4th US FDA–Drug Information Association pharmacogenomics workshop, held 10–12 December, 2007

by Felix W Frueh, Ronald A Salerno, Lawrence J Lesko, Richard D Hockett Pharmacogenomics (2009) 10(1) reprinted permission granted by Future Medicine Ltd.

The 4th US FDA/Industry workshop, in a series on Pharmacogenomics, was on 'Biomarkers and Pharmacogenomics in Drug Development and Regulatory Decision Making' and was held on December 10–12, 2007 in Bethesda, MD, USA, with clear objectives to continue the dialogue that began in 2002 for enabling the use of biomarkers and pharmacogenomics in drug development and regulatory decisionmaking.

This brief commentary will highlight the major topics and outcomes discussed at this meeting that was jointly sponsored by the FDA, The Pharmacogenomics Working Group (PWG), The Pharmaceutical Research and Manufacturers of America (PhRMA), The Biotechnology Industry Organization (BIO) and The Drug Information Association (DIA).

Follow link to continue reading:

http://www.biologicsconsulting.com/articles/Pharmacogenomics_2009.pdf

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(<http://www.bcg-usa.com/staff/expertise.php>)

Upcoming BCG Presentations & Conference Appearances

(For complete list and speakers... <http://www.bcg-usa.com/appearances/appear.php>)

BCG consultants attend numerous conferences every year during which they are available to provide company information or consulting expertise. Below are some conferences that BCG consultants will be attending in the near future. Please feel free to contact the attending consultant either before, or during the conference for company information or to discuss a business opportunity.

Date	Sponsoring Organization	Conference and Presentation Title	BCG Attendee(s)/ Speaker (s)	Location
Apr. 9, 2009	North Carolina Biotechnology Center	Combination Products Meeting	Angela Blackwell, MS (panelist)	Research Triangle Park, NC
Apr. 15, 2009	University of California, British Consulate-General, Canadian Consulate	Stem Cell Research and Regenerative Medicine The Promise of Stem Cell Research to Enable Regenerative Medicine	Darin Weber, Ph.D.	San Francisco, CA
Apr. 16, 2009	BenAstrum	Selection and Validation of Test Methods for Host Cell Proteins	Nadine Ritter, Ph.D.(speaker)	Webinar
Apr. 25-29, 2009	CMC Strategy Forum Europe 2009	"CMC Perspectives on Biological Investigational Medicinal Products in Clinical Trials"	Nadine Ritter, Ph.D.(speaker) Ruth Wolff, Ph.D. (speaker)	Lisbon, Portugal
Apr. 26 - May 1, 2009	American Academy of Neurology	Annual Meeting	Wilson W. Bryan, MD	Seattle, WA

May 3-6, 2009	International Society for Cellular Therapy (ISCT)	Annual Meeting Pre-Conference Symposium: Translation of Stem Cell Therapies Symposium "Product Development Challenges for Stem Cell Therapies" "Quality and Manufacturing Considerations - From Concept to Pre-BLA" Session: Balancing Regulatory Expectations and Industry Realities in Proof of Concept Studies and Preclinical Data "Nonclinical Development of Cell Therapy Products – Reconciling FDA Expectations with Industry Realities"	Darin Weber, Ph.D. (speaker) David J. Pepperl, Ph.D. (speaker)	San Diego, CA
May 6, 2009	UMBC Graduate Program in Biotechnology	"Laboratory Quality Practices: R&D, GLP and GMP"	Nadine Ritter, Ph.D.(speaker)	Baltimore, MD
May 11-13, 2009	Pharmaceutical Education and Research Institute (PERI)	Clinical Trial Planning and Management "Trial Design for Efficient Drug Development "	Wilson W. Bryan, MD (co-director)	Arlington, VA
May 18-21, 2009	BIO	BIO 2009 (booth #5232)		Atlanta, GA
May 21-22, 2009	Prescription Pharma Support	CMC Analytical, Comparability And Stability Studies For Biotechnology Products: Current Expectations, Practical Considerations "Analytical and Stability Studies for Biotechnology Products"	Nadine Ritter, Ph.D.(speaker)	Singapore
May 27-29, 2009	Cambridge Health Institute	Biomarker World Congress 2009	Ron Salerno, PhD	Philadelphia, PA
June 2, 2009	BenAstrum	Regulatory Expectations for Biologics Facilities: an ex-FDA Inspector's Outlook	John R. Godshalk, MSE, MBA (trainer)	webinar Time: 1:00 PM EST
Jun. 8-11, 2009	Seton Hall Law School	Health Care Compliance Certification Program "Advertising & Promotion of Medical Devices"	Stuart Portnoy, MD (speaker)	Newark, NJ
Jun. 10, 2009	BenAstrum	"Comprehensive Forced Degradation Studies to Validate Stability-Indicating Methods for Biotechnology Products"	Nadine Ritter, Ph.D.(speaker)	Webinar

Jun. 22-24, 2009	American Association of Pharmaceutical Scientists (AAPS)	AAPS 2009 National Biotechnology Conference "Phase I INDs for Biologics: How Much Data is Adequate"	Ron Marchesani (speaker)	Seattle, WA
Jun. 25-26, 2009	IIR-PTI	CMC Analytical, Comparability and Stability Studies for Biotechnology Products "Current Expectations, Practical Considerations"	Nadine Ritter, Ph.D.(speaker)	London , UK
Aug. 17-18, 2009	Cambridge Healthtech Institute	Production & Manufacturing of Vaccines (part of the ImVacs Immunotherapeutics & Vaccine Summit) "Essential Quality Considerations for Today's Manufacturing of Vaccines: The Do's and Don'ts for Successful Audits and Inspections"	Ron Marchesani (speaker)	Providence, RI
Sept. 12-13, 2009	SEAK, Inc.	National Non-Clinical Careers For Physicians "Networking Your Way Into a Non-Clinical Career: Industry, Government & Consulting"	Stuart Portnoy, MD (speaker)	Chicago, IL

Contact Us:

Main Office

1317 King St
Alexandria, Virginia 22314
Tel: (703) 739-5695
Fax: (703) 548-7457
bcg@bcg-usa.com

West Coast Office

1840 Gateway Drive
Suite 200
San Mateo, California 94404
P (650) 378-1303
F (650) 378-1399

North Carolina Office

5001 Weston Parkway
Suite 200A
Cary, North Carolina 27513
Tel: (919) 657-0435
Fax: (919) 657-1737

New England Office

310 N. Main Street

Unit 610

Mansfield, Massachusetts 01757

Tel: 508-541-8883

Beijing Office - Beijing, China

Beijing China Life Tower

5/F China Life Tower

16 Chao Wai Street

Chaoyang District

Beijing 100020

China

BCG-Japan - Tokyo, Japan

Shinkawa KS Building 3F

2-22-6 Shinkawa

Chuo-ku, Tokyo 104-0033

Telephone Number: +81-(0)3-6802-9230

Fax Number: +81-(0)3-3555-3717