

To view the BCG Bulletin online, go to: http://www.bcg-usa.com/news/newsletter_issue43.php

BCG Welcomes:

HOLLY SCOTT

Holly McNair Scott, a former FDA Field Investigator, will be joining Biologics Consulting Group, Inc., as a Senior Consultant for Biologics and Dietary Supplement inspections, investigations, and audits, on September 1, 2009.

Holly comes to BCG with over 18 years of multi-office experience with the Food and Drug Administration, including 4 years as a Consumer Safety Officer with the Center for Biologics Evaluation and Research, and 14 years as a Field Investigator with the Office of Regulatory Affairs Florida District Office (Miami and Orlando), specializing in the inspections of Blood, Plasma, and Human Tissue establishments, and Dietary Supplement Manufacturers. In addition, Holly brings many years of experience as a Clinical Investigator, IRB, Sponsor/Investigator, and Drug GMP Inspector. In 2002, Holly was awarded her FDA Level II Certification in Blood Banks and Plasma Centers, recognizing her expertise in the area of Biologics Inspections.

Read Announcement

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

See Curriculum Vitae

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

Job Openings

Position available

Title: Associate – Electronic Publishing

Biologics Consulting Group, Inc. (BCG) seeks to hire a full-time electronic publishing associate with practical experience publishing electronic IND, Master File, BLA, and NDA submissions.

Candidate will work from BCG's Alexandria, Virginia office.

Responsibilities:

Major Duties and Responsibilities:

- Convert source documents in various formats to FDA guidance compliant PDF documents
- Bookmark and hyperlink PDF documents per FDA specifications
- Compile PDF documents into both legacy and eCTD submissions
- Detailed tracking of project progress
- Audit of submissions for completeness, bookmark/hyperlink accuracy, correct document placement, etc.
- Write proposals for publishing projects

Qualifications:

- BS or BA degree; relevant discipline preferred
- 1-2 years hands-on experience with electronic submissions publishing
- experience with multiple tools/plugin used for publishing FDA guidance compliant PDF documents
- experience with eCTD publishing software
- proficiency in formatting of MS Word documents
- familiarity with documents normally included in FDA submissions
- familiarity with all FDA electronic submissions guidance documents
- ability to communicate clearly with clients regarding ongoing projects
- attention to detail
- ability to work on multiple projects simultaneously while maintaining deadlines
- ability to work on projects involving large numbers of documents
- requires minimal instructions on routine work and new assignments
- comfortable working in a team environment

Biologics Consulting Group, Inc. (BCG) is an international consulting firm whose consultants provide national and international regulatory and product development advice on the development and commercial production of biological, drug, and device products. Our staff consists of experts in regulatory affairs, product manufacturing and testing, pharmacology/toxicology, facility inspections, statistics, program management, and clinical trial design and evaluation. Many of our consultants are former CBER, CDER, and CDRH reviewers, certified FDA inspectors, and senior scientists from the biotechnology industry. We offer a great work environment, as well as a highly competitive salary and benefit package, including healthcare and 401k plans.

An immediate start is preferred.

Email Curriculum Vitae to: epubjob@bcg-usa.com

Position available: Project Manager

Biologics Consulting Group, Inc. (BCG) seeks to hire a full-time Project Manager with practical experience with INDs and/or BLAs, and related regulatory maintenance activities. The successful candidate will assist clients with producing quality regulatory documents for submission to the FDA within projected timelines.

Candidate may work predominantly from home; however, must be located in sufficient proximity to work in BCG's Virginia office, as necessary.

Responsibilities:

Assist clients with:

- Understanding current FDA regulations, policies and guidelines.
- Managing preparation, organization and submission of IND's (legacy and CTD format), BLA's, annual reports and other documents critical to product life cycle.
- Coordinating BCG review teams.
- Planning of documents, participants, and resources for FDA meetings.
- Write/coordinate proposals for projects.
- Perform budget tracking for projects.

Qualifications:

- BS or BA degree required; relevant discipline and/or FDA experience preferred.
- 7+ years experience in IND and/or BLA Project Management and in coordinating documents, participants, etc. for FDA meetings.
- Familiarity with documents normally included in FDA submissions.
- Comprehensive knowledge of current FDA regulations, policies and guidelines.
- Attention to detail.
- Ability to work on multiple projects simultaneously while maintaining deadlines.
- Able to work both independently and in a team environment.
- Proficiency in formatting of MS Word documents.
- Proficiency in MS Word, MS Excel; MS Project proficiency desirable.

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An immediate start is preferred.

Email Curriculum Vitae to: pmjob@bcg-usa.com

**BCG exhibiting at RAPS, BioWest, ISBTC,
Mid-Atlantic Bio, BioFlorida**

RAPS Annual Conference
September 13-16
Philadelphia, PA

BCG representatives at the meeting will include:

Dr. John Jessop, Director of Pharmacology-Toxicology at BCG who has expertise in pharmacology-toxicology, regulatory affairs and product development for biologics and drugs and served as an FDA reviewer at CDER for nine years.

Contact Dr. Jessop <http://www.bcg-usa.com/contact/cform.php?staffid=17>

Dr. Melanie Hartsough, Senior Consultant (Pharmacology-Toxicology) at BCG who has expertise in pharmacology and toxicology, nonclinical development of biologic products and nonclinical and clinical immunogenicity issues served as an FDA reviewer at CBER for five years. Dr. Hartsough is speaking on "Implementation of the Case-by-Case Approach: Practical Applications" during the conference.

Contact Dr. Hartsough <http://www.bcg-usa.com/contact/cform.php?staffid=28>

Ms. Calley Herzog, Consultant (Medical Devices) at BCG who has expertise in regulatory project management for all types of premarket submissions and served as an FDA biomedical reviewer at CDRH for three years.

Contact Ms. Herzog <http://www.bcg-usa.com/contact/cform.php?staffid=64>

Dr. Ian Millett, Senior Consultant (Medical Devices) at BCG who has expertise in driving successful regulatory strategies for medical devices and combination products in the EU, Canada, and U.S. and served as an FDA IVD reviewer at CDRH for three years.

Contact Dr. Millett <http://www.bcg-usa.com/contact/cform.php?staffid=65>

Dr. Miriam Provost, Senior Consultant (Medical Devices) at BCG who has expertise in developing successful regulatory strategies for medical devices and combination products and served as an FDA reviewer at CDRH for thirteen years. Dr. Provost is speaking on "Navigating the Scientific and Regulatory Dividing Line Between Drugs and Devices" and chairing a session titled "Tissue Engineered Combination Products— Coordination Is Key."

Contact Dr. Provost <http://www.bcg-usa.com/contact/cform.php?staffid=59>

Ms. Kelly Reich, Associate at BCG with eight years of expertise in project management and regulatory submissions including INDs and BLAs.

Contact Ms. Reich <http://www.bcg-usa.com/contact/cform.php?staffid=2>

Ms. Holli Vaughan, Associate at BCG with twelve years of regulatory affairs expertise in product development strategies, planning and management as well as being responsible for all regulatory activities, including the preparation of regulatory submissions, the drafting of protocols and reports, the establishment of SOPs and the assurance of data quality and integrity.

Contact Ms. Vaughan <http://www.bcg-usa.com/contact/cform.php?staffid=48>

Please visit us at booth #520!

International Society for the Biological Therapy of Cancer

October 28-31

Washington, DC

2009 BioWest Conference

November 10

Denver, CO

2009 Mid-Atlantic Bio Conference

November 4-6, 2009

Washington, DC

BioFlorida 12th Annual Conference

November 4-6, 2009

Orlando, FL

View BCG's Expertise Listing

(<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
Sept. 8-9, 2009	IIR	Stability Testing for Biologics "Stability Testing Performed Over A Product Lifecycle"	David Lin, Ph.D. (speaker)	Prague, Czech Republic
Sept. 9, 2009	BenAstrum	USP – Chapter 467 & GMP Requirements for Testing Residual Solvents	Nanda Subbarao, Ph.D. (speaker)	Webinar 1:00-4:00pm EDT
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
Sept. 13-16, 2009	RAPS	Annual Conference - Booth #520 "Implementation of the Case-by-Case Approach: Practical Applications" (Hartsough) "Combination Products & Cross Labeling -- Fact or Fiction?" (Portnoy) "Navigating the Scientific and Regulatory Dividing Line Between Drugs and Devices" (Provost) "Tissue Engineered Combination Products— Coordination Is Key" (Provost)	Melanie Hartsough, PhD (speaker) Calley Herzog Ian Millett, PhD Stuart Portnoy, MD (speaker) Miriam Provost, PhD (speaker/chairperson) Michael Trapani, MS, MBA Kelly Reich, MS Holli Vaughan, MS, RAC	Philadelphia, PA
Sept. 16-17, 2009	PDA	PDA Combination Products Workshop "Status of Current Regulatory Frameworks and Perceived Problems" (Gross) "Plenary Session 6 - Safety Reporting" (Portnoy)	Michael Gross, Ph.D. (speaker) Stuart Portnoy, MD (speaker)	Washington, DC
Sept. 21-23, 2009	Genetics Policy Institute	World Stem Cell Summit	Ellen M. Areman, MS, SBB	Baltimore, MD

Sept. 24-25, 2009	AAPS (American Association of Pharmaceutical Scientists)	Current Trends in Stability "Stability requirements for Biologics"	Nanda Subbarao, Ph.D. (speaker/moderator)	National Harbor, MD
Sept. 28, 2009	DIA	Biosimilar Workshop	John Jessop, Ph.D., MPH	London, UK
Sept. 29-30, 2009	IBC Life Sciences	Forced Degradation studies for Biopharmaceuticals	Nanda Subbarao, Ph.D. (course instructor)	Boston, MA
Sept. 30 - Oct. 2, 2009	Roche Colorado	Roche Colorado Corporation Peptide Symposium	Blair Fraser, Ph.D. (speaker)	Boulder, CO
Oct. 1-2, 2009	IBC Life Sciences	GLPs and GMPs for Biopharmaceutical Development	Nanda Subbarao, Ph.D. (course instructor)	Boston, MA
Oct. 7-10, 2009	Biomedical Engineering Society (BMES)	BMES 2009 Annual Fall Scientific Meeting "Translational Bioengineering: Overcoming the Ultimate Barrier to Entry: Commercialization, Regulation, and the FDA"	Ian Millett, Ph.D. (speaker)	Pittsburgh, PA
Oct. 24-27, 2009	AABB (American Association of Blood Banks)	Annual Meeting & TXPO Validation Rules & Regs: How do they apply to me?	Joseph Fratantoni, MD Ellen M. Areman, MS, SBB (moderator)	New Orleans, LA
Oct. 26, 2009		FDA Immunotoxicology Forum	Melanie Hartsough, PhD John Jessop, Ph.D., MPH	Silver Spring, MD
Oct. 26-29, 2009	Seton Hall Law School	Health Care Compliance Certification Program "Advertising & Promotion of Medical Devices"	Stuart Portnoy, MD (speaker)	New Brunswick, NJ
Oct. 28-31, 2009	iSBTc (International Society for the Biological Therapy of Cancer)	2009 Annual Meeting	Michael Salgaller, Ph.D.	Washington, DC

Nov. 1-4, 2009	American College of Toxicology (ACT)	30th Annual Meeting	Melanie Hartsough, PhD John Jessop, Ph.D., MPH	Palm Springs, CA
Nov. 4-6, 2009	Mid-Atlantic BIO	2009 Mid-Atlantic Bio	Jim Kenimer, Ph.D.	Washington, DC
Nov. 4-6, 2009	BioFlorida	12th Annual Conference	Michael Salgaller, Ph.D. Holly Scott	Orlando, FL
Nov. 9-10, 2009	IBC Life Sciences	Forced Degradation studies for Biopharmaceuticals	Nanda Subbarao, Ph.D. (course instructor)	San Francisco, CA
Nov. 9-11, 2009	IBC Life Sciences	Well Characterized Biologicals	Nadine Ritter, Ph.D.(chairperson)	Bethesda, MD
Nov. 10, 2009	BioWest	Annual Meeting (Booth #34)	Julia Barrett, MD Calley Herzog Michael Salgaller, Ph.D. Ann Sutton Annie Zurbay	Denver, CO
Nov. 11-12, 2009	IBC Life Sciences	GLPs and GMPs for Biopharmaceutical Development	Nanda Subbarao, Ph.D. (course instructor)	San Francisco, CA
Nov. 12-13, 2009	IBC Life Sciences	De-Risking Next Generation Biologics	Blair Fraser, Ph.D. (speaker)	Bethesda, MD
Dec. 5-8, 2009	American Society of Hematology	51st ASH Annual Meeting and Exposition	Joseph Fratantoni, MD	New Orleans, LA

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