

To view the BCG Bulletin online, go to: http://www.bcg-usa.com/news/newsletter_issue44.php

BCG Welcomes:

BARBARA J. POTTS, PHD

Barbara Potts joined Biologics Consulting Group, Inc. in November 2009 as a Senior Consultant. Barbara has 28 years experience in the science, compliance and business aspects of the control of adventitious agents (TSE, viruses, mycoplasma) in the bio pharmaceutical, HIV vaccine and immuno therapy, xenotransplantation and cell therapies industries. This experience was gained at the University of California, School of Medicine, San Francisco, the NICDS/NIH, NIAID/NIH, University of MN School of Veterinary Medicine, two contract testing companies and three biotechnology companies. She is an experimental pathologist with a specialty in virology and has experience from product R&D to IND and BLA acceptance. She has interacted with regulatory agencies, biotechnology companies, Veterinary, Medical, animal owner communities (raw material sources) and recently with the manufacturing diagnostic industry on the development of a commercial PCR kit for the detection of mycoplasma in GMP lot release testing.

Read Announcement

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

See Curriculum Vitae

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

AARON TETTEH-AHINAKWA, M.S.

Aaron Tetteh-Ahinakwa joined Biologics Consulting Group, Inc. in November 2009 as an Associate Project Manager. Aaron has over 14 years of Regulatory Affairs/submission and Project Management experience working as an independent consultant for large pharma groups including Pfizer, Sanofi-Aventis, Glaxosmithkline (GSK) and Bristol Myers Squibb (BMS).

Read Announcement

<http://www.biologicsconsulting.com/announcements/html/tetteh-ahinakwaannouncement.html>

See Curriculum Vitae

<http://www.biologicsconsulting.com/cvfiles/html/tetteh-ahinakwa.html>

BEN WIMMER

Ben Wimmer joined Biologics Consulting Group, Inc. in November 2009 as an Associate for our e-publishing group. Prior to joining BCG Ben worked as an electronic publishing specialist at PPD, Inc. providing clients with submission-ready, regulatory-compliant deliverables in CTD/eCTD, eNDA, and hybrid formats.

See Curriculum Vitae

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

Spotlight on Comprehensive Regulatory Affairs Support article by [Louise Johnson](#), BCG Sr. Consultant

Biologics Consulting Group's experts augment your internal regulatory affairs capabilities by offering comprehensive services – from developing the Global Regulatory Strategy to complete regulatory affairs management of all biologic, device, diagnostic, combination product, and drug submissions. Because of our extensive FDA and industry experience, our advice is likely to be accurate and current from the onset – thereby avoiding the time-consuming and expensive process of having to recover, revise, or revisit a failed or incomplete strategy. We understand the changing development and regulatory environment, and consider both FDA and global regulatory authority expectations when crafting strategies.

Our consultants have extensive experience creating and submitting successful INDs, BLAs, NDAs, CTAs, MAAs, 510(k)s, PMAs, and RFDs. We also have experience with pharmacogenomic and biomarker voluntary submissions, WHO Prequalification Product Summary Files, and orphan product designation requests. We provide expert advice throughout the product development life-span – starting with initial submission planning, content writing, review, and regulatory agency discussions. We have led numerous meetings with regulatory authorities, guiding and coaching clients to increase the probability of successful negotiations.

Regulatory Submissions – The Complete Overview

We serve as project managers of entire submissions to ensure consistent messaging, identify any discrepancies within the submission, and ensure the submission meets current agency expectations. Further, our consultants bring their cumulative CMC, preclinical and clinical experience from previous submissions to give guidance on approaches likely to be successful.

We take a broad view of each submission, identifying and highlighting gaps, unclear issues, and topics likely to prompt agency questions. We understand how the FDA reviews submissions, and provides advice on formats, approaches to support discussions or conclusions, and ways to frame information so that the FDA can easily understand the issues.

Benefits from Biologic Consulting Group Expertise

Since 1993, all of this deep and extensive understanding has produced to a consistently effective work process for creating the submission, greater likelihood of successful outcomes, and enhances a company's reputation at the agency. Biologics Consulting Group, known for scientifically valid, thoughtful, responsible, and easily reviewable submissions, has the trust of reviewers – which is especially useful for future discussions when unforeseen problems may arise.

Biologics Consulting Group will work with your company in whatever manner matches your business needs – from planning and preparing a submission to acting as a project manager, or filling the role of a regulator affairs liaison for the team.

Agency Negotiations

We have extensive experience meeting with regulatory agencies and responding to agency requests. We quickly understand any issues raised by the agency, put them into perspective, and help your organization successfully respond to questions. We can also identify a seemingly simple question that may actually touch on a fundamental issue for your product; thus avoiding unpleasant surprises and outcomes.

Labeling Negotiations

We understand the importance of successful labeling negotiations, and help define language that supports your business goals and is likely to gain approval from the agency. We compare current label language for similar products, if available, and help streamline the process of drafting the label for agency review. When the agency suggests restrictive changes, we identify alternative wording that still support strategic business and commercialization goals.

Marketed Products

Once your product is marketed, we support your product with promotional material review, assessment of newly reported adverse experiences, and planning for the appropriate approvals for any manufacturing changes.

If a new and serious safety signal arises, we evaluate the signal, plan any new studies needed to investigate, and discuss with the agency both the work as well as any needed labeling change. Lastly but importantly, we can be an independent advisor when your staff may be overwhelmed.

Over 16 years of deep and comprehensive regulatory affairs and product development experience makes Biologics Consulting Group a powerful ally to assist you with biologics, devices, diagnostics, combination products, and drugs.

Spotlight on BioSimilar Protein Products

article by [Blair Fraser, PhD](#), BCG Sr. Consultant

For almost three decades, recombinant DNA (rDNA) technology has enabled production of a variety of protein products that can be used in treating many life-threatening, chronic

diseases. Over the past decade, much interest has arisen about “Biosimilar” protein products – primarily due to the expiration of their patent protection. These protein products are intended to be sufficiently similar to an already-approved, reference product to permit the biosimilar applicant to rely, in part, on certain scientific knowledge about the approved product to demonstrate safety and effectiveness in a marketing application.

In contrast to small-molecule generic drugs, where the active ingredient is pharmaceutically equivalent (identical) to the listed drug, characteristics of the biopharmaceutical are critically dependent on the manufacturing process. These biopharmaceuticals are typically complex protein products whose features mirror the particular protein expression constructs, culture conditions, extraction processes, purification processes, storage conditions, and liquid formulations.

Differences arise as a result of this complexity of structure and manufacture. These may affect pharmacological behavior, safety, and clinical performance, such as:

Differences between the biosimilar and the reference product (similarity)

Differences when approved protein products undergo major manufacturing changes (comparability)

Differences designed to improve performance, while maintaining the same mechanism of action as the original product (Second Generation Protein Products)

Europe

The European Union was the first major regulatory authority to adopt a procedure allowing regulatory approval of biosimilar medicines. In 2004, using a specially adapted approval procedure developed by the European Medicines Agency, the biosimilar approach allows an abridged development program, wherein the applicant may rely upon certain scientific knowledge about the efficacy and safety of a reference product in supporting their marketing application. This procedure is based on a thorough demonstration of "comparability" of the "biosimilar" product to an existing approved product.

World Health Organization

In 2007, as part of its mandate for assuring global quality, safety, and efficacy of biotherapeutics, the World Health Organization recognized the need to provide guidance for the development and evaluation of biosimilar protein products. The result of multiple consultations was “Guidelines On Evaluation Of Similar Biotherapeutic Products (SBPs).”

United States

In the US, the Food and Drug Administration (FDA) has taken the position that new legislation will be required to address the issue of similar enough to rely upon the Agency’s prior findings of safety and efficacy. FDA also believes that the Public Health Service Act does not contain an abbreviated approval pathway analogous to the Federal Food Drug and Cosmetic Act. Part of the current healthcare legislation pending before Congress provides for amending the Public Health Service Act with an “Approval Pathway For Biosimilar Biological Products.”

How can Biologics Consulting Group help?

Biologics Consulting Group (BCG) experts are uniquely qualified to assist clients with the scientific, product development, and regulatory issues that are associated with Biosimilar Biological Products. Our FDA and industry experience enables us to advise clients about various types of biosimilar products, second-generation protein products, and within-product manufacturing changes. Working with clients from the early stages of development, BCG consultants can help you plan the full or abridged product development necessary to achieve commercial success.

BCG Contributions to: Cellular Therapy: Principles, Methods, and Regulations

Edited by Ellen M. Areman, MS, SBB(ASCP), and Kathy Loper, MHS, MT(ASCP)

This manual was designed as a compendium of state-of-the-art practices and methods for cellular therapy to aid in the development and operation of a clinical cellular therapy facility. Designed for those in academia, government and industry, it is also an essential reference for those in regulatory affairs and quality assurance as well as for laboratory technologists, managers, directors, physicians and scientists. Through descriptions of the rationale and methodology for a variety of cell processing and evaluation techniques, it will assist laboratory staff in developing procedures that comply with applicable regulations and standards. In addition to numerous examples and templates for laboratory document preparation, several methods are provided that include a general overview of the critical steps, materials and equipment used in each process. Each section has been compiled and edited by a team of experts in the field, with subchapters contributed by specialists in the specific subject matter. Also included is a fully searchable CD-ROM with appendices on Methods and Forms in Word format so they can be fully customized.

(AABB, 2009, soft cover, CD-ROM included, ISBN# 978-1-56395-296-8)

In addition to BCG Sr. Consultant [Ellen Areman](#) the following BCG consultants also contributed to this book: [Dr. Darin Weber](#), [Mr. John Godshalk](#) and [Mr. Dan Offringa](#).

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
Dec. 5-8, 2009	American Society of Hematology	51st ASH Annual Meeting and Exposition	Joseph Fratantoni, MD John Humphries, MD	New Orleans, LA
Jan. 24-27, 2010	CaSSS	CMC Strategy Forum/WCBP Industry-FDA meeting	Nadine Ritter, Ph.D.(speaker)	Washington, DC
Feb 2-5, 2010	DIA	Generating and Weighing Evidence in Drug Development and Regulatory Decision Making "Development of an IVD with Approved Drugs"	Ron Salerno, PhD session chair	Bethesda, MD
Feb 3-5, 2010	Pharma Conference	6th Annual FDA and the Changing Paradigm for HCT/P Regulation "Labeling for HCT/Ps – Convergence or Divergence?"	Darin Weber, Ph.D. (speaker)	Orlando, FL
Mar 15-19, 2010	PDA	2010 PDA Annual Meeting "Update on the Activities of the Mycoplasma Task Force"	Nadine Ritter, Ph.D.(speaker) Barbara Potts, PhD (speaker)	Orlando, FL
Apr 20-21, 2010	PDA	2010 PDA Workshop on the Impact of Bio-Films on Pharmaceutical and Biopharmaceutical Manufacturing	Barbara Potts, PhD (co-chair)	Frankfurt, Germany
Apr 22, 2010	PDA Mycoplasma Task Force Filtration sub group	Consensus rating for evaluating filters for the removal of mycoplasma.	Barbara Potts, PhD (training co-leader)	Frankfurt, Germany
Apr 25-28, 2010	CaSSS	EU CMC Strategy Forum	Nadine Ritter, Ph.D.(speaker)	Vienna, Austria
May 16-19, 2010	AAPS	National Biotechnology Conference	Nadine Ritter, Ph.D.(speaker)	San Francisco, CA
Jun 14-15, 2010	USP	Bioassay Workshop	Nadine Ritter, Ph.D.	Rockville, MD
Jul 19-20, 2010		CMC Strategy Forum	Nadine Ritter, Ph.D.(speaker)	Bethesda, MD
Aug 1-6, 2010	ACS	Recovery of Biological Products XIV	Nadine Ritter, Ph.D.(speaker)	Lake Tahoe

Sep 13-15, 2010	PDA	Annual Conference/Joint Task Force Meeting	Nadine Ritter, Ph.D.(speaker)	Washington, DC
Oct 9-12, 2010	AABB	Annual Meeting & TXPO	Joseph Fratantoni, MD	Baltimore, MD
Oct 20-21, 2010	CaSSS	Bioassay Workshop	Nadine Ritter, Ph.D.(speaker)	Bethesda, MD
Nov 14-18, 2010	AAPS	Annual Meeting	Nadine Ritter, Ph.D.	New Orleans, LA
Dec 4-7, 2010	American Society of Hematology	Annual Meeting	Joseph Fratantoni, MD John Humphries, MD	Orlando, FL

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