

To view the BCG Bulletin online, go to: http://www.bcg-usa.com/news/newsletter_issue46.php

BCG's Corporate Office Has Moved!!
Please update your records to our new address:
400 N. Washington Street
Suite 100
Alexandria, VA 22314

BCG Welcomes:

L. BRUCE PEARCE, PH.D.

Bruce Pearce joined the BCG team in July of 2010. Bruce is a pharmacologist who brings 20 plus years of academic and industry experience encompassing many aspects of biologics development including design, development, analysis, oversight, and regulatory reporting of pharmacology, toxicology, pharmacokinetic, safety pharmacology, physiologic research and Phase I-III clinical trials. Expertise in non-clinical and clinical pharmacology/toxicology, program strategic/technical design, quantitative outcomes analysis, and benefit-risk balance assessment. Therapeutic areas include; treatment of anemia due to surgery, trauma, chemotherapy, emergency research under exception to informed consent (21 CFR 50.24) including in/pre-hospital resuscitation from hemorrhagic shock due to trauma. Treatment of cardiac, cerebral and peripheral ischemia and therapeutic use of botulinum toxin.

Read Announcement

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

See Curriculum Vitae

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

DAVID ROUSE, M.S.

David comes to BCG with over 23 years experience in the research, review and regulation of biological products within FDA/CBER and the biopharmaceutical industry. Most recently, David was the head of CMC Vaccines regulatory affairs group for Pfizer Pharmaceuticals, Inc. (previously Wyeth Pharmaceuticals, Inc.) at the Sanford, NC location. David led a department of nine regulatory affairs professionals responsible for the development of global regulatory strategies to support successful domestic and international regulatory submissions for licensed and clinical vaccines. Prior to joining Wyeth, David was a biologist for over 12 years at the Food and Drug Administration's Center for Biologics Evaluation and Research, Office of Vaccines Research and Review.

Read Announcement

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

See Curriculum Vitae

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

President/CEO Job Opening

Biologics Consulting Group, Inc. (BCG), a nationally recognized biopharmaceutical product development and regulatory consulting firm, with offices in Alexandria, VA (head office); Cary, NC; Franklin, MA; San Francisco, CA, and Tokyo, Japan, is seeking candidates for the position of President and Chief Executive Officer (President/CEO).

Specific Role:

BCG has developed a prominent reputation in the biopharmaceutical regulatory community. The President/CEO will be expected to represent BCG in a manner which will continue to grow and enhance that reputation.

The President and CEO will assume full operational and executive responsibilities for the day-to-day activities of BCG, operating from its head office in Alexandria, VA. and will report directly to the Board of Directors.

Responsibilities and duties of the CEO include:

- Overall responsibility for BCG consulting staff, administrative staff, and all operational activities.
- Lead and contribute to the maintenance of a culture which supports the retention and recruitment of an exceptional consulting staff.
- Maintain working knowledge of BCG expertise and employee utilization to provide appropriate consultants to projects as required.
- Responsible for all US Agent activities performed by BCG.

- Prepares such reports as the Board of Directors may require to maintain an on-going awareness of BCG operations.

Professional Qualifications:

- Recognized for his/her expertise in biopharmaceutical regulatory affairs and product development.
- Minimum of fifteen years experience in biopharmaceutical regulatory affairs with demonstrable knowledge of the policies and practices of the US FDA as they pertain to approval of biotechnology products. Previous FDA experience is desirable, but not required.
- An M.D. or Ph.D. in a relevant discipline is desirable, but not required.
- Able to develop a strategic direction for the company and to apply and adapt strategies to achieve organizational goals.
- Understand financial statements (including income statements, balance sheets, and cash flow statements) and understand the importance of achieving outstanding financial results. Ability to work closely with VP Finance in order to anticipate and resolve potential financial issues.
- A demonstrated ability to plan, direct, and manage the operations, programs, and staff of a complex organization.
- Strong communication skills.

Compensation:

- BCG, Inc. offers an excellent salary and benefits package.

Qualified candidates should forward their CV and statement of qualifications for the position to: cejob@bcg-usa.com

The Changing Regulatory Environment in 2010

FDA (CDER) GCP Inspections

article by Michael Trapani, MS, MBA, BCG Sr. Consultant

If your company is planning a submission of a BLA or NDA in the foreseeable future, you should be paying close attention to the changing regulatory environment related to FDA inspections of clinical trials. You will need to be prepared for a comprehensive FDA inspection process which may further delay the approval of your drug. And, if you are outsourcing your clinical studies, you will need to demonstrate how you provided adequate oversight of the CRO for assuring compliance with Good Clinical Practices (GCPs) and FDA regulations. The following paragraphs provide background for FDA's new inspectional approach.

Background

FDA verifies the reliability of clinical data submitted as part of a BLA or NDA through its Bioresearch Monitoring Inspection Program (BIMO). Once a BLA or NDA is considered filed for review by the FDA review team, the responsible BIMO inspectional unit begins planning inspections of clinical study sites. For BLAs and NDAs submitted to Center of Drug Evaluation and Research (CDER), the Division of Scientific Investigations (DSI) schedules inspections of clinical study sites participating in pivotal trials used to substantiate the safety and efficacy of the drug. DSI would select four or five clinical study sites for inspection. If the outcome of the inspections did not uncover serious GCP violations, FDA considered the clinical data from all the clinical sites to be reliable even if more than 250 clinical sites participated in the study. If the outcome of the FDA inspections noted GCP violations at some, but not all of the clinical sites inspected, FDA would exclude the data from the clinical sites where GCP violations occurred and assume that the data was reliable from the remainder of the clinical sites participating in the study.

This FDA inspectional approach for verifying the reliability of clinical trial data received criticism during the past five or six years from the US Congress and other interested parties who questioned the adequacy of FDA's oversight of clinical research. The very public criticism of the FDA for the approval of an antibiotic in 2004 subsequently associated with several patient deaths resulted in a change in FDA policy and the recent comprehensive inspectional approach for clinical trials.

New Inspectional Approach

According to the March, 2010 presentation by Leslie Ball, Director, DSI, FDA has recently moved to a more robust inspection process. DSI will select four or more clinical study sites but will also schedule inspections at the Study Sponsor and/or CRO¹ responsible for monitoring the clinical study. If GCP violations are noted during the clinical study site inspections or if there is evidence of inadequate monitoring of the study, FDA will schedule more clinical site inspections to determine the extent of GCP violations across all study sites. If the additional inspections uncover further noncompliance, FDA will request the Sponsor to conduct QA audits of a large sample (e.g. > 25%) of the clinical study sites participating in the clinical study. The outcome of these audits will help determine the reliability of the clinical data and whether FDA will accept the data for BLA or NDA approval.

How to Prepare

With the changes in the FDA inspectional approach, it is in your best interest to start the preparation process early in the clinical trial program. If you plan to outsource the conduct of your clinical studies, you will need to play a more active role in the oversight of the CRO. You will also be expected to perform QA audits of a greater percentage of the clinical study sites participating in the clinical study and/or of the CRO. These QA audits, when performed early in the clinical study, could help identify and correct GCP violations before they negatively impact on reliability of your clinical study data or to the subsequent approval of your BLA or NDA.

If you are interested in learning more about how BCG may assist you in this changing regulatory environment, please Contact Michael A. Trapani.

Michael Trapani

908-359-9519

¹ CDER increased the number of Sponsor/ Monitoring Inspections from 25 in 2007 to 73 in 2009.

Challenges of a Quality Assurance Unit at Early Product Development

article by **Ellen Raaf, MT ASCP, BCG Sr. Consultant**

A Quality Management System should encompass collective practices to minimize nonconformances to specifications, standards, and customer satisfaction in an efficient and cost effective manner.

Managing and overseeing these multiple quality facets can be a daunting task for the Quality Assurance unit, especially when supporting start-up companies at very early product development. Frequently, the Quality unit is understaffed and required to wear multiple hats trying to balance the science with compliance.

The growing pains when advancing from Phase 1, 2 to Phase 3 are numerous. Ideally, all essential Quality elements should be in practice to include controls of the production system, facilities and equipment, laboratory, materials, and packaging and labeling. Realistically, many systems may not be adequately in place. Systems currently in place should be assessed by performing gap analysis. Those systems that are deficient should be identified and prioritized based on risk assessment. Review of the Quality elements should be a joint effort with all departments involved to mitigate unnecessary deviations and to optimize the efficiency.

Additional specific systems overseen, monitored or performed by the Quality unit:

- Documentation and documentation control (i.e. SOPs, batch records, protocols)
- Training
- Tracking and Trending data, and other metrics
- Nonconformances (OOS, deviations, investigations, stability failures)
- Customer Complaints
- Adverse Events
- CAPA
- Calibration and Preventative Maintenance
- Audits
- Supplier Quality
- Change Control
- Batch review and disposition

Many of early phase companies are drowning in paper-based systems which often lend themselves to fail to address systemic quality problems. Paper-based systems cause clutter and stress the archiving systems. Batch and data retrieval are often difficult.

Consideration should be taken to evaluate electronic quality management systems. It has been established that electronic quality management systems shorten cycle times and improve overall product and process quality through the ability to perform trend analysis and identify quality issues more timely.

Most software packages are 'out of the box' and off the shelf modules which meet 21 CFR part 11. A few packages used in the life sciences include: Pilgrim, Master control, Title 21, Metric Stream and Sparta Systems. These systems generally provide validation scripts and provide ease of implementation. The electronic quality system vendor needs to address a best fit solution for the individual company. Ideally, one should purchase a one-time package that will address future growth to preclude another software purchase later down the road. The key to successful implementation requires thorough understanding of the work flows; this is where inter-departmental collaboration is required.

Although cost may be a major budget constraint, many software companies provide discount to smaller companies based on the number of employees. There are many benefits of having an electronic quality management system which far out way the cost; shortened and improved batch release and improved product quality.

Consultants from Biologics Consulting Group (BCG) are actively involved in assisting early stage companies struggling with implementation and optimization of Quality Systems. Additional expertise is available to include assisting with implementation of electronic quality management systems. If you are interested in learning more about how BCG may assist you, please Contact Ellen Raaf, MT ASCP.

Ellen Raaf
919-774-8819

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
Sep 13-15, 2010	PDA	Annual Conference/Joint Task Force Meeting	Nadine Ritter, Ph.D.(speaker)	Washington, DC
Sep 20-24, 2010	IBC	IBC BioProcessing International Conference “Global Adventitious Agent Regulations of Raw Materials Used in Biopharmaceutical Manufacturing”	Barbara Potts, Ph.D.(speaker)	Providence, RI
Sep 29-Oct 1, 2010	BEBPA (Biopharmaceutical Emerging Best Practices Association)	Annual BEBPA Bioassay meeting "Quality Practices in Bioassay Labs: R&D, GLP or GMP?"	Nadine Ritter, Ph.D.(speaker)	Barcelona, Spain
Oct 9-12, 2010	AABB	Annual Meeting & TXPO	Joseph Fratantoni, MD	Baltimore, MD
Oct 12, 2010	Medical Design & Manufacturing (MD&M)	510(k) Reform: Impact on preclinical testing requirements	Miriam Provost, PhD (speaker)	Minneapolis, MN
Oct 14-15, 2010	Informa PTI-UK	Training Class: CMC Analytical, Comparability and Stability Studies for Biotechnology Products	Nadine Ritter, Ph.D.(instructor)	London, UK
Oct 19-20, 2010	International Pharmaceutical Academy (IPA)	Advances and Efficiencies in Stability Testing for the Pharmaceutical & BioTech Industry	Nanda Subbarao, Ph.D. (speaker)	Montreal, Canada Montreal, Canada
Oct 20-22, 2010	IBC	Well Characterized Biopharmaceuticals: 14th Annual Meeting	Nadine Ritter, Ph.D.(speaker)	Bethesda, MD

Oct 24-27, 2010	RAPS	Annual Conference and Exhibition	Andra Miller, Ph.D. Blair Fraser, Ph.D. Barbara Potts, Ph.D. Darin Weber, Ph.D. Stephen Rhodes, M.S. (speakers)	San Jose, CA
Oct 25-27, 2010	PDA	PDA's 5th Annual Global Conference on Pharmaceutical Microbiology "The Myths of Virology and Mycoplasmaology" PDA Mycoplasma Filtration class	Barbara Potts, Ph.D.(speaker)	Washington, DC
Oct 27-29, 2010		World Drug Discovery and Development Summit 2010	Orest Hurko M.D.(speaker)	Copenhagen, Denmark
Oct 27-28, 2010	Informa Life Sciences	BioProduction 2010	Nanda Subbarao, Ph.D. (speaker)	Barcelona, Spain
Nov 7-8, 2010	American College of Toxicology (ACT)	31st Annual Meeting	John Jessop, Ph.D., MPH	Baltimore, MD
Nov 8-9, 2010	CaSSS	2nd Annual Bioassays 2010: Scientific Approaches and Regulatory Strategies	Nadine Ritter, Ph.D.(speaker)	Bethesda, MD
Nov 14-18, 2010	AAPS	Annual Meeting	Nadine Ritter, Ph.D.	New Orleans, LA
Nov 15-17, 2010	Informa Life Sciences	Regulatory Affairs for Biopharmaceuticals Workshop: "CMC Regulatory Compliance for Biopharmaceuticals"	Nadine Ritter, Ph.D.(speaker)	Berlin Germany
Nov 16-19, 2010	Informa Life Sciences	11th Annual EuroTIDES 2010 "Peptides and Stability Testing Requirements"	David Lin, Ph.D. (speaker)	Barcelona, Spain

Dec 4-7, 2010	American Society of Hematology	Annual Meeting	Joseph Fratantoni, MD	Orlando, FL
Dec 7-9, 2010	CBI	Stability Programs Forum “Stability Testing for Biotechnology/Biologic Products”	David Lin, Ph.D. (speaker)	Philadelphia, PA
Mar 6-10, 2011	Society of Toxicology (SOT)	Annual Meeting & ToxExpo	John Jessop, Ph.D., MPH	Washington, DC

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