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## **BCG Welcomes:**

### **Steven C. Kunder, Ph.D., DABT - Sr. Consultant**

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**STEVEN C. KUNDER, Ph.D., DABT**

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

Steven Kunder, Ph.D., DABT., has joined BCG as a Senior Consultant. Dr. Kunder is an immunopharmacologist (Ph.D., Medical College of Pennsylvania, Philadelphia, PA) who brings 12 years of experience with the U.S. Food and Drug Administration (FDA) in both the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER).

Read Announcement:

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

See Curriculum Vitae

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

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## **BCG GCP & GLP Consulting Services**

article by Carl Anderson & Michael Trapani, MS, MBA, Senior Consultants at BCG

With the estimated costs of bringing a new biopharmaceutical product to market exceeding \$1.2 Billion, it is important that companies ensure the quality and integrity of their research data and that the studies are performed in compliance with good laboratory (GLP) and good clinical practices (GCP). If you are in the process of planning for submission of a BLA or NDA you should include assessment of GCP/GLP compliance of the studies being submitted in support of the market application. The time to identify and correct deficiencies is prior to the FDA Pre-approval Inspection (PAI) or Bioresearch Monitoring (BiMo) audit.

Biologics Consulting Group, Inc. (BCG) has a team of consultants with extensive FDA compliance inspection experience and extensive experience in clinical regulatory affairs and quality assurance. These Senior Consultants have a proven record in helping clients navigate regulatory hurdles potentially affecting product approval. Compliance services that BCG provide include Mock GLP and GCP inspections, data quality and integrity audits, compliance gap assessments, Sponsor/Monitor audits, clinical data due diligence assessments and Clinical Investigator audits. A more detail list of GLP and GCP compliance services is listed below:

- Clinical site audits, sponsor audits, including clinical databases, in the context of complex study design or preparation for FDA inspections
- “For-Cause” audits for data integrity and data quality issues.
- Independent audits and assessment for suspected research misconduct
- Vendor qualification including contract research organizations (CROs), clinical laboratories, non-clinical laboratories, institutional review boards (IRBs), and contract manufacturers
- Development of a quality systems program
- Quality presentations at investigator meetings
- GCP training for clinical investigators, study staff, and sponsor staff including FDA preparedness training for regulatory inspections
- GLP regulatory training for laboratory staff and vendors
- Preparation and review of standard operating procedures (SOPs)
- Qualification of clinical sites

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## **BCG Nonclinical Consulting Services**

article by John Jessop, PhD, MPH, Director of Pharmacology/Toxicology at BCG

BCG provides a full array of nonclinical pharmacology-toxicology consulting services that span the entire biologic/drug development process, from discovery through marketing application and approval. At the early stages of biologic/drug development, BCG toxicologists review the product information and conduct a gap analysis, evaluating currently completed studies and considering the product class, proposed indication and mechanism of action and providing an appropriate nonclinical plan for development through marketing application. Biologics and therapeutic biologics, and vaccines in particular, are generally designed to affect the immune system, and BCG offers toxicologists with knowledge of immunology that are especially equipped to understand the nonclinical requirements for this type of development program. This nonclinical plan can be provided in the form of a Product Development Plan, including a detailed outline of the most effective and efficient nonclinical program for initiation of a Phase I clinical trial, and ultimately for submission of a BLA/NDA.

BCG toxicologists have visited numerous toxicology CROs throughout the U.S. as well as abroad, and are well-equipped to aid the client with their toxicology outsourcing needs, including recommendations as to the best toxicology CRO for a specific development program, obtaining bids for specific studies, GLP auditing, monitoring ongoing studies and reviewing study reports. BCG toxicologists have extensive experience in writing pre-IND briefing packages and participating in pre-IND meetings with the FDA. With previous experience as FDA reviewers in most cases, in addition to previous experience in industry, the BCG toxicologists are in an excellent position to determine the best nonclinical path to first-in-man clinical trials, taking into consideration the FDA regulatory requirements, client resource requirements and the importance of client timelines. BCG toxicologists also have extensive experience in writing and/or review of IND pharmacology-toxicology sections, in standard as well as CTD format.

With firm knowledge of toxicological principles, FDA regulatory requirements and immunology, they are well-equipped to provide a clear, concise IND document that will best serve the

client. They also have the expertise to evaluate specific toxicology data in terms of strengths and weaknesses in support of a specific clinical trial.

In addition to pre-IND meetings, BCG toxicologists also offer expertise in preparation and participation in all formal FDA meetings, including end-of-Phase II meetings and pre-BLA/NDA meetings. They understand the nonclinical requirements to marketing application, and can provide advice in this area that can ultimately save clients a great deal of time and resources. BCG toxicologists can also write/review the pharmacology-toxicology sections of marketing applications (BLA/NDA) and have considerable experience in this area. Other services provided by the BCG toxicologists include review of toxicology study protocols and toxicology study reports, preparation of detailed toxicology study protocols, analysis of pharmacokinetic data, conducting due diligence evaluations for potential product acquisitions, and preparation/evaluation of comparability protocols related to manufacturing changes. And BCG toxicologists also offer extensive experience and expertise in GLP auditing, study monitoring and toxicology study protocol review and evaluation.

BCG toxicologists offer product expertise and experience in virtually all of the biologic and therapeutic biologic product classes in addition to development of drugs (small molecules) for many indications. Those biologic and therapeutic biologic product classes include vaccines, therapeutic proteins, cytokines, monoclonal antibodies, blood products, gene therapy products, cell and tissue products and allergenic products. BCG toxicologists also have considerable experience in the development of drugs, including drugs for CNS, G.I., anti-inflammatory, antiviral and oncology indications. Experience also includes nonclinical development of peptides, synthetic peptides and co-polymer products. Therefore, BCG has all of the bases covered in terms of nonclinical pharmacology-toxicology expertise as relates to the various biologic, therapeutic biologic and drug product classes and indications.

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## **Analytical Methods Highlights from BioProcess International**

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<http://www.bioprocessintl.com>

### **Understanding Analytical Methods** by Leah Rosin

Using the Assay Toolbox to Understand Your Process

BioProcess International Vol. 6, No. 4: p 78 (April 2008)

[http://www.biologicsconsulting.com/articles/BPI\\_Understanding\\_analytical\\_methods.pdf](http://www.biologicsconsulting.com/articles/BPI_Understanding_analytical_methods.pdf)

As biosimilars move into the forefront of consciousness in the biopharmaceutical industry, analytical methods, especially comparability studies, have an increasingly important role to play. Additionally, as more products progress from phase 1 to 2–3 studies and require production-scale manufacturing, analytical methods are an important component of technology transfer or in-house scale-up efforts...

**In the Drug Delivery Zone Patients Are the Priority** by Cheryl Scott

April 2008 | Volume: 6, Supplement: 2

[http://www.biologicsconsulting.com/articles/BPI\\_Patients\\_are\\_the\\_priority.pdf](http://www.biologicsconsulting.com/articles/BPI_Patients_are_the_priority.pdf)

A rule of thumb in drug development states that the larger a therapeutic molecule is, the more trouble it will be to make, ship/store, and administer to patients.

**A Rose By Any Other Name?** by Nadine Ritter Ph.D., Sr. Consultant, Biologics Consulting Group, Inc.

Distinctions Between Bioanalytical and Analytical Test Methods

BioProcess International Vol. 2, No. 11: p 80 (December 2004)

[http://www.biologicsconsulting.com/articles/BPI\\_Distinction\\_between\\_bioanalytical\\_and\\_analytical\\_methods.pdf](http://www.biologicsconsulting.com/articles/BPI_Distinction_between_bioanalytical_and_analytical_methods.pdf)

Analytical methods used for the characterization, release, and stability testing of biotechnological/biological products are often automatically referred to as “bioanalytical” methods. Many times this term is used when trying to distinguish between analyzing small-molecule chemical products and macromolecular biologically-based products. It seems sensible enough....

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## **BCG-Japan is Open for Business**

BCG is pleased to announce the opening of BCG-Japan in Tokyo. BCG-Japan is a subsidiary of the Biologics Consulting Group, Inc. and currently has three staff members:

[T.W. Tanaka, Ph.D. - President & COO, BCG-Japan](#)  
[Shin-ichi Kamachi, Ph.D. - Member of the Board & Sr. Consultant](#)  
[Masamichi Gotoh - Sr. Consultant](#)

The new office is located at 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

[James Kenimer, Ph.D.](#), (Chairman & CEO of BCG-Japan) and [Ruth Wolff, Ph.D.](#), (Board Member - BCG-Japan) attended the opening party at the BCG-Japan offices and nearby restaurant on April 2. BCG-Japan will provide Japanese regulatory and product development consulting services to all interested BCG clients, as well as enhance BCG-USA interaction with it's current and prospective clients in Japan.



## View BCG's Expertise Listing

(<http://www.biologicsconsulting.com/areasofexpertise.htm>)

### Upcoming BCG Presentations & Conference Appearances

(For complete list and speakers...<http://www.biologicsconsulting.com/appearances.htm>)

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             |
|------------------|----------------------------------|--|---------------------------------------|----------------------|
| June 8-11 2008   | Preclinical Training Institute   | Study Directing: Principles and Practices<br>"Your "other boss": How an FDA reviewer reads your reports" | Melanie Hartsough, Ph.D.<br>(speaker) | South Lake Tahoe, CA |
| June 11-12, 2008 | Orange County Regulatory Affairs | 11th Annual FDA/OCRA Educational Conference  | Ruth Wager, Ph.D.                     | Irvine, CA           |

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|------------------|---|---|---|------------------|
| June 12-13, 2008 | Center for Business Intelligence (CBI)    | 3rd Annual Stability Programs: Impurity Control, Global Compliance, Program Design and Stability Data Management for the Bio/Pharmaceutical Industry "Develop Complex Stability Programs for Biologics" | David Lin, Ph.D. (speaker)                                | Philadelphia, PA |
| June 16-19, 2008 | Seton Hall Law School                     | Health Care Compliance Certification Program<br><br>"Advertising & Promotion of Medical Devices"  | Stuart Portnoy, MD (speaker)                              | Newark, NJ       |
| June 17-20, 2008 | BIO (Biotechnology Industry Organization) | BIO 2008 (Booth #1939)  | Jim Kenimer<br>Ron Marchesani<br>Ron Salerno<br>Gil Salud | San Diego, CA    |
| June 22-26, 2008 | Drug Information Association              | 44th Annual Meeting   | Annie McElderry-Zurbay, RN, MSN, ND                       | Boston, MA       |
| June 25-26, 2008 | IIR                                       | Stability Testing for Biotechnology Products  | Nadine Ritter, Ph.D. (speaker)                            | London, UK       |
| July 24-25, 2008 | CASSS                                     | CMC Strategy Forum  | Nadine Ritter, Ph.D.                                      | Bethesda, MD     |
| Aug. 14, 2008    | Cambridge Healthtech Institute            | Clinical Risk Management and Safety for Vaccines  | Julia Barrett, M.D., MPH (speaker)                        | Cambridge, MA    |
| Sept. 2-5, 2008  | Terrapinn Ltd.                            | Asia Antibody Congress<br><br>Preconference Masterclass A: Gaining Regulatory Approval for Therapeutic Monoclonal Antibody for the US and EU Markets  | Lei Zhang, MD, Ph.D. (speaker)                            | Singapore        |

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