

Curriculum Vitae



James G. Kenimer, Ph.D.

jkenimer@bcg-usa.com

CEO

Biologics Consulting Group, Inc.

1317 King Street

Alexandria, VA 22314

P (703) 739-5695

F (703) 548-7457

EXPERIENCE

Biologics Consulting Group, Inc., CEO

Alexandria, VA (Sept. 1993 to present)

- Chief Executive Officer of BCG responsible for the overall management of company activities including negotiation of consulting agreements/contracts, management of administrative personnel and functions, marketing, and employee recruitment.
- Senior Consultant - responsible for the scientific and regulatory review and analysis of a wide range of biologic products at all stages of product development, from pre-IND through post-marketing.

FDA, Center for Biologics Evaluation and Research, Division of Vaccines and Related Products Applications, Acting Deputy Director and Supervisory Pharmacologist (GM-14).

(Jan. 1993 to Sept. 1993)

- Management/supervision of PLA/IND reviewers;
- Review of INDs/PLAs for vaccines and related products;
- Development of CBER managed review policy; and
- Inspection of CBER licensed facilities.



FDA, Center for Biologics Evaluation and Research, Division of Bacterial Products, Chief, Laboratory of Allergy and Immunochemistry. *Supervisory Pharmacologist (GM-14)* (1991 to Dec. 1992)

- Supervision of research, testing, and regulatory activities;
- Supervision of the hybridoma facility;
- Review of INDs;
- Participation on PLA review committees (monoclonal antibody and allergenic products); and
- Inspection of CBER licensed facilities.

FDA, Center for Biologics Evaluation and Research, Division of Bacterial Products, Chief, Laboratory of Cellular Physiology. *Supervisory Pharmacologist (GM-14)* (1989 to 1991)

- Supervision of research, testing, and regulatory activities;
- Supervision of the hybridoma facility;
- Review of INDs;
- Participation on PLA review committees (monoclonal antibody and allergenic products); and
- Inspection of CBER licensed facilities.

FDA, Center for Biologics Evaluation and Research, Division of Bacterial Products, Chief, Laboratory of Cellular Physiology. *Research Pharmacologist (GS-13)*. (1984 to 1989)

- Supervision of research, testing, and regulatory activities;
- Supervision of the hybridoma facility;
- Review of INDs;
- Participation on PLA review committees (monoclonal antibody and allergenic products); and
- Inspection of CBER licensed facilities.

FDA, Center for Drugs and Biologics, Office of Drugs, Division of Drug Biology, *Research Chemist (GS-13)*. (1978 to 1984)

- Responsibilities included research into the mechanism of action of drug and hormone receptors

National Institutes of Health, Dr. Marshall Nirenberg's lab at the Laboratory of Biochemical Genetics, *NIH Staff Fellow*. (1976 to 1978)

Georgetown University, Dr. Melvin Blecher's lab at the Department of Biochemistry, *Postdoctoral Fellow* (1974 to 1976)



UCLA, Dr. Jerome Hershman's lab at the Department of Medicine, *Research Associate*
(1972 to 1974)

EDUCATION

Ph.D. Emory Univ.; Biochemistry (1972)
B.S. Emory Univ.; Chemistry (1966)

HONORS AND AWARDS

2006 Appointment to [PDA Biotechnology Advisory Board \(BioAB\)](#)
2002 Appointment to the [Governor's Advisory Board for the Virginia Biotechnology Initiative](#) by Governor Warner
1993 FDA Group Recognition Award
1991 FDA Cash Award
1990 FDA Commendable Service Award
1990 Foreign Research Fellowship awarded by the Japan Health Sciences Foundation

PROFESSIONAL SOCIETIES

Regulatory Affairs Professional Society

- 1995 - Biologics Editor of RAPSNews
- 1996 - Member of Educational Program Planning Committee

International Association for Biologicals
International Society for Cellular Therapy
Parenteral Drug Association

FDA SPECIAL ASSIGNMENTS

- Member of the Application Policy Task Force - Development and implementation of CBER policies and procedures
- Member FDA Hybridoma Committee - Preparation of the "Points to Consider in the Manufacture and Testing of Monoclonal Antibody Products for Human Use" (1987)
- FDA Inspector (1986-1993)

RECENT CONFERENCE/SYMPOSIUM PARTICIPATION

October 2006 Biologics Track Chair for the 2006 RAPS Annual Conference
May 2006 American Society of Gene Therapy (ASGT) meeting
January 2006 Facilitate Cell and Gene Therapy Meeting
October 2005 RAPS 2005
September 2005 PDA/FDA Joint Regulatory Conference
July 2005 Trade Mission to the Czech Republic & Poland
June 2005 BIO
November 2004 [MEDICA Trade Fair](#), Dusseldorf, Germany
October 2004 RAPS 2004
September 2004 [Jetro BioMission](#), BioJapan 2004, Tokyo, Japan
September 2004 PDA/FDA Joint Regulatory Conference

June 2004	BIO 2004
April 2004	RAPS Mission to Russia
January 2004	Williamsburg BioProcessing Conference
October 2003	JETRO BioMission to Osaka
May 2003	ISCT 2003 Annual Meeting, Arizona
April 2003	Therapeutics Vaccine Meeting

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Kenimer, J.G. PDUFA, REGO and Other Regulatory Reforms: Current and Future Impact on CBER. Regulatory Affairs Focus, Vol 2, Issue 11: 17-19 (1997)

Kenimer, J.G. Vaccines: current regulatory issues. Current Opinion in Biotechnology 8: 357-360 (1997)

Shah, D.N., and J. G. **Kenimer**. Product License Applications (PLAs) and Establishment License Applications (ELAs) for Biological Products. *In* Encyclopedia of Pharmaceutical Technology, Volume 13 (ed) J. Swarbrick and J. C. Bolan. Marcel Dekker, Inc., New York (1995).

Araki, T., J. G. **Kenimer**, A. Nishimune, H. Sugiyama, R. Yoshimura, and H. Kiyama. Identification of the metabotropic glutamate receptor-1 protein in the rat trigeminal ganglion. Brain Research 627, 341 (1993)

Takashima, A. and J. G. **Kenimer**. Regulation of muscarinic stimulation of norepinephrine release and PI hydrolysis during cell growth in PC12 cells. Neurosci. Letters (In press).

Leininger, E., P. G. Probst, M. J. Brennan, and J. G. **Kenimer**. Inhibition of *Bordetella pertussis* filamentous hemagglutinin-mediated cell adherence with monoclonal antibodies. FEMS Microbiology Letters 106, 31 (1993). [PDF](#), [HTML](#)

Leininger, E., C. A. Ewanowich, A. Bhargava, M. S. Pepler, J. G. **Kenimer**, and M. J. Brennan. Comparative Roles of the Arg-Gly-Asp Sequence Present in the *Bordetella pertussis* Adhesins, Pertactin and Filamentous Hemagglutinin. Infect. and Immun. 60, 2380 (1992).

Myojo, Y., K. Inoue, J. G. **Kenimer**, and H. Higashida. Phosphoinositide-Dependent Ion Channels and Secretion in Neuron-like Cells. *In* Protein, Nucleic Acid and Enzyme, Supplement 36, No. 3: Phospholipid Metabolism and Pathological Condition in Animal Cells, 615-619 (1991) Kyoritsu, Tokyo, Japan (Japanese).

Kenimer, J. G., P. G. Probst, A. B. Karpas, D. L. Burns, and H. R. Kaslow. Monoclonal Antibodies Against the Enzymatic Subunit of Both Pertussis and Cholera Toxins. Develop. Biol. Standard. 73, 113-141 (1991).

Leininger, E., M. Roberts, J. G. **Kenimer**, I. G. Charles, N. Fairweather, P. Novotny, and M. J. Brennan. Pertactin (P69) an Arginine-Glycine-Aspartic Acid-containing *Bordetella*

- pertussis* Protein that Promotes Adherence to Mammalian Cells. Proc. Natl. Acad. Sci. USA 88, 345 (1991).
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- Thompson, J., G. Dickson, S. E. Moore, H. J. Gower, W. Putt, J. G. **Kenimer**, and F. S. Walsh. Alternative Splicing of the Neural Cell Adhesion Molecule (N-CAM) Gene Generates Variant Extracellular Domain Structure in Skeletal Muscle. Genes and Development 3, 348 (1989).
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