

**Ronald A. Salerno, Ph.D.**

**rsalerno@bcg-usa**

2228 Wentz Lane  
Skeppack Township  
Schwenksville, PA 19473

215-896-2067

December 2009

Curriculum Vitae

**SUMMARY OF EXPERTISE**

- Nineteen years experience in Regulatory Affairs for Vaccines, Biologics and Drugs
- Regulatory strategy, assessment and competitive analysis for development and licensure of vaccines, biologics and drugs;
- Regulatory Liaison with regulatory agencies for regulations, guidance and meetings;
- IND, BLA, NDA, VGDS management, reviews, and due diligence
- Application of pharmacogenomics in regulatory and clinical decision making;
- Application of pharmacogenetic diagnostic testing and personalized medicine;
- Organization of regulatory workshops, stakeholder communications and partnerships

**EDUCATION**

Ph.D. *Zoology*, University of Maryland, College Park, MD

M.S. *Zoology*, University of Maryland, College Park MD

M.S. *Biology*, Villanova University, Villanova, PA

B.A. *Biology*, Saint Vincent College, Latrobe, PA

**EXPERIENCE**

**Biologics Consulting Group, Inc., Senior Consultant**

Alexandria, Virginia (Feb. 2008 - present)

- During 2008 and 2009 provided regulatory affairs support for small and large pharmaceutical companies developing vaccines, biologics, drugs or IVDs. Specific projects included:
  - Vaccines: (DNA, Viral and Bacterial): pre-IND meeting strategy, preparation and liaison functions; IND CMC writing; eCTD CMC writing for International Dossier; project management and preparation of eCTD IND; WHO Prequalification Submission strategy and review of chapters
  - Biologics (antibody, tumor inhibitors): regulatory strategy, guidance, review of type C meeting package
  - Drugs (oncology, antiviral): Regulatory Liaison for clinical development; regulatory advisor for pharmacogenomics and voluntary exploratory data submission for biomarker

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- Devices (In vitro diagnostic test): Regulatory advisor and Liaison for Molecular Diagnostic Company for Pharmacogenomic test; and Voluntary Exploratory Data Submission for PG biomarker
- Application of pharmacogenomics in regulatory and clinical decision making; Application of pharmacogenetic diagnostic testing and personalized medicine;
- Steering Committee Member of Pharmacogenomic regulatory workshop

**Wyeth Research, Vaccines, Senior Director & Therapeutic Area Head, Global Regulatory Affairs**

Collegetown, PA and Blue Hill, NY (July 2006 – Jan 2008)

- Directed Vaccine Research Group of 4 to 6 regulatory strategists (Sr. Manager to Director) for vaccine products in discovery to early and late clinical development, and for marketed vaccines

**Wyeth Research, Director II, Global Regulatory Affairs**

Collegetown, PA (June 2001 – June 2006)

- Regulatory Affairs strategist and manager for investigational antiviral, cardiovascular and monoclonal antibody products
- Regulatory Liaison for Translational Medicine Group that explores pharmacogenomics, pharmacogenetics in the clinic to define biomarkers that are predictive of drug response and new targets for discovery research – including six therapeutic areas
- Regulatory Liaison with FDA on developing regulatory workshops and guidance for pharmacogenomics
- Prepared and submitted three Voluntary Genomic Data Submissions
- Chair of the Pharmacogenetics Working Group consisting of 21 international companies engaged in pharmacogenomic research
- Member of the PhRMA Genomics Technical group
- Member of Wyeth Translational Medicine Review Board, and Wyeth Bioethics Committee

**Merck & Co., Inc., Director, Biologics Licensing, Manufacturing Division**

West Point, PA (Feb. 1997 – June 2001)

- Direct preparation, submission, and filing strategy for Chemistry and Manufacturing changes to marketed and developmental vaccines
- Support all vaccine registration activities worldwide, with emphasis on CBER and European registration procedures
- Liaison with review officials; Director for group of 9 to 31 staff

**Merck & Co., Inc., Director, Regulatory Liaison, Worldwide Biologics and Vaccines, Merck Research Laboratories West Point, PA (Jan. 1996 – Feb. 1997)**

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- Directed mutual recognition approval of a viral vaccine in European countries after obtaining licensure in the reference member state
- Directed licensure of a bacterial vaccine in U.S.
- Direct Liaison with WHO, CBER, European Agencies on development of guidelines for DNA vaccines and gene therapy

**Merck & Co., Inc., Director, Europe, Regulatory Liaison, Worldwide Biologics and Vaccines, Merck Research Laboratories**

Starnberg (Munich) Germany (Jan. 1994 – Dec. 1995)

- Two year assignment in Germany managing regulatory affairs in Europe for all MRL vaccines in development (pre-clinical, clinical and Chemistry Manufacture and Control)
- Directed registration of Hepatitis A vaccine in the first country in the world for Merck & Co. and the first approval by the mutual recognition procedure in Europe.
- Provided key regulatory support to our European Clinical group and the Aventis Pasteur Merck Vaccine Joint Venture, Lyon, France
- Developed working relationships with national control agencies

**Merck & Co., Inc., Associate Director, Regulatory Liaison, Worldwide Biologics and Vaccines, Merck Research Laboratories (Jan 1990 – Dec 1993)**

- Represented MRL as an agent in matters of FDA registration and licensure of biologics, vaccines, antibiotics and antivirals.
- Directed regulatory approval of one antibiotic and 30 antibiotic supplements for efficacy, labeling or manufacturing changes
- Submitted over 15 IND's for bacterial vaccines, and a recombinant protein.

**Merck & Co., Inc., Senior Project Biologist, Merck Manufacturing Division (Jan. 1981 – Dec. 1989)**

- Provided technical support to Biological Quality Control, Production, Analytical Development, International Technology Transfer projects including on site evaluations in Taiwan, Korea and Egypt

**Merck & Co., Inc., Senior Research Virologist, Merck Research Laboratories (June 1973- Dec 1980)**

- Developed vaccines for feline leukemia virus and Herpes simplex types 1 and 2. Tested and published first sub-unit vaccine for feline leukemia

**Microbiological Associates, Senior Technician, Associate Scientist and Associate Investigator Bethesda, MD (1969- 1973)**

**PROFESSIONAL SOCIETY MEMBERSHIPS/ACTIVITIES**

- Regulatory Affairs Professional Society

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- Received special recognition award in 1995 for organizing the first international conference in Barcelona, Spain
- Chaired the biologics sessions in Vienna, in 2000
- Drug Information Association
- Past chair of the Pharmacogenetics Working Group (PWG) 2003-4
  - Chaired several DIA sessions on pharmacogenomics
- PhRMA Genomics TG member
- Co-chaired three major FDA/Industry workshops in Pharmacogenomics and Drug Development.

### SELECTED PRESENTATIONS

Dec 11, 2007	Fourth Workshop on Pharmacogenomics in Drug Development and Regulatory Decision Making, Bethesda, MD. <i>Pharmacogenomics: Five Years of Progress</i>
June 21, 2006	DIA Annual Meeting, Philadelphia, PA. <i>Impact of “regulatory” initiatives on use of Pharmacogenomics</i>
May 24, 2006	2006 Rozman Symposium, Drug Metabolism Discussion Group, Langhorne, PA. <i>Pharmacogenomic Initiatives in Global Drug Development.</i>
March 7, 2006	DIA Euro Meeting, Paris, France. <i>Impact of PGx Regulatory Initiatives.</i>
Nov 18, 2005	Medical College of Wisconsin, Pharmacogenomics, Proteomics, Pharmacology Toxicology Forum, Milwaukee, WI. <i>Pharmacogenomics for Drug Discovery and Patient Management.</i>
May, 24 2005	CHI Biomarkers for Molecular Diagnostics Translation from Discovery to the Clinic, Philadelphia, PA. <i>Genomic Biomarkers in Drug Development and Regulatory Decision-Making.</i>
Apr 11, 2005	Pharmacogenomics in Drug Development and Regulatory Decision Making – Workshop 3, Bethesda, MD. <i>Overview of FDA/Industry Pharmacogenomics Workshops.</i>
Oct 5, 2004	R & D Leaders Forum. Phacilitate, Geneva, Switzerland. <i>FDA Pharmacogenomics Guidance. Impact on Drug Development.</i>
Sept 18, 2004	Japanese Society of Clinical Pharmacology and Therapeutics, Shizuoka, Japan. <i>FDA Pharmacogenomics Guidance: Impact on Drug Development</i>
June 17, 2004	DIA Annual Meeting, Washington, DC. <i>Developing the Regulatory Pathway for Pharmacogenomics: FDA and Industry Open Dialogue.</i>
Mar 11, 2004	DIA Euro Annual, Prague, Czech Republic. <i>Pharmacogenomic-Guided Drug Development: Regulatory and Research Policy Perspectives – Industry Perspective.</i>
Feb 19, 2004	II R Conference, London UK. <i>Regulatory Developments in</i>

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	<i>Pharmacogenomic Data Submissions.</i>
June 17, 2003	DIA Annual Meeting, San Antonio, Texas. <i>PWG Response to "Safe Harbor" Proposal and Examples of Data Submissions</i>
Feb 26, 2003	ICDD, Barton Creek, Austin, Texas, <i>Pharmacogenetics Working Group Comments on an FDA Proposal of "Safe Harbor" for Pharmacogenomic Data</i>
April 17, 2002	PhRMA Biologics and Biotechnology, Scottsdale, Arizona, <i>Regulatory Environment Facing Pharmacogenomics in Drug Development</i>

**SELECTED PUBLICATIONS**

1. FW Freuh, **RA Salerno**, LJ Lesko, RD Hockett. *4<sup>th</sup> US FDA-Drug Information Association Pharmacogenomics workshop, held 10-12 December, 2007*. *Pharmacogenomics* (2009) 10 (1), 111-115
2. **RA Salerno**, LJ Lesko. *Three years of Promise, Proposals, and Progress on Optimizing the Benefit/Risk of Medicines: A Commentary on the 3<sup>rd</sup> FDA-DIA-PWG-PhRMA-BIO Pharmacogenomics Workshop*. *The Pharmacogenomics Journal* (2006) 6, 78-81
3. **RA Salerno**. *Improving Efficacy, Safety with Pharmacogenomics*. *Drug Discovery & Development* 8 (12) 48, 2005
4. **RA Salerno**. *Pharmacogenomics Advancing the Science*. *PharmaVoice*, November, 2005.
5. **RA Salerno**. *Pharmacogenomics in Drug Development*. *Genetic Engineering News* 25 (12) 14, 2005
6. **RA Salerno**. *Post-Guidance Pharmacogenomics..* *Pharmacogenomics Reporter*. April 21, 2005.
7. **RA Salerno**. *FDA Pharmacogenomics Guidance: Impact on drug development*. *Clin Eval* 32 (1) 2005 (published in Japanese in Japan)
8. **RA Salerno**. *Developing the Regulatory Pathway for Pharmacogenomics*. *Regulatory Affairs Focus* (2004) 9 (8) 12-15.
9. **RA Salerno**, LJ Lesko. *Pharmacogenomic Data: FDA voluntary and required submission guidance*. *Pharmacogenomics* (2004) 5(5), 503-505
10. **RA Salerno**, LJ Lesko. *Pharmacogenomics in Drug Development and Regulatory Decision-Making: The Genomic Data Submission (GDS) Proposal*. *Pharmacogenomics* (2004) 5(1), 25-30
11. LJ Lesko, **RA Salerno**, BB Spear, DC Anderson, T. Anderson, C Brazell, J Collins, A Dorner, D Essayan, B Gomez-Mancila, J Hackett, SM Huang, S Ide, J Killinger, E Mansfield, R Meyer, S. Ryan, V Schmidh, P Shaw, F Sistare, M Watson, A Worobec. *Pharmacogenetic and Pharmacogenomics In Drug Development and Regulatory Decision*

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*Making: Report of the First FDA-PWG-PhRMA-DruSafe Workshop.* J of Clinical Pharmacology (2003) 43 (4) 342-358

12. DC Anderson, B. Gomez-Mancilla, BB Spear, DM Barnes, K Cheesman, PM Shaw, J. Friedman, A McCarthy, C Brazell, SC Ray, D McHale, L Hashimoto, R Sandbrink, ML Watson, **RA Salerno**, N Cohen, CE Lister. *Elements of informed consent for pharmacogenetic research; perspective of the pharmacogenetics working group.* The Pharmacogenetics Journal (2002) 2, 284-292.
13. **RA Salerno**, C ODELL, JMcCauley, R Manicinelli, W Morges, A Gray. Quantitative analysis of 23 –valent Pneumovax by automated rate Nephelometry. Journal of Biological Standardization (1984) 12, 447-450
14. **RA Salerno**, VM Larson, AH Phelps, MR Hilleman. Infection and Immunization of Cats with the Kawakami-Theilen Strain of Feline Leukemia Virus. Proc of the Society for Experimental Biology and Medicine (1979) 160, 18-23
15. **RA Salerno**, ED Lehman, VM Larson, MR Hilleman, Feline Leukemia Virus Envelop Glycoprotein Vaccine: Preparation and Evaluation of Immunizing Potency in Guinea Pig and Cat. J Natl. Cancer Inst (1978) 61(6), 1487-1493
16. **RA Salerno**, GM Ramm, CE Whitmire. Chemical Induction of Subcutaneous Tumors in BALB/c and Swiss Mice infected with Wild Type C-RNA Viruses Derived from BALB/C Tissues. Cancer Research (1973) 33 69-77
17. **RA Salerno**, CE Whitmire, IM Garcia, RJ Huebner. Chemical Carcinogenesis in Mice Inhibited by Interferon. Nature New Biology (1972) 239, 31-32

**Conference Organizing Committees: 2001 – 2006**

<b>Date</b>	<b>Meeting</b>	<b>Location</b>	<b>Role</b>
June 21, 2006	<b>DIA Annual Meeting.</b> Session. Pharmacogenetics: FDA/EMEA	Philadelphia, PA	Session Chairperson
March 7, 2006	<b>DIA Euro Annual Meeting.</b> Session 4. Biomarkers: Preclinical, Clinical, Exploratory and Confirmatory use	Paris, France	Session Chairperson
Feb 13-16, 2006	<b>ICCD: Increasing the success rate of the Critical Path To Drug Development.</b> <b>Session Theme:</b> A new clinical trial continuum- Efficacy Biomarkers and Clinical Endpoints	Barton Creek Austin, TX	Session Moderator, and Conference Planning Committee

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<b>Date</b>	<b>Meeting</b>	<b>Location</b>	<b>Role</b>
Oct 6-7, 2005	<b>FDA, DIA, PhRMA, BIO, NIH, PWG</b> Application and Validation of Genomic Biomarkers for Use in Drug Development and Regulatory Submissions	Bethesda, MD	Organizing Committee
May 24, 2005	<b>CHI</b> Biomarker World Congress 2005. Track 4 Regulatory Acceptance of Biomarkers	Philadelphia, PA	Track chair
March 7-9, 2005	<b>DIA Euro Annual:</b> Session 8. Applications of Pharmacogenomics- Challenges of Parallel Diagnostic and Drug Development	Lisbon, Portugal	Session Chairperson
Apr 11-13, 2005	<b>FDA, DIA, PWG, PhRMA, BIO :</b> Pharmacogenomics in Drug Development and Regulatory Decision Making – Workshop 3 Three years of promise, proposals and progress on optimizing the benefit/risk of medicines	Bethesda, MD	Steering Committee Co-chairperson
Feb 14 –17, 2005	<b>ICDD:</b> Challenge and Innovation on the Critical Path to Drug Development	Barton Creek, Austin, TX	Conference Planning Committee
Oct 4, 2004	<b>Phacilitate: R&amp;D Leader’s Forum:</b> How can your organization build an optimal relationship with the regulators	Geneva, Switzerland	Plenary Session Chair
July 29, 2004	<b>FDA, DIA, PhRMA:</b> Co-Development of Drug, Biological, and Device Products.	Arlington, VA	Program Co-Chairman
Feb 23-26, 2004	<b>ICDD:</b> Innovation, Efficiency and Predictability of Drug Development; Session- FDA’s Risk Minimization Initiatives	Barton Creek, Austin, TX	Conference Planning Committee and Session Moderator
Nov 13-14, 2003	<b>FDA, PWG, PhRMA, BIO, DIA:</b> Pharmacogenomics in Drug Development and Regulatory Decision Making: The Genomic Data Submission Proposal	Rockville, MD	Steering Committee Co-Chairperson
May 16-17, 2002	<b>FDA, PWG, PhRMA, DIA:</b> Pharmacogenetics and Pharmacogenomics in Drug Development and Regulatory Decision Making: First FDA-PWG-PhRMA-DruSafe Workshop	Rockville, MD	Steering Committee Co-Chairperson