



JOEL I. FALK

Executive Vice President

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EDUCATION

- 2004 Executive Management Program – Kellogg School of Management, Northwestern University
- 1988 Certification in Project Management, American Management Association, Washington, DC
- 1973 Graduate program – Public Health, Fairleigh Dickinson University, Teaneck, NJ
- 1971 BS Ed., Life Sciences, State University of New York at Plattsburgh, Plattsburgh, NY

EXPERIENCE

Joel Falk is an Executive Vice President at The Weinberg Group where he has global responsibility for all of the activities of the Product Regulation & Compliance group which encompasses Pharmaceuticals and Biotechnology, Medical Devices, Quality and Compliance, Clinical Pharmacology and Biopharmaceutics. Mr. Falk has over 35 years of experience in the health care industry performing a variety of functions including: regulatory affairs, medical writing, clinical development, design and monitoring, project management, strategic and portfolio management, and due diligence of products and companies. He has either led or been instrumental in more than 20 major drug submissions in the United States and abroad in a variety of therapeutic areas such as: cardiovascular-renal, allergy, pulmonology, infectious disease, CNS and oncology. Since joining The Weinberg Group, Mr. Falk has been actively involved in managing programs specifically geared toward the problem solving of health care product development issues for large and small firms, always with an eye toward enhancing the client's position. He has spoken at a number of international symposia relating to effective management of clinical projects, due diligence practices, a variety of regulatory issues and new and efficient techniques for data management. Mr. Falk's experience at The Weinberg Group includes:

Clinical Development and Regulatory Support

Consultation in the research and development of FDA-regulated products: Drugs, biologics, and medical devices. Full scientific, regulatory, and strategic support is provided over the life cycle of the project, including preclinical and clinical development, and data management and analysis. Representative projects are:

- Design and implementation of a clinical development and marketing programs for products in the areas of: wound-healing, hypertension, cancer, asthma, allergy, cardiovascular disease, infectious disease, analgesia, psychiatry and others.
- Provide oversight and project management for the conduct of clinical trials.
- Representation for a major pharmaceutical company as agent regarding all regulatory aspects of a marketed product. Includes management of CMC, clinical, adverse effects and marketing issues.
- Provided scientific support for defense of a variety of drug products.
- Development of a comprehensive data validation plan for data from a multi-center clinical trial conducted in Europe for submission to the FDA.

Prior to joining The Weinberg Group, Mr. Falk's experience included the following:

MIMC, INC., Executive Director, Clinical Operations

Responsibilities encompassed complete oversight of all activities relating to ongoing and potential clinical programs including preparation of strategic and clinical development plans, protocol and CRF development, site management and clinical and QA monitoring, data management, biostatistics and general project management. Therapeutic areas included, among others, hypertension, gastrointestinal, renal failure, allergy, asthma, sinusitis, imaging, and attention deficit disorder.

Examples of experience included:

- Provided due diligence required to create comprehensive Clinical Development Plans for three agents in the treatment of inflammatory bowel disease.
- Managed all clinical development aspects of a drug used in treatment of attention deficit hyperactivity disorder.
- Provided oversight for all activities in the clinical development of a new antihypertensive agent.

IN VIVO INC., Executive Director, Planning, Project Management and Clinical Operations (Sept. 1991 – Aug. 1993)

Responsibilities entailed oversight of all clinical activities including project management and site monitoring. Therapeutic areas included, among others, cardiovascular, lipid-lowering agents, anti-infective, and central nervous system. Examples of experience include:

- Developed and managed a Phase IV program for a lipid-lowering agent.
- Wrote, managed, and completed a program to study a quinolone antibiotic to use in the treatment of urological infections.
- Devised several studies to comprise the Phase IIIB/Phase IV program for a new hypnotic agent.



SANOPI PHARMACEUTICALS, INC., Director of Project Management (Sept. 1990 – Sept. 1991)

Responsible for the coordination of all clinical programs to be conducted in the United States for our French parent company. Also involved in product licensing and product due diligence. Therapeutic areas included cardiovascular, hematology, central nervous system, osteoporosis and immunosuppression. Examples of experience include:

- Assisted in the preparation of the clinical development plan for a new bisphosphonate for the treatment of osteoporosis.
- Responsible for the coordination of all clinical activities related to a multi-center, multinational study of an anti-platelet for the prevention or reinfarction.
- Researched and provided input regarding potential development candidates.

RHONE-POULENC PHARMACEUTICALS, INC., Director, Planning and Project Management (June 1985 – Aug. 1990)

Responsibilities included the coordination of North American clinical research efforts as well as the regulatory strategy for the receipt and use of preclinical and clinical data from Rhone-Poulenc Sante. Therapeutic areas included cardiovascular, central nervous system and analgesia, anti-infective, AIDS, hematology, and oncology. Examples of experience include:

- Participated in the development of the Clinical Plan for HPA-23, an anti-viral for AIDS.
- Responsible for the creation of Clinical Plans for the development of various antibiotics, cardiovascular agents, and CNS agents in North America.

G.H. BESSELAAR ASSOCIATES, Project Manager (June 1984 – June 1985)

Responsible for the management of a number of clinical projects in the cardiovascular and central nervous system areas.

KNOLL PHARMACEUTICAL COMPANY, Medical Writer and Sr. Clinical Research Associate (June 1978 – June 1984)

Responsible for clinical monitoring for up to 25 sites. Areas of study included stable and unstable angina and arrhythmias and analgesia. Also responsible for the preparation of medical reports relating to Knoll-sponsored clinical trials.



LEDERLE LABORATORIES, Scientific Technical Writer (May 1973 – June 1978)

Primary responsibility was to prepare summary data of preclinical pharmacology and toxicology studies for regulatory submission. Therapeutic areas included, among others, anti-infective, central nervous system, cardiovascular/renal, metabolic disease therapy, suture and devices (including surgical disinfectant sponges).

TICONDEROGA HIGH SCHOOL, Teacher (July 1971 – May 1973)

PROFESSIONAL AFFILIATIONS

American Heart Association
American Management Association
Associates of Clinical Pharmacology
Drug Information Association
Food and Drug Law Institute
Institute for International Research
Project Management Institute

EDITORIAL BOARD

Regulatory Affairs Journal (Drugs)

PRESENTATIONS

Falk JI. 2011. Ensuring Successful FDA Meetings. A Webinar presented by The Weinberg Group Inc.; 16 Jun; Washington, DC.

Falk JI. 2011. The 505(b)(2) NDA Pathway – An Innovative FDA Strategy that Everyone Should Understand. A Webinar presented by The Weinberg Group Inc.; 13 Apr; Washington, DC.

Falk JI. 2010. Taking Full Advantage of the 505(b)(2) NDA Pathway. A Webinar presented by The Weinberg Group Inc.; 10 Nov; Washington, DC.

Falk JI, Swit MA. 2010. Regulatory, Quality & Clinical Due Diligence: The Oft-Overlooked Keys to Successful Transactions. A Webinar presented by The Weinberg Group Inc.; 23 Jun; Washington, DC.

Falk JI. 2010. A Look at European Pharmaceutical Regulatory Bodies and Their Interplay with EMEA. A Webinar presented by The Weinberg Group Inc.; 14 Apr; Washington, DC.



Falk JI, Minear DE. 2010. Understanding CDRH's Utilization of New Science in Regulatory Decision-Making. A Webinar presented by The Weinberg Group Inc.; 24 Feb; Washington, DC.

Falk JI. 2010. A Look at Other European Pharmaceutical Regulatory Bodies and their Interplay with EMEA. Presented at: American Conference Institute: European Pharmaceutical Regulatory Law BOOT CAMP; Jan; New York, NY

Falk JI, Fleischer NM. 2009. ANDA vs. 505(b)(2) – When and Why? A Webinar presented by The Weinberg Group Inc.; 30 Sep; Washington, DC.

Falk JI. 2009. The Evolution of Gene Therapy Regulation in the U.S. Presented at: RAPS 2009 Annual Conference & Exhibition; 13-16 Sep; Philadelphia, PA.

Falk JI. 2009. Biosimilars: Overview of Current Status. Presented at: RAPS 2009 Annual Conference & Exhibition; 13-16 Sep; Philadelphia, PA.

Falk JI, Swit MA. 2009. The Top Ten Ways to Ensure Successful FDA Meetings. A Webinar presented by The Weinberg Group Inc.; 2 Mar; Washington, DC.

Falk JI, Antos JD. 2009. The Ten Most Common Obstacles to Meeting Your Development Milestones. A Webinar presented by The Weinberg Group Inc.; 29 Jan; Washington, DC.

Falk JI. June 2008. The Basic Importance in Conducting Due Diligence in the Health Care Industry. Presented at: Drug Information Association 44th Annual Meeting; 22-26 Jun; Boston, MA.

Falk JI. 2007. The Basic Importance in Conducting Due Diligence in the Health Care Industry. Presented at: RAPS 2007 Horizons Conference & Exhibition; 28-30 Mar; San Francisco, CA.

Falk JI. 2003. Combination Products: The Impact of Drug Requirements. An Overview of the FDA's Combination Products Program – A Breakfast Briefing. Jointly sponsored by Wilson, Sonsini, Goodrich & Rosati PC and The Weinberg Group Inc; Feb; Palo Alto, CA.

Falk JI. 2002. Combination Products – An Opportunity Not To Be Missed. Presented at: Medical Alley Combination Products Program; Oct; St. Louis, MO.

Falk JI. 2002. Pre-Conference Short Course: Off Label Prescribing and Impact on Safety Issues. Presented at: Institute for International Research, Clarifying the Regulatory Framework of Off-Label Usage: Addressing Issues in Promotion, Liability and Regulatory Information; Jul; Washington, D.C.

Falk JI. 2001. Pharmacovigilance: Adverse Event Reporting (United States and Europe). Presented at: The Center for Business Intelligence, Global Harmonization of Adverse Reporting Systems; Apr.

Falk JI, Coyne TC. 1996. Achieving a 'Seamless' Business Unit. Presented at: Institute for International Research, Partnerships with CROs Meeting.



Falk JI. 1995. Cost-effective pen-based approaches to data capture. Presented at: The Automated Data Capture meeting sponsored by the Institute for International Research; Sep.

Falk JI. 1995. Creating efficiencies in the clinical research process - a CRO perspective. Presented at: The Re-Engineering of Clinical Research meeting sponsored by the International Quality and Productivity Center.

Falk JI. 1995. Cost-effective pen-based approaches to data capture. Presented at: The Automated Data Capture meeting sponsored by the Institute for International Research; Mar.

Falk JI, Anders RJ. 1994. Managing cost efficiencies in global clinical trials. Presented at: Partnerships with CROs Conference sponsored by the Institute for International Research.

Callahan TJ, Klischer KA, and Falk JI. 1994. Implementation of fax-based documentation in the processing of ambulatory electrocardiographic recordings. Presented at: ACP Annual Meeting.

Falk JI, Brady L. 1994. Comparison of two systems of data collection and data management for use in clinical trials. Poster presented at ACP Annual Meeting.

Thompson M, Falk JI. 1992. The need for project management systems in the emerging biotechnology company: important considerations in the design and implementation. Accepted for presentation by the Project Management Institute's Annual Meeting.

Falk JI. 1992. Global project management: A clinical research organization perspective. Poster presented at ACP Annual Meeting.

RECENT PUBLICATIONS

Falk JI, Davidson RA. 2010. Coping with the Regulatory Realities of Follow-on Biologics and the Nuances of US and European Regulations. *Drug Information Journal*. 44(2):137-146.

Falk JI, Schulman DE, Becker DM. 2009. Thriving and Surviving in Lean Times. *FDLI Update*. (2):57-59.

McTyre RB, Hilton SE, Falk JI. 2003. Guest editorial: the many faces of risk management and why the issue is important to industry. *Regul Aff J*. 14(12):899-901.

Falk JI, Roth RI. 2003. Accomplishing long term follow up (LTFU) of gene therapy patients. *Regul Aff J*. 14(2):99-100.

Falk JI, Rabe CS. 2002. Post-marketing submission requirements in the U.S. *Regul Aff J*. 3(12):987-990.

Mandell D, Falk JI. 2002. Current U.S. regulation of combination products. *Regul Aff J*. 10(4):289-293.



Weinberg MS, Falk JI, Huggard JA. 2002. Abstract: impact of public health policies on technological development, submitted for the Public Health Education and Health Promotion of the 130th Annual Meeting, Philadelphia, PA.

Falk JI, Nichols BR. 2002. Guest editorial: Understanding U.S. HIPAA privacy regulations and plotting a course toward compliance. *Regul Aff J.* 3:171-172.

Falk JI. 2001. Guest Editorial: Dietary supplement and herbal medicines – potential impact on clinical trials. *Regul Aff J.* 12(5):372-373.

Falk JI, Manieri J. 2000. A 10-year review of the international regulatory scene (USA). *Regul Aff J.* 11(11):803-810.

Falk JI. 2000. Guest Editorial: Realities and experiences in global clinical trials. *Regul Aff J.* 11(8):554-554.

Falk JI, Rosania L. 1999. Chemistry, manufacturing and controls (Part 2). *Regul Aff J.* 3:165-168.

Falk JI, Rosania L. 1999. Chemistry, manufacturing and controls (Part 1). *Regul Aff J.* 10(2):99-105.

Falk JI, Fleischer NM. 1998. FDA modernization efforts. *Regul Aff J.* 7:469-471.

