Sr. Vice President, Global Regulatory Affairs and Quality Assurance

AREAS OF EXPERTISE

- **Crafting and implementing regulatory and product development strategies for new chemical entities, generic drugs and marketed product life-cycle management.**
- **Submission of regulatory documents including INDs, CTDs, NDAs, ANDAs, DMFs and Amendments and Supplements.**
- **Experience in therapeutic areas including neurology, oncology, cardiovascular, endocrine and gastrointestinal medicine.**
- **Developing, managing and auditing quality assurance programs encompassing global GMP, GLP and GCP regulatory requirements and expectations while balancing business and market challenges.**
- **Conducting audits of API, finished product, supplier and contractor operations to assess compliance with regulatory requirements and expectations.**
- **Responses to audit observations (FDA 483s), Warning Letters, and the conduct of remediation efforts both outside of and within Consent Decree situations.**
- **Leader and manager of global RA and QA staffs, direct negotiator with regulatory agencies, member of global senior management team with direct responsibility for budgets, planning and implementation of RA/QA programs.**
- **Phase I-IV clinical study services**

INTRODUCTION

Consultant has more than 40 years of pharmaceutical regulatory affairs and quality assurance experience having held senior positions at the FDA, large and small pharmaceutical companies and CMC and clinical contract service providers (CMO/CROs). Career began in 1976 as an FDA Investigator and over the course of 12 years moved into positions of increasing responsibility in the Agency including Assistant Director of Congressional Operations, Associate Director of Program Management and Deputy Associate Commissioner for Public Affairs. A graduate of FDA's Executive Development Program, was one of the key authors of the Agency's last major rewrite of the IND and NDA regulations, managed several key FDA regulatory initiatives including establishment of tamper-resistant packaging regulations following the cyanide poisonings with Tylenol in 1982, and a member of the Commissioner's staff during passage of the "Hatch-Waxman" Act and the development and implementation of the ANDA process for generic drugs.

In 1987, consultant joined Abbott Laboratories as Associate Director of Regulatory Affairs. At Abbott was responsible for managing regulatory affairs activities including INDs, NDAs and BLAs in the neuroscience and cardiovascular therapeutic areas. In 1992, consultant moved to the contract pharma R&D and manufacturing (CMO) business as Director of Regulatory Affairs at Applied Analytical Industries soon becoming Sr. VP of Global RA/QA and a member of the Executive Committee as the company went public as AAI Inc. and expanded with the addition of clinical research (CRO) services in the US, Europe, Japan and China. In 2001, consultant joined a small group of entrepreneurs to establish Endeavor Pharmaceuticals, a start-up focused on women's health. Endeavor was acquired in 2004 and consultant returned to AAI to assist in its restructuring and rebranding as AAIPharma, the sale of the clinical business, and a return to the company's roots as a CMO.

Now as a consultant, conducts GxP quality assurance audits and has assisted many firms in the preparation for successful FDA audits in the US, Mexico, Canada, South America, Europe, India, Japan and the Middle

East. Helped clients respond appropriately to FDA 483s and Warning Letters and implement remediation plans where FDA has found regulatory compliance problems. Assisted pharma industry, private equity and investment groups with regulatory affairs needs including the conduct of due diligence, the development of regulatory strategies and FDA meeting packages, assistance with regulatory filings, and is the named US Agent and regulatory representative on filings to FDA. Working with various law firms, consultant has also written expert reports, been deposed and testified in court with respect to GMPs, drug development, ANDAs, NDAs and FDA regulations.

Consultant has a Bachelor's degree in Biology from Michigan State / Oakland University, Rochester, MI, and a Master's degree in Microbiology from Wayne State University, Detroit, MI. Member of the Regulatory Affairs Professional Society (certified RAC), the Parenteral Drug Association, the American Society for Quality (certified CQE), and the Society for Quality Assurance (SQA). Several publications including *"Laboratory Operations: A Vital Link,"* GMP Compliance, Productivity, and Quality (Interpharm Press, 1998), "Speed Dating: the Rapid Way to Phase I Clinical Studies," PMPS Journal (Winter 2006) and *"A Fish Story: The One That Got Bigger,"* Communicating in a Healthcare Crisis, (FDANews, 2007). Is a sought-after speaker and panel participant on regulatory and quality issues affecting the pharmaceutical industry and has presented on topics including drug development, GMPs, 505(b)(2) NDAs, Quality Systems, quality agreements, regulatory compliance, outsourcing and vendor management, stability, PAIs, and interactions with regulatory agencies.

WORK EXPERIENCE

2011 – Present
Industry Consultant
Duties:

- Regulatory Affairs and Quality Assurance services including assistance with regulatory filings, meetings with FDA, assignment as US Agent, vendor audits, mock pre-approval inspections, phase I clinic and Trial Master File audits, development of compliance and regulatory strategies, "third party" oversight under Consent Decree, meetings with regulatory authorities, etc.

2004 – 2010
AAIPharma Inc., Wilmington, NC
Sr. Vice President, Global Regulatory Affairs and Quality Assurance
Duties:

- Key executive in well-established provider of contract GLP/GMP/GCP research and development services including formulations; clinical materials and marketed product manufacturing (non-sterile and sterile); analytical, micro and bioanalytical methods development, validation and testing; stability program management; Phase I first-in-man programs (clinics in US and Europe); Phase II-IV clinical study management; pharmacovigilance and RA/QA consulting.
- Returned to successfully lead the rebuilding of strong and respected RA/QA functions and assist new Board and management team in the rebuilding of AAIPharma and achieving record revenues in 2007 and 2008.
- Directed RA staffs in the US and Europe offering advice and strategy, meetings with regulatory agencies and assistance in the writing, compilation and filing of various investigational and marketing applications in the US, Canada and Europe.
- Directed QA staffs in the US, Canada, Europe and South America setting policy and developing and carrying out programs to oversee company compliance with global GMPs, GLPs and GCPs while assisting clients in balancing development needs and cost-containment in light of regulations, guidances and regulatory and business expectations.

- Instrumental in assuring AAIPharma maintained an outstanding compliance history with the US, European and South American regulatory agencies and clients and advised executive management regarding RA and QA policies, programs, requirements, needs and challenges.
- Routinely represented the company in business development, legal and financial activities including client meetings, contract negotiations and problem resolution.
- Often sought-after speaker for national and international conferences.

2001 – 2003
Endeavor Pharmaceuticals, Wilmington, NC
Vice President, Regulatory Affairs and Quality Assurance
Duties:
- Executive Management Committee member of this privately funded pharmaceutical start-up focused on women's health.
- Responsible for all RA strategy and programs; filed three INDs and one NDA. Developed and managed QA programs to establish, monitor and assure the quality of activities with vendors including contract CMC and clinical services providers.
- Grew company to 20+ employees, but as marketing plans were implemented in anticipation of NDA approval, investors (private equity) sold the intellectual property, INDs and NDA to Barr Laboratories. The NDA was approved and the drug is marketed.
- Left because company was sold.

1993 – 2000
AAI Inc., Wilmington, NC
VP, Global Regulatory Affairs, Quality Assurance and Validations, (1999 – 2000)
VP, Regulatory Affairs, Quality Assurance, Validations and Training, (1997 – 1998)
Sr. Director, Regulatory Affairs and Quality Assurance, (1995 – 1996)
Director, Regulatory Affairs and Stability Operations, (1993 – 1994)
Duties:
- Career move to join a fast-growing CRO with goals of becoming a public company and establishing global drug research and development services.
- Built RA consulting franchise while managing a growing Stability Department.
- Directed RA services while building QA consulting services and assuming leadership of all internal QA, Training and Validations functions.
- Managed company's Pharmaceutical Seminars Division planning, coordinating and hosting a series of professional seminars on key topics in pharmaceutical research and development.
- Advanced to position on Executive Management Committee as the company grew into a successful, publicly traded full service CRO with facilities throughout US and Europe and added phase I clinics, bioanalytical laboratories and phase II-IV clinical study management services.
- Left for an opportunity as a founding member of a pharmaceutical start-up.

1987 – 1992
Abbott Laboratories, Inc., Abbott Park, IL
Associate Director, Regulatory Affairs
Duties:
- Career move to join a well-established, Fortune 100, "big pharma" company and transfer, develop and advance regulatory affairs skills within private industry.
- Primarily responsible for all RA activities in the neuroscience therapeutic area including products in development and marketed.
- Secondarily responsible for RA activities in the cardiovascular therapeutic area including biological cardiovascular products under development and marketed.

- Responsible for routine regulatory activities including active participation in project strategy and planning meetings, teleconferences and meetings with the FDA, writing, compiling and submission of new INDs and NDAs and the maintenance of applications already filed.
- Left for career excitement and better weather.

1976 – 1987
US Food and Drug Administration
Deputy Associate Commissioner, Public Affairs, (1987)
Associate Director, Program Management, (1986)
Assistant Director, Congressional Operations, (1984 – 1985)
Public Information Specialist, (1982 – 1983)
FDA Executive Development Program, (1980 – 1981)
Investigator, Detroit District Office, (1976 – 1979)
Duties:
- Conducted inspections of GMP pharmaceutical operations, GLP laboratories and GCP phase I clinics and phase II-IV clinical study sites.
- One of seven candidates accepted for FDA's prestigious Executive Development Program.
- Promoted to Agency headquarters in Rockville, Maryland, developing excellent organization, management and communication skills and quickly advancing to positions of greater responsibility, independence and decision-making.
- Represented the Agency to Congress and Congressional Oversight Committees, crafted speeches and testimony formulating and communicating Agency policy and programs, led new program and budget initiatives, wrote regulations and guidelines including the IND and NDA "rewrites" of the 1980s, and managed several crisis response initiatives including responses to Toxic Shock Syndrome, the Tylenol poisonings and the Selacryn and Oraflex market withdrawals.
- Advanced to Deputy Associate Commissioner to head FDA's public affairs staffs including press, publications and FOI services.

EDUCATION

1982 – 1984
American University, Washington, D.C.
MBA coursework

1979
Ferris State College, Big Rapids, MI (FDA sponsored)
Pharmacy courses

1974 – 1976
Wayne State University, Detroit, MI
Masters of Science: Microbiology

1969 – 1973
Michigan State / Oakland U, Rochester, MI
Bachelor of Art: Biology

AFFILIATIONS

- Regulatory Affairs Professional Society (Regulatory Affairs Certified)
- American Society for Quality (Certified Quality Engineer)
- Drug Information Association
- Parental Drug Association
- American Association of Pharmaceutical Scientists
- RegAffairsNC (Member, Board of Directors)

PUBLICATIONS

- "A Fish Story: The One That Got Bigger," Communicating in a Healthcare Crisis, FDANews, 2007.
- "Speed Dating: the Rapid Way to Phase I Clinical Studies," Pharmaceutical Manufacturing and Packaging Sourcer, Winter 2006.
- "Laboratory Operations: A Vital Link," GMP Compliance, Productivity, and Quality: Achieving Synergy in Healthcare Manufacturing, Interpharm Press Inc., 1998.
- "A Fish Story: The One That Got Bigger," When Lightning Strikes: A How-To Crisis Manual with Classic Case Studies, Washington Business Information Inc., 1994.

PRESENTATIONS

- "Preparing for an FDA GCP Audit," Client training, 2012 - 2017.
- "Preparing for an FDA GMP audit," Client training, 2012 - 2017.
- "Conducting and Documenting Investigations that Impress Regulators," Institute of Validation Technology Lab Week, Philadelphia, PA, 2015
- "Auditing Stability Programs," Institute of Validation Technology Lab Week, Philadelphia, PA, 2015
- "An Introduction to FDA," "Navigating and FDA Inspection," Current US FDA GMP Initiatives," CPhI/UBM Workshops, Mubai and Ahmedabad, India, 2015
- "Meeting ICH Q10 Objectives in Manufacturing," Innovative Approaches to Quality Systems, Pharmaceutical Technical Exchange Association, Kansas, 2013.
- "Inspection Case Study – A Consultant's View," 37th International GMP Conference, University of Georgia College of Pharmacy, Athens, 2013.
- "Regulation Review," Institute of Validation Technology Conference, San Diego, 2012.
- "A Deep Dive into Quality Agreements," Planning Committee Member, Moderator and Speaker at the FDA/Xavier University "Global Outsourcing Conference," Cincinnati, 2012 (also a member of the conference strategic planning committee and moderator for several conference sessions).
- "Planning for Success When Outsourcing Stability," International Pharmaceutical Academy Advances in Stability Testing, Boston 2012.
- "Auditing Your Stability Program Before the FDA Steps In," International Pharmaceutical Academy Advances in Stability Testing, Somerset, NJ 2012.
- "Due Diligence, Mock PAI and GxP Audits, FDA/Xavier University Global Outsourcing Conference, Cincinnati 2011 (and member of conference strategic planning committee).
- "Auditing Your Stability Program Before the FDA Steps In," International Pharmaceutical Academy Advances in Stability Testing, Boston 2011.
- "Planning for Success When Outsourcing Stability," International Pharmaceutical Academy Advances in Stability Testing, Boston 2011.
- "505(b)(2) New Drug Applications," RegAffairsNC Spring Conference, Chapel Hill, NC April 2011.

- "Quality Agreements: Truly Adding Value Without Needless Burden," Clinical Supply Forum, Durham, NC, February 2011.
- Workshops on FDA Inspections and Outsourcing Stability Programs, Institute of Validation Technology, December 2010.
- "Quality Systems: Expectations from the FDA," Novatek International QSM Webinar Series, April 2009.
- "PQS – the new GMPs?" International Pharmaceutical Academy GMP Update, October 2008.
- "Navigating an FDA Audit of Stability Operations," Center for Business Intelligence Annual Forum on Stability Programs, 2007 and 2008.
- "Applying Good Manufacturing Practices During Drug Development," Marcus Evans Pharma Edge Manufacturing Summit, January 2007 and Clinical Evolution Summit, 2007.
- "Preparing for and Surviving an FDA Inspection," Institute of Validation Technology Workshop, June 2006 and September 2006.
- "Selecting a Stability Study Management Contractor," Institute of Validation Technology Seminar, 2005 and 2006.
- "FDA Regulations and ICH Guidelines for Stability Testing," Institute of Validation Technology Workshop, 2005.
- "Surviving an FDA Inspection," Novateck Stability Seminar/Workshop, 2005.
- "Outsourcing and the Impact on the PAI Process: Balancing the Needs of Regulators and Industry," FDA Investigator Training Program, 2001.
- "The Drug Development Process," Project Management: the Plan, the Process, the Pitfalls, Seminar Series, AAI International Seminars, 2000 and 2001.
- "Applying GMPs to Clinical Trial Supply Manufacturing," Complying with Global GMPs for Clinical Supplies, Institute for International Research Seminars, 2000.
- "Laboratory Efficiency and Compliance: Meeting the Challenges of Both in the Pharmaceutical Industry," AAI International Seminars, 2000.
- "Outsourcing: Out-of-Sight Does Not Mean Out-of-Mind," Auditing Techniques for Pharmaceutical Operations, AAI International Seminars, 1999 and 2000.
- "Evaluating the Supply Chain Before the PAI: A View from the Vendor's Perspective," Pre-Approval Inspections, Center for Business Intelligence, 1999.
- "Implementing a Biotech Stability Program and the Impact of the New FDA Stability Guidance for Industry," Biotech Stability: Current Scientific and Regulatory Issues, AAI International Seminars, 1998.
- "An Industry Perspective on Compliance," Cleaning Validation in the Pharmaceutical Industry, AAI International Seminars, 1998.
- "Validation Requirements for Pharmaceutical and Biotech Analytical Laboratories," AAI International Seminars, 1998.
- "Pharmaceutical Photostability Testing: The FDA Perspective," Photostability Scientific, Regulatory and Practical Issues, AAI International Seminars, 1997.
- "Planning for FDA Approval," Contract Process Development, Barnett International Seminars, 1997.
- "Preparing for and Facilitating Key FDA Meetings," Pharmaceutical Education and Research Institute, 1997.
- "Regulatory Aspects of Validation: Industry Perspective," Process Validation: Successful Strategies for Pharmaceutical Dosage Forms, AAI International Seminars, 1997.
- "Controlled Substances: Compliance Issues and Practices for the Pharmaceutical Industry," AAI International Seminars, 1997.