

STEPHEN A. WALD

Profile

- *Highly experienced and proven pharmaceutical executive with broad background in chemical and pharmaceutical process R&D, supply chain and alliance management in the pharmaceutical industry*
- *Creative problem solver with broad scientific background and strong appreciation for business needs and risk management, experienced at balancing internal resources and external vendors. Highly experienced with “virtual”/out-sourcing model*
- *Proven technical leadership and team building skills, experienced in both an entrepreneurial environment (7th employee hired at Sepracor) and in a fully integrated pharma company.*
- *Strong operational experience with a successful track record of consistently reaching operational, financial, and strategic targets to ensure business success (e.g., led preparation of five NDAs and oversaw four product launches)*
- *Negotiated numerous CMC contracts, including supply, quality and R&D master service agreements. In addition, acted as key internal resource to legal group, supporting negotiations relating to drug development and manufacturing aspects of licensing agreements.*
- *Diligence team leader responsible for evaluation of all aspects of chemistry and formulation R&D, and commercial product supply chains. Strong appreciation for intellectual property and its value to drug development and commercialization, along with diverse experience with a range of corporate cultures.*
- *Initiated and/or managed various reorganizations within Sepracor to better align R&D and/or commercial groups with current corporate objectives*

Work experience

Pick-Two Consultancy, LLC

Valley Cottage, NY

8/08 - Present

Principal – *Provides a broad range of consulting services to pharmaceutical industry, including*

- *Critically assessed formulation plans for both clinical supply and commercial product development*
- *Provided advice and guidance on a biotech company's upcoming product launch*
- *Recommended new business models to a pharmaceutical development organization faced with a research pipeline based on new technologies*
- *Conducted a competitive analysis on a sector in which a service company wants to improve its marketing and grow its offerings*
- *Acted as interim head of a new Alliance Management group with experience with a range of partners (from big Pharma to small biotechs)*

Senior Vice President, Commercial Technical Operations (7/05 – 8/08)

- Directed and managed new department, integrating supply chain operations, commercial quality and technical service functions, responsible for production, testing and warehousing of commercial products (Xopenex[®], Lunesta[®], Omnisar[®], Alvesco[®] and Brovana[™]) and associated supply chains
- Responsible for annual operating budget over \$80 million. Bolstered supply chain by increasing robustness (identified, qualified and obtained approval for several second sources) and reduced costs (identified and implemented several multi-million dollar cost reduction projects)
- Oversaw four product launches. Initiated and led an Executive Sales and Operation Planning meeting that reviews and approves production plans and post-approval projects .
- Negotiated numerous supply contracts, master service and option agreements both with contract manufacturers and licensing partners
- Initiated and led Operational Excellence initiative to re-engineer senior management processes

Senior Vice President, Chemistry and Pharmaceutical Sciences (11/00 – 7/05)**Vice President, Chemical Research and Development (4/95 – 11/00)**

- Directed and managed process chemistry, formulation and analytical R&D groups composed of chemists, pharmacists and engineers, overseeing the development of both drug substance and drug product processes in an integrated manner. Responsible from “first gram” to commercial-scale process validation, including senior management oversight of remote, chemical pilot plant (Sepracor Canada Ltd).
- Stewarded the growth of a world class, pharmaceutical R&D group from 14 to 50, including the development of a formulation development capability for Sepracor
- Chemical and pharmaceutical R&D culminated in five New Drug Applications, including oral solids, sterile solutions and a complex metered dose inhaler application (Xopenex HFA[®]). Led the teams preparing the CMC sections of various INDs and all NDAs, providing strategic direction. Actively involved in multiple FDA meetings and CMC negotiations.
- Became acting head of drug discovery, composed of 15 medicinal chemists, pharmacologists and biologists (2002-2004). Successfully nominated one drug candidate into development.

Vice President, Process Development & Engineering (7/93 –4/95)

Manage a process R&D group composed of 14 (8 Ph.D.) biologists, chemists and engineers for chiral chemical process development/production. Project manager for the design and construction of a new, greenfield, chemical pilot plant (Sepracor Canada Ltd., Windsor, Nova Scotia).

Director, Technology Transfer and other positions (11/85 - 7/93)

Extensive on-site experience in technology transfer to international companies, including Tanabe Seiyaku, Nagase and YF Chemicals (Taiwan). Project manager for the Tanabe Seiyaku program, culminating in successful start-up of 50 MT per year plant of a chiral intermediate utilizing proprietary enzymatic resolution and membrane bioreactor technology.

Fermentation Pilot Plant Supervisor and Process Development Engineer (1981 - 1985).

Responsible for supervise fermentation pilot plant (55 to 6000 liter scale) and conducted process improvement for all agricultural products produced via fermentation (plant growth regulators, biological insecticides).

Education

University of California Berkeley, California 1979 - 1981
Masters of Science, Chemical Engineering
Thesis: "Enzyme Hydrolysis of Rice Straw for the Production of Ethanol"

Cornell University Ithaca, New York 1975 - 1979
Bachelor of Science, Chemical Engineering