PICK-TWO CONSULTANCY

Managing timeliness, quality and economics for the pharmaceutical industry

STEPHEN A. WALD

CONSULTANT WITH BROAD OPERATIONS BACKGROUND IN PHARMACEUTICAL R&D (API AND DOSAGE FORM), TECHNICAL OPERATIONS, SUPPLY CHAIN AND ALLIANCE MANAGEMENT

- *Strong technical knowledge, risk-based decision making and operational experience, in both R&D and commercial settings*
  - *Led all of Sepracor's CMC development activities, resulting in numerous INDs and 5 NDAs submitted (four approved) over 7 years*
  - *Managed four, on-time product launches for Sepracor and Clinical Data/Forest*
- *Extensive experience in entrepreneurial environment (7th employee hired at Sepracor), operating both with in-house resources and/or via a virtual operating/out-sourcing model*
  - *Spearheaded a three person team that managed API, formulation and packaging CMOs through scale-up, validation and production planning, resulting in on-schedule launch of new anti-depressant*
- *Built and fostered collaborative relationships with internal (e.g.. R&D, Sales, Marketing, Business Development, Legal, Finance) and external customers (e.g., FDA, CDMOs, alliance partners)*
  - *Customer understanding aided in timely problem solving and debottlenecking to accelerate timelines with key CDMOs (stepped in to complete time-critical supply contract negotiation or solve a supply shortfall), alliance partners (overcome inter-company cultural differences) and FDA (negotiated specifications and data plans for NDAs and post-approval changes)*
- *Diligence lead, responsible for all aspects of pharmaceutical R&D, and commercial supply chains, for both licensing and acquisition. Experienced at preparing drug candidates for licensing.*
- *Negotiated numerous CMC contracts, including supply, quality and R&D master service agreements. Strong appreciation for intellectual property and its value to drug development and commercialization, along with diverse experience with a range of corporate cultures.*

Work experience

Pick-Two Consultancy, LLC Valley Cottage, NY *1/09 – 3/10, 7/11 – present*

Principal – *Focused on managing the tradeoffs between timeliness, quality and economics in the pharmaceutical industry. Provided a broad range of CMC consulting services, including*

- Acted as interim head of manufacturing for a speciality pharma company with novel oral delivery technology. Managed developmental manufacturing/QC/engineering functions, made major contributions to EOP2 briefing book and helped bolster quality systems.
- Served as virtual CMC head for emerging biotech. Managed CDMOs, assessed projects and obtained proposals for a fast-track biotech project for a MAb and protein

- Identified gaps in a supply chain (API, excipients, componenty and manufacturers) for a metered dose inhaler product in late Phase 2 clinical development. Developed new suppliers to fill gaps.
- Acted as key witness, representing development history and science, in intellectual property lawsuit
- Conducted a gap analysis for U.S. development of a European inhalation product
- Relationship manager for API CMO, responsible for commercial supply, capacity expansion and new supplier identification (Forest Labs)
- Prepared a launch preparedness gap analysis, including supply chain, NDA and staffing plans, with action plan and launch timeline for Trovis Pharmaceuticals
- Conducted a competitive analysis on aerosol development services for a CRO that wants to improve its marketing and grow its service offerings

Trovis Pharmaceuticals LLC, a division of Clinical Data, Inc. *4/10 – 6/11*

New Haven, CT (acquired by Forest Laboratories, Inc on 4/13/11)

Vice President, Technical Operations

Responsible for development and commercial technical operations. Commercial responsibilities encompassed process validation, launch preparation and commercialization of a new anti-depressant, Viibryd™ (vilazodone HCl tablets), spanning key intermediates, API, tablets, packaging and warehousing. Developmental responsibility for chemical, analytical and formulation process development, at CDMOs, of all late-stage drug candidates, along with support of CMC IND preparation.

- Developed integrated strategy for the supply chain development and production plans for Viibryd™ based on acquisition, co-market and go-it-alone sales scenarios. Built inventory of trade and samples to successfully launch, on schedule, by Forest Labs.
- Developed close and effective relationships with CMO management and negotiated supply agreements. Prepared CMC response during NDA review, along with container label negotiations. Handled all CMC aspects of out-licensing/diligence activities, culminating in Forest acquisition.
- Led the vial-to-prefilled syringe transition program, including identification and selection of commercial syringe filler as part of an integrated supply chain, for Stedivaze (apadenosan) for injection. Provided strategic input into preparation of new IND CMC submission.

Sepracor Incorporated Marlborough, MA *1985 - 2009*

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

Managed new department, integrating supply chain operations, commercial quality and technical service functions, responsible for production, testing and warehousing of commercial products (Xopenex®, Lunesta®, Brovana™, Omnaris®, Alvesco®) and associated supply chains at CMOs.

- Successfully managed annual operating budget (~$80 million) to target and met cost reduction goals by identifying and implementing several multi-million dollar cost reduction projects
- Strengthened supply chain by increasing responsiveness and robustness (identified, qualified and obtained approval for several, key second sources) and negotiated numerous supply agreements.
- Initiated and led an Executive Sales and Operation Planning meeting that reviews and approves production plans and project initiatives
- Interim head of new alliance management function, clarified internal roles and oversaw contract compliance/modification. Alliance Manager for key European partner, managing alliance at critical stage of final EMEA review, NDA filing and initiation of pre-commercialization activities (9/08-3/09)

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 chemists, pharmacists and engineers, responsible for development of both drug substance and drug product

processes. Responsible from "first gram" to commercial-scale process validation, including management oversight of API manufacturing plant (Sepracor Canada Ltd).

- Stewarded the growth of a world class, pharmaceutical R&D group from 14 to 50. 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®). Provided strategic direction and led teams preparing CMC sections of various INDs and all NDAs. Actively involved in numerous FDA meetings and CMC negotiations.
- Stepped up to become acting head of drug discovery group, composed of 15 medicinal chemists, pharmacologists and biologists. Successfully nominated one drug candidate into development and recruited permanent head of Drug Discovery.

Vice President, Process Development & Engineering (7/93 - 4/95)
Managed 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.

Abbott Laboratories North Chicago, IL *1981-1985*

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.

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

Patents, Publications and Presentations

10 patents, 30 publications