

Mark Staples, Ph.D.: Independent Consultant

"Pharmaceutical Technology Solutions"

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Objective

To expedite pharmaceutical product development, worldwide regulatory approval and commercialization of new therapeutic products through good science and effective project management.

Specialization

Broad-based experience with technical operations concerning development of drugs, biologics, and combination products (includes R&D, Preclinical, Manufacturing, Quality Systems and Regulatory). Pharmaceutical development of proteins and peptides: physical and chemical characterization, preformulation, formulation, technology transfer to manufacturing (GMP), product line extension (improved dosage forms), project management of the technical (CM&C) portion of regulatory submissions.

Education

- M.B.A., Northeastern University, Boston, MA, 1985
- Ph.D., Biochemistry, University of Kansas, Lawrence, KS, 1979
- B.A., Chemistry, Biochemistry, English, University of Kansas, Lawrence, KS, 1975

Experience

– MicroCHIPS, Bedford, MA, Vice President, Research and Development, 2004-2007; Vice President, Pharmaceutical Technology, 2003-2004

- Directed research that proved an implant can deliver highly concentrated polypeptide (Leuprolide), using remotely controlled electronic activation, for six months in dogs. Multiple patents and publications document this work, which had a critical and positive impact on collaborator and investor interest.
- Scope of authority included a wide range of technologies: materials science, preclinical studies, and pharmaceutical science; mentor to project managers on MicroCHIPS' most important program, an implantable glucose sensor; leader of initiative to implement Quality Systems to support human trials
- Member of senior executive team: reported regularly to Board of Directors; contributed to all operational and strategic decisions; regularly created and delivered presentations for meetings with potential investors and partners. Executive team performance recently led to a \$13.4 million dollar round of investment funding.
- Created project proposals applying MicroCHIPS' technology to osteoporosis and cancer; led efforts to develop partnerships with pharmaceutical companies

– GlycoGenesys, Boston, MA, Vice President, Development and Manufacturing, 2002-2003

- Redesign of formulation and filling process reinitiated stalled clinical trials, allowing company to continue operations until funding was not available
- Completed site selection and planning for company's first development lab
- Managed all external technical contractors and GCS-100 project team

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– Praecis Pharmaceuticals, Waltham, MA, Sr. Director, Pharmaceutical Sciences, 2002; Director, 1997-2002

- Project manager for CMC section of NDA and MAA Part II; filed NDA ahead of schedule
- Developed innovative controlled release prostate cancer therapeutic product from research stage to commercializable dosage form.

– Biogen, Cambridge, MA, 1988-1997, Group Leader (Section Head) 1992-1997; Program Exec in addition to line function 1995-1996; Sr Process Scientist 1989-1992; Process Scientist II 1988-1989

- Managed pharmaceutical development resulting in IND approvals (rsCD4, LFA3TIP, anti-CD40L, gamma-IFN, anti-VLA4 small molecule/aerosol, gelsolin).
- Developed one product from clinic to market (Avonex™: beta-Interferon), led company-wide technical team for two years; participated in FDA and EMEA inspections.
- Program Executive, Avonex™ pre-filled syringe project. Regular presentations to the Biogen Operating Team, technology transfer of process for pre-filled syringes to a Netherlands manufacturer (co-author of patent and approved for marketing).
- Developed one product from preclinical to NDA and out-licensing (Hirulog™-now marketed as Angiomax), including authorship of CMC section (finished product), technology transfer to sites in the US, Belgium and Germany.
- Founded analytical biochemistry group. Directed for seven years (1989-1996).
- Founded pharmaceutical development group. Directed for eight years (1989-1997).
- Initiated non-parenteral dosage form capabilities in group (aerosol and oral).
- Managed a program to apply advanced drug delivery technologies to Biogen products (1992-1997).

– Immunogen, Cambridge, MA, Research Chemist, 1987-1988

- Led development resulting in an IND approval; founded a biochemistry laboratory

– Seragen, Hopkinton, MA, Project Manager, 1986-1987; Research Chemist, 1985-1986

- Supervised new drug development; built an analytical protein chemistry group

– New England Nuclear, Boston, MA, Production Supervisor (Lipids Group), 1982-1984; Chemist, 1980-1982

- Conducted research and development on leukotrienes and other lipid products
- Supervised production of seventy radiolabeled lipid products
- Created new products (ten overall, 1980-1984)

– Harvard Medical School, Department of Biological Chemistry, Boston, MA Postdoctoral Research Fellow, 1979-1980; Research Associate, 1982-1986, quarter-time

- Initiated project in Dr. E.R. Blout's peptide lab, leading to publications

Professional Activities

- American Association of Pharmaceutical Scientists: BIOTEC Section leadership (Membership Chair 2001-2003, Vice-Chair 2004, Chair-Elect 2005, Chair 2006); Chair, AAPS Distance Learning Committee 2007; Chair, AAPS Newsmagazine Committee 2004 (member 2002-2005)
- Parenteral Drug Association New England Chapter: PDA Chapter Volunteer Award, 2007; Chapter Board Member-At-Large 2005-2006, President 2003-2004, Treasurer 1993-2002, Activities Committee since 1990