Mark Staples

Owner, Cusp PharmaTech Consulting LLC

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Summary

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

Highlights of projects Dr. Staples has worked on include:
• MicroCHIPS, Inc., 2003-2007 (VP R&D, 2004-2007): led Pharmaceutical Technology research leading to highly concentrated leuprolide and PTH(1-34) formulations suitable for delivery from an implantable MEMS-based device.
• GlycoGenesys, Inc., 2002-2003 (VP Development and Manufacturing): re-engineered the manufacturing process for the polysaccharide anti-cancer agent GCS-100, enabling clinical trials to resume.
• Praecis Pharmaceuticals Inc., 1997-2002 (Dir Pharmaceutical Sciences): compiled the CMC section for Plenaxis(TM), an extended release prostate cancer therapeutic (launched in 2004).
• Biogen, 1988-1997 (Section Head 1992-1997): played critical roles developing and launching the MS drug, AVONEX®, and led analytical and formulation development for the ANGIOMAX® anticlotting peptide.

Specialties

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.

Experience

Principal (Consultant) at Cusp PharmaTech Consulting LLC
July 2007 - Present (2 years)

Services that may be applied to the needs of start-up, clinical development, or commercial organizations include:

• DEVELOPMENT
=>Preformulation, formulation and dosage form design

=>Analytical method development: spectroscopic, thermal, chromatographic, ELISA; method transfer to QC
=>Process design, finished product manufacturing
=>Technology transfer to manufacturing (GMP)

• TECHNICAL WRITING, MANAGEMENT
=>Write and compile CMC sections
=>Project management, CMC teams
=>Product lifecycle management
=>CRO/CMO management
8 recommendations available upon request

VP R&D at MicroCHIPS
2003 - 2007 (4 years)

Bedford, MA
VP, R&D, 2004-2007
VP, 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.
• 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.

VP Development and Manufacturing at GlycoGenesys
2002 - 2003 (1 year)

Boston, MA
VP, Development and Manufacturing, 2002-2003
• Redesign of formulation and filling process reinitiated stalled clinical trials, allowing company to continue operations
• Completed site selection and planning for company's first development lab
• Managed all external technical contractors and GCS-100 project team

Dir Pharmaceutical Sciences at Praecis
1997 - 2002 (5 years)

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.

Section Head Development at Biogen
1988 - 1997 (9 years)

Cambridge, MA
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)
• Program Executive, Avonex™ pre-filled syringe project (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
• Founded pharmaceutical development group
• 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).

Research Chemist at Immunogen
1987 - 1988 (1 year)

Cambridge, MA
• Led development resulting in an IND approval; founded a biochemistry laboratory

Project Manager at Seragen
1984 - 1987 (3 years)

Hopkinton, MA
Project Manager, 1986-1987
Research Chemist, 1985-1986
• Supervised new drug development; built an analytical protein chemistry group

Production Supervisor at New England Nuclear
1980 - 1984 (4 years)

Boston, MA,
Production Supervisor (Lipids Group), 1982-1984
Chemist, 1980-1982
• Production supervisor, seventy radiolabeled lipid products; introduced ten new products

Education

Harvard Medical School
postdoctoral, Biological Chemistry, 1979 - 1986

Northeastern University - Graduate School of Business Administration
MBA, Finance, Quantitative Analysis, 1982 - 1985
Activities and Societies: Beta Gamma Sigma Honor Society

University of Kansas
Ph.D., Biochemistry (Protein Chemistry), 1975 - 1979

University of Kansas
B.A., Chemistry, Biochemistry, English, 1972 - 1975
Activities and Societies: James Davis National Merit Scholar

Honors and Awards

American Association of Pharmaceutical Scientists: BIOTEC Section leadership (Chair 2006)
Parenteral Drug Association New England Chapter: PDA Chapter Volunteer Award, 2007; Chapter President 2003-2004
New England Camera Club Council B&W Class B Image of the Year 2007
President, Boston Camera Club, 2005-2008

Interests

Arts, Literature, Photography, Rollerblading, Snorkeling

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8 people have recommended Mark

"Dear Michael W, I've written this recommendation of your work to share with other LinkedIn users. Details of the Recommendation: "Mark was my client at Biogen and subsequent companies where he handled numerous complex projects related to injectable/oral products for human use. Mark is scientific, goals-oriented and works well with team members. It was pleasure working with him.""

— Michael W Lovell*, Vice President, BioDevelopment Labs, Genzyme Transgenics*, was a consultant or contractor to Mark at Cusp PharmaTech Consulting LLC

"Mark has over 20 years of experience in CMC development of biopharmaceuticals. He has developed several proteins and peptides from clinic to market, including Avonex# Beta Interferon. Mark is widely regarded as the industry leading expert in analytical development, pharmaceutical development and drug product manufacturing of protein/peptide pharmaceuticals. Mark consulted for PDL Biopharma (now Facet Biotech) in 2008 and managed our drug product CMO for several of our antibody products including both liquid and lyophilized formulations. Mark has done a superb job in managing our drug products manufacturing and also provided his expert advice in many other areas including supply chain management, tech transfer, quality and regulatory filings. Mark is highly responsible. He always delivers work or advice that is of the highest quality, in the shortest timeframe, and with extreme efficiency (which is important for small companies that has limited funding). I highly recommend Mark’s work. Sharon Wang, Ph.D. Sr. Director, Pharmaceutical Development and Supply Chain Management Facet Biotech"

— Sharon Wang, was Mark's client

"I had the pleasure of being in Mark's reporting chain in my first job at Praecis. I consider myself lucky to have stayed in touch with Mark through various work projects since I joined WLI. Mark is meticulously detail-oriented but doesn't lose the forest for the trees. He helps his clients and colleagues define the work needed to accomplish an identified goal and then provide clear communication during its pursuit. I highly recommend Mark for his scientific insight and skills, and his sense of humor makes working together most enjoyable!"

— Nicole Damour Krilla*, Project Manager, Wolfe Laboratories, Inc.*, was with another company when working with Mark at Cusp PharmaTech Consulting LLC

"Mark is well recognized as an expert in the development of biopharmaceuticals. He is definitely

someone I go to with tricky questions that require a thoughtful scientifically sound answer. I particularly appreciate his understand of GMP process related to biopharmaceutics."

— Jeff Sailstad, *President, Sailstad and Associates Inc.*, was with another company when working with Mark at Cusp PharmaTech Consulting LLC

"I have enjoyed working with Mark, he is extremely professional, knowledgeable and great to travel with. He made our project easy to complete and sucessful with the client"

— Michelle Sceppa, *Owner, MSceppa Consulting*, was with another company when working with Mark at Cusp PharmaTech Consulting LLC

"Mark is thoughtful, knowledge and experience professional in the Pharmaceutical industry. His specialty is in the CMC product development area which include manufacturing. When Mark was working for me, he successfullt led the effort to file an NDA and a MAA in Europe. Both NDA and MAA were approved with minor questions from the Regulatory authority. Mark is also a personable person. He will evaluate all issues with much considerations and his judgements were always accurate and practical. Heow Tan"

— Heow Tan, *Vice President, Praecis Pharmaceuticals*, managed Mark at Cusp PharmaTech Consulting LLC

"I've known Mark since 1991. He is an astute scientist with a solid understanding of the "bigger picture" in the development of pharmaceutical products. His ability to solve problems and complete assignments in the areas of formulation development and assay development is unsurpassed. He's easy to work with, knowledgeable, creative, and results-oriented. What more could you ask for?"

— Peter Levy, *Director Development Engineering, biogen*, worked with Mark at Cusp PharmaTech Consulting LLC

"Mark is a gentleman and an excellent scientist with much expertise in formulation science and development of protein therapeutics."

— Ron Bowsher, Ph.D., *Partner & President, B2S Consulting*, worked directly with Mark at Cusp PharmaTech Consulting LLC

Contact Mark on LinkedIn