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Objective

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

Specialization

Broad-based management oversight of 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 (CMC) portion of regulatory submissions.

Experience

— Cusp PharmaTech Consulting LLC, Cambridge, MA, Consultant (Principal), 2007-present;

[Representative recent assignments]

- Directed preclinical to Phase I CMC program, including vendor management, for a parenteral peptide therapeutic and also for a synthetic tetra-peptide vaccine.
- Provided CMC-related gap analysis, CMC sections for pre-IND briefing documents, and FDA pre-IND meeting support, various small molecule and peptide projects.
- Served as technical advisor in protein formulation to a biologics start-up.
- Provided Expert Witness reports and testimony in formulation-related IP cases, including depositions in two cases in 2011.

—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. Multiple patents and publications document this work.
- Scope of authority included a wide range of technologies, including 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 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.
- Completed site selection and planning for company's first development lab.
- Managed all external technical contractors and GCS-100 project team.

—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 (7 Ph.D.s and 13 non-Ph.Ds.); 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. This product formulation was patented and commercialized.
- 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

- Production supervisor, seventy radiolabeled lipid products; introduced ten new products.

—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.

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

Professional Activities

- American Association of Pharmaceutical Scientists: BIOTEC Section leadership (Chair 2006); various volunteer positions since 2002.
- Parenteral Drug Association New England Chapter: PDA Chapter Volunteer Award, 2007; Chapter President 2003-2004, various volunteer positions since 1990.