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Objective Employing extensive drug development experience provide consulting services in pharmaceutical R&D for start-up or established pharmaceutical companies

Overview

- Extensive drug development experience with variety of sterile and non-sterile dosage forms from API and proof of principle through post-approval changes with start-up and established companies.
- Wrote, edited, and/or approved CMC (Module 3) sections in eCTD format for more than 6 NDAs/ANDAs, more than 10 INDs, and their ex-US regulatory counterparts; prepared Pharmaceutical Development Reports to support regulatory filings
- Interacted with FDA in various formats including meetings at various stages of development, telephone conferences, and PAIs. Prepared, reviewed, and approved pre-IND, End of Phase Two, and pre-NDA information packages and written responses to queries from FDA and European MOHs.
- Developed, conducted GMP/GLP assessments, and managed relationships with variety of contractors (API synthesis, formulation development, drug product manufacture, clinical supply packaging and distribution, analytical chemistry support and stability assessment, and preclinical studies). Aided in realistic timeline development as well as assisting in project management of CMC activities.

Experience

Oct, 2006 – Present **President, Paul Laskar Associates, Inc**, Napa, CA
Provide consulting services in areas of strategic CMC, pharmaceutical, and preclinical development plans and timelines; formulation development focusing on ophthalmic, dermatological, respiratory, parenteral, oral, and nasal drug products; stability assessment design, execution, and reporting; CRO/CMO identification, qualification, GMP/GLP assessment, and management; API source evaluation; regulatory planning; preparation of clinical trial materials; and manufacturing process development and technology transfer. Aid in project management of CMC development activities. Prepare reports for regulatory filings from IND to NDA. Write and edit CMC (Module 3) sections in eCTD format for pre-INDs, INDs, IMPDs, and FDA meetings. Write and edit Pharmaceutical Development Reports. Participate in meetings and other interactions with regulatory agencies.

2003 - Oct, 2006 **Dey, L.P.**, Napa, CA
Senior Director, Pharmaceutical Development
Lead formulation development, clinical trial materials supply, preclinical development, pilot operations, manufacturing process development, and technology transfer functions for Dey's respiratory and nasal projects. Identify CROs for preclinical, clinical packaging and distribution, and contract manufacturing activities. Write CMC and preclinical documentation in support of 1 NDA, 2 ANDAs, 2 INDs, 2 sNDAs, 1 Canadian NDS, 1 IMPD, & 1 EU MAA. Prepare preclinical and CMC recommendations for in-license opportunities.

- Managed department of 11 professionals (3 Ph.D.; 7 BS) with a budget of >$5000K (2006) in >10 development projects at various stages from preclinical to post-approval
- Prepared CMC sections for NDA, ANDAs, MAA/NDS, several INDs, sNDAs, and IMPD. Prepared preclinical sections for 1 NDA and several INDs
- Participated in several FDA meetings (pre-IND and end of Phase Two)
- Prepared technical reviews of more than 10 in-license candidates annually

1994-2003 **Santen, Inc.,** Napa, CA
Principal Director, Pharmaceutics and Technology
Director/Vice President, Pharmaceutical Development
Lead formulation development, analytical chemistry, clinical materials supply, stability assessment, preclinical function for Santen's ophthalmic projects. Identify contractors to source manufacture of API and drug products, prepare clinical trial kits, conduct analytical and stability studies, and perform preclinical studies. Work with peers at headquarters in Japan and European subsidiary to develop formulation and preclinical development strategies and execute technology transfer. Write and approve CMC and preclinical documentation for regulatory submissions. Interact with FDA. Prepare recommendations following CMC review of in-license candidates. Project leader for early stage and feasibility projects.

- Developed and managed project timelines and budgets (>$3000K)
- Built lean and efficient department up to 10 persons (4 Ph.D.s; 1 DVM, 1 MS) despite evolving strategy for conducting pharmaceutical and preclinical development
- Prepared and/or directed preparation of CMC sections of 5 INDs, 1 CTX, 3 approved NDAs, 1 NDS, 2 MAAs, and 2 sNDAs.
- Directed development of systems to facilitate formulation development, technology transfer, stability assessment and clinical material tracking
- Helped develop and implement CMC and preclinical development strategy for several projects
- Served as CMC and preclinical liaison among R&D at Santen in Japan, US, and Finland
- Established and maintained effective working relationships with Japanese and Finnish colleagues to facilitate progress of global preclinical and later stage development projects
- Prepared technical reviews of in-license candidates
- Guided process validation for API and drug products; participated in PAIs for API and drug product

1993-1994 **CoCensys Inc.,** Irvine, CA
Director, Pharmaceutical Sciences
Guide preformulation, formulation development, stability assessment, clinical materials supply, and research QC functions in early stage development of neurosteroid and glystatin compounds. Develop and manage relationships with consultants and CROS and CMOs for development projects.

- Wrote CMC sections for 2 INDs
- Developed documentation and systems to ensure compliance with cGMPs
- Initiated formulation development of 2 compounds (1 oral, 1 parenteral) in multiple presentations

1989-1993 **Allergan/Herbert Laboratories**, Irvine, CA
Manager/Director, Product Development, Herbert Laboratories
Guide formulation development, analytical chemistry, stability assessment, and research QC functions for skin care division. Interact with other discovery and other nonclinical & clinical departments, manufacturing, business development, and marketing. Interact with FDA verbally and in person to gain registration approval. Develop and manage budget of ~$1200K. Evaluate, recommend, and suggest products for potential acquisition.

- Grew department from 6 to 16 scientists and technicians
- Developed formulations to meet global requirements including parenterals, solid (immediate and extended release), and topicals
- Responsible for preparation of CMC sections of 11 INDs, NDAs and NDSs and a CTX
- Scaled up several products from laboratory through pilot to commercial scale manufacture; guided site transfer of three products from US to Europe
- Developed cost and timing estimates in project planning process
- Developed and managed relationships with several third party contractors

1988-1989 **Procyte Corporation,** Redmond, WA
Director, Pharmaceutical Development

- Developed proof of principle formulation for lead compound.
- Developed and initiated implementation of pharmaceutical development manpower strategy (recruited two section heads)
- Designed formulation and analytical chemistry laboratory
- Shared responsibility with another person for preparation and filing of successful IND on lead compound
- Contributed to contract negotiations on joint venture with a major pharmaceutical company

1982-1988 **Allergan, Inc.,** Irvine, CA
Scientist/Section Manager, Pharmaceutics,

- Brought two significant ophthalmic projects to registration status in Europe and US. Developed oral formulation, which enhanced bioavailability 2 ½-fold in animal model
- Formulated stable, elegant ocular solution product of 2 physically incompatible antimicrobials and developed a lyophilization cycle for its manufacture
- Supervised 3 BS personnel in up to 10 projects

1974-1982

1. **School of Pharmacy, Creighton University,** Omaha, NE
   Associate Professor of Pharmacy
2. **College of Pharmacy, University of Illinois-Medical Center,** Chicago, IL
   Assistant Professor of Pharmacy

- Taught basic pharmaceutics, pharmaceutical technology, pharmacokinetics, and therapeutics courses
- Developed self-instructional and videotape educational materials

Education

MBA, University of California at Irvine, (General Management, International Management, Marketing)

Ph.D., Pharmaceutical Sciences, Oregon State University
(Minor: Biostatistics)

MS, Pharmacy, University of Illinois – Medical Center

BS, Pharmacy, University of Illinois – Medical Center

BA, General Science (Chemistry, Biology), University of Rochester

Presentations

SR Nadkarni & PA Laskar, “Comparison of Release Kinetics of Indomethacin from Gelucire Dispersions”, AAPS, November 1992

S Matsumoto, et al., “Potential Irritation by Dermatological Vehicles Assessed with *In Vivo* and *In Vitro* Tests”, AAPS, November 1992

SR Nadkarni & PA Laskar, “Investigation of Solid Dispersions of Indomethacin in Gelucires as Potential Sustained Release Systems”, AAPS, November 1991

KA Kelley, PA Laskar, GD Ewing, SH Dromgoole, AA Sakr, JL Lichtin, “In Vitro Evaluation of Sunscreen Sustained Release Systems”, AAPS, November 1991

Publications

KA Kelley, PA Laskar, GD Ewing, SH Dromgoole, JL Lichtin, & AA Sakr, “In Vitro Sun Protection Factor Evaluation of Sunscreen Products,” J Soc Cosmet Sci, 44(3):139-151(May-June 1993)

PA Laskar & JW Ayres, “Degradation of Carmustine in Mixed Solvent and Nonaqueous Media”, J Pharm Sci 66: 1976 (1977)

HR Manasse Jr. & PA Laskar, “Some Considerations Regarding Norm-Referenced and Criterion Referenced Testing in Pharmaceutical Education”, Am J Pharm Educ 40:275 (1976)

JW Ayres, D Lorskulsint, A Lock, L Kuhl, PA Laskar, “Absorption and Distribution of Radioactivity from Suppositories Containing 3H-Benzocaine in Rats”, J Pharm Sci 65:832 (1976)

JW Ayres & PA Laskar, “Diffusion of Benzocaine from Ointment Bases”, J Pharm Sci 64:1402 (1974)

JW Ayres & PA Laskar, “Evaluation of Mathematical Models for Diffusion from Semisolids”, J Pharm Sci 63:351 (1974)

JW Ayres & PA Laskar, “Student Experiments in Pharmaceutics: IV Additives, Chemical Incompatibilities, Kinetics, and the Arrhenius Equation”, Am J Pharm Educ 38:58 (1974)

PA Laskar & RG Mrtek, “Synthesis and Biological Activity of Deuterio-benzyl-d_7-penicillin”, J Pharm Sci 59:1727 (1970)

Patents

WO/1993/020796, “Method and Composition for Treating Acne”, 28 October 1993, with S Nadkarni

Application (US20050009836), “Ophthalmic Composition Containing Quinolones & Method of Use,” with SD Hickok

Other

Registered Pharmacist: California and Illinois (inactive)

Western Region, AAPS: Fundraising Chairperson, 1992-1993; Academic Award Chairperson, 1991; Publicity Chairperson, 1989-1991; Meeting Chairperson, 1988; Meeting Co-Chairperson, 1987; Program Chairperson, 1986; Poster Session & Publicity Chairperson, 1985

AAPS Provisional Biotechnology Section: Chairperson, Program Committee, 1988

Graduate student advisor & adjunct faculty, University of Cincinnati, College of Pharmacy, 1990-1993

Author/co-author, Instructional Videotapes, “Extemporaneous Preparation of Hard Gelatin Capsules,” Extemporaneous Preparation of Ointments,” and Extemporaneous Preparation of Suppositories,” UIMC, 1973-4

Member and vice chair, Napa County Tobacco Advisory Board, 2011 to present