Fernandez and Associates
Jim Fernandez, Principal
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Objective: Develop high quality projects to advance the development, registration and commercialization of novel products and technologies in pharmaceuticals and biopharmaceuticals.

Education:

Masters of Business Administration, June 1994
St. Mary's College
Moraga, CA
Business skills development including international business, communications skills, organizational management, financial analyses, and marketing.

Bachelors of Science, Biochemistry, 1976
California Polytechnic State University
San Luis Obispo, CA
Emphasizing analytical biochemistry in the field of medical, clinical, and diagnostic biochemistry and chemistry. Extensive coursework in microbiology.

Ongoing Education:
Seminars and coursework in Drug and Biochemical Stability, Personnel Management, Project Management, Validation of Pharmaceutical Production, Immunology, Computer operations and applications (MS Word, Excel, PowerPoint, Access, Photoshop, Notes, Filemaker, Project 98, and misc. office administration applications)

Experience:

December 1990 to December 2000 Berlex Biosciences/Schering AG

Scientist/Manager – Technology Transfer responsible for a wide range of product development activities from mid-development into commercialization emphasizing Phase II, III and IV of biological therapeutics. Worked under constrained supply modes. Resposible for drug supply and technology transfer in bulk drug substance production for the small molecule chemotherapeutic, Fludara®. Responsible for technology transfer between the US and Europe for the production of clinical and commercial supplies of Betaseron®. Coordination of technical communications between six major technology centers and hundreds of individual scientists and business staff. Extensive Regulatory experience with applications to US, EU, Japan, S. Africa, Australia including development of ICH and USA overlapping regulatory strategies. Assisted in development of supply contracts between contract manufacturers' of therapeutic proteins and product owners. Development of contract manufacturer database for therapeutic protein production and contract laboratory services database. Citations for excellence in creativity, initiative, teamwork and education.

August 1986 to December 1990 Triton Biosciences/Royal Dutch Shell - Biotechnology

Manufacturing Associate responsible for validation activities in therapeutic development and manufacturing including establishment of policy, operational protocols, implementation of equipment control and change systems, input to facility design, design and control of calibration programs, new process validation and implementation. Responsible for process validation from fermentation through fill/finish and labeling.
Pharmaceutical Analyst responsible for development of analytical procedures for biotechnology therapeutics in early development (Phase I/II.) Design, equip, staff and operate analytical laboratory for three beginning to mid-level scientists.

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December 1983 to July 1986 Collagen Corporation

Quality Assurance Supervisor – Chemistry, responsible for laboratory functions covering routine production output, new product development, product stability, final product, in-process and raw material analyses, including method development and validation. Extensive experience in all aspects of cGMP and how they relate to new product lines, delivery devices, packaging, labeling and regulatory submissions.

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August 1982 to November 1983 Barnes-Hind Pharmaceuticals

Quality Control Supervisor, Chemistry and Methods Development Chemist – instituted methods of analyses not previously used in the ophthalmic division of this drug and device company. Instituted various elements of cGMP to improve laboratory output. Developed personnel and managerial skills pertaining to systems evaluations, personnel development and drug and device regulations. Administered QA Chemistry Laboratory, Stability programs, control chart programs, and QA technical development.

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May 1977 to July 1982 Cutter Laboratories/Bayer AG

Assistant Corporate QA Chemist and Associate Corporate QA Chemist – developed and performed numerous assays as an analytical biochemist. Emphasis on protein and nutritional chemistry with experience using LC, HPLC, analytical ultracentrifuge, spectrophotometer (IR, UV/Vis, Raman, Schlieren,) GC, Technicon Autoanalyzer and other instruments. Administrative: Managed laboratory purchasing and accountability for 15 chemists.

Publications:

Development of Specifications for Biotechnology Products; ed: F. Brown and J. Fernandez, International Association of Biological Standardization, volume 91, 1997.

"The Applicability of SDS-PAGE to the quantitation of Fragments of Immune Serum Globulin Preparations"; Vox Sang. 3:250-257 (1980)

Other:

- Member of ACS, AAAS, PDA
- 2001 to present – member of PDA Science Advisory Board specializing in Biotechnology issues and new technology developments
- Numerous activities with PDA organizing interdisciplinary meetings on pharmaceutical technology, regulatory developments, biotechnology developments, gene technology developments
- Founding group (1989) and President of West Coast Chapter of the PDA (1993 – 1995)
- Steering Committee of WCCPDA – 1989 - 1997