Ernest H. Pfadenhauer

Santa Barbara, CA 93109
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EDUCATION

1963 to 1967 — University of California, Santa Barbara
Bachelor of Science degree in chemistry. Graduated cum laude; named outstanding graduating senior in the Chemistry Department.

1969 to 1970 — University of California, Santa Barbara
Master of Arts degree in physical chemistry. Research to theoretically describe the NMR relaxation mechanisms of ^{19}F inorganics.

EMPLOYMENT

2011 to 2013 — Epiomed Therapeutics, Inc.
CHIEF OPERATING OFFICER. Management of two major pharamacetical development projects, a NCE for emesis and a new formulation of scopolamine via nasal spray. Responsible for regulatory, pharamaceutical, financial and R&D functions.

2007 to 2009 — Cenomed BioSciences, LLC
VICE-PRESIDENT PHARMACEUTICAL DEVELOPMENT. Responsible for medicinal and analytical chemistry research. CNS lead compound and clinical candidate selection. Overall responsibility for CMC, DMPK and project management for regulatory submissions.

2002 to 2007 — Consultant to the Pharmaceutical Industry
Assist in compiling the CMC sections of Regulatory Submissions. Development of drug products. Drug Chemistry problem resolutions. Bioanalytical aspects of ADME/PK studies.

1996 to 2002 — NeoTherapeutics, Inc., Irvine
DIRECTOR, CHEMISTRY RESEARCH. New drug development for the treatment of CNS related disorders. Management of Chemistry, Manufacturing and Control aspects of the drug development process. Responsible for bioanalytical and pharmaceutical methods development and validation, human and animal metabolism and pharmacokinetic studies, drug stability, formulation, clinical supplies management, and related regulatory submissions. Group leader for drug discovery.

1995 to 1996 — Baxter Healthcare Corp. Cardiovascular Surgery, Irvine
PROJECT SCIENTIST. Development of new and improved chemical fixation techniques for tissue heart valves. Analytical method development for new reagents, process design and transfer of the process and methods to manufacturing and QC. Studies of cross-linking reagents and their effect on tissue properties including biocompatability, calcification,

and durability. Project leader for a new proprietary bioprosthetic valve technology.

1992 to 1995 — Baxter Diagnostics, Inc.
STAFF SCIENTIST. Conducted feasibility studies of non-isotopic immunoassay technologies. Designed and evaluated new clinical laboratory instrumentation. Managed field trials of new clinical chemistry tests. Developed a unique, widely applicable, immunoassay technology currently being used for the measurement of thyroxine.

1987 to 1992 — Baxter Healthcare Corporation, Dade Division, Irvine
SENIOR RESEARCH SCIENTIST. Developed new clinical immunoassays for the Paramax high-throughput analyzer. Conducted feasibility studies, optimization using response-surface techniques, and final formulation characterization of apolipoprotein A-I and B immunoturbidimetric assays. For these assays, fluid-bed techniques were used to produce a tablet formulation containing all necessary ingredients for the analysis. Wrote manufacturing process and control records for transfer to production. Participated in the IFCC apolipoprotein standardization process.

1970 to 1987 — Newport Pharmaceuticals International, Inc., Newport Beach
SENIOR RESEARCH SCIENTIST. Manager of a small research group dealing with most chemical and biochemical aspects of new drug development. A significant portion of the research involved the analysis of new drugs and the identification and distribution of their metabolites. Independently developed assay methodology using TLC, HPLC, GLC, and radioimmunoassay. Labeled new drugs with ^{3}H, ^{14}C, and ^{125}I for pharmacokinetic studies. As radiation safety officer, administered the radioactive materials safety program and handled regulatory matters.

Organized and wrote the chemistry (quality control and manufacturing), biochemistry and bioavailability sections of IND supplements, NDA, NDS, and PLA submissions for new drug approval.

Formerly, SUPERVISOR, QUALITY CONTROL DEPARTMENT. Responsible for the development and validation of analytical control methods, and composition and updating of records and procedures to satisfy Food and Drug Administration regulations. Designed specifications, testing methods, validation and stability studies for raw materials, intermediates, and finished products for generics and new drugs. Purified and provided documentation for reference materials.

1969 to 1970 — University of California, Santa Barbara.
TEACHING ASSISTANT: Teaching and grading of undergraduate laboratories.

Publications (abbreviated, posters and abstracts omitted)

E.H. Pfadenhauer and Douglas C. McCain. Nuclear Magnetic Resonance of Fluoroscandate Anion, ScF_6^{-3} in Aqueous Solution. J. Phys. Chem. 74, 3291 (1970).

E.H. Pfadenhauer. Rapid Determination of Some Plasma Oxypurines Using High-Pressure Liquid Chromatography. J. Chromatography 81, 85 (1973).

A.J. Glasky, E.H. Pfadenhauer, R. Settineri, and T. Ginsberg. Isoprinosine, a Purine Derivative; Metabolic, Immunological and Antiviral Effects. Combined Immunodeficiency - A Molecular Defect. Birth Defects Institute Symposium IV, (H. Meuwissen, Ed.), Academic Press, New York.

E.H. Pfadenhauer. A High-Pressure Gradient Chamber for Liquid Chromatography. Anal. Chem. 46, 628 (1974).

T. Ginsberg, D.G. Streeter and E.H. Pfadenhauer. Metabolism of the N,N-Dimethylamino-2-Propanol (DIP) and p-Acetamidobenzoic Acid (PAcBA) Components of Isoprinosine in Rhesus Monkeys. Analysis of Urinary Excretion Products. Presented at the 7th International Congress of Pharmacology, Paris, France. July 18-21, 1978.

E.H. Pfadenhauer and Sun-De Tong. Determination of Inosine and Adenosine in Human Plasma Using HPLC and a Boronate Affinity Gel. J. Chromatography 162, 585 (1979).

E.H. Pfadenhauer, C.E. Jones, and K.W. Maxwell. Radioimmunoassay of NPT 15392 in Human Serum and Urine. J. Pharm. Sci. 72(8), 716 (1983).

D.G. Streeter and E.H. Pfadenhauer. Inosiplex: Metabolism and Excretion of the Dimethylaminoisopropanol and p-Acetamidobenzoic Acid Components in Rhesus Monkeys. Drug Metabolism and Disposition 12(2), 199 (1984).

E.H. Pfadenhauer, C.S. Bankert, J. Jensen, C.E. Jones, E.E. Jenkins and J.A. McClosky. Identification of the Metabolites of erythro-9-(2-Hydroxy-3-nonyl)-hypoxanthine from Laboratory Animals. Drug Metabolism and Disposition 12(3), 280 (1984).

E. H. Pfadenhauer. HPLC Assay in Urine for Metabolites of a Drug after Extraction by Antiserum to the Drug: An Example Using erythro-9-(2-Hydroxy-3-nonyl)-hypoxanthine. J. Chromatography 425(2), 407 (1988).

E.H. Pfadenhauer, G. Liggins, and R. Edwards. Performance Characteristics of an Assay for Apolipoprotein A-I on the Paramax Analytical System. Clin. Chem. 36(6), 966 (1990). Abstract.

E.H. Pfadenhauer, G. Liggins, P. Dutta, and R. Edwards. Performance Characteristics of an Assay for Apolipoprotein B on the Paramax Analytical System. Clin. Chem. 36(6), 966 (1990). Abstract.

Stephen E. Kahn, Robert F. Labbe, Ernest H. Pfadenhauer, A. Dee Kanonchoff, and Russell T. Joseph. Multicenter Evaluation of Automated Immunoturbidimetric Assays for Measurement of Apolipoproteins A-I and B in Serum and Plasma. Clin. Chem. 40(9), 1722-1729 (1994).

Rita Ellithorpe, Paul Mazur, Glenwood Gum, Gerry Button, Julian Le, BS, Ernest. H. Pfadenhauer, Robert A. Settineri, Garth Nicolson, Comparison of the Absorption, Brain and Prostate Distribution, and Elimination of CaNa2 EDTA of Rectal Chelation Suppositories to Intravenous Administration. JANA Vol. 10, No. 2, 2007.

PATENTS

High Pressure Gradient Chamber for Liquid Chromatography. U.S. Patent Number 3,830,369.

Liquid Reagent Container Having a Primary and Secondary Closure Mechanism. U.S. Patent Number 5,542,575.

Liquid Reagent Container. U.S. Design Patent D363354.

Homogeneous Sol-Sol Assay. U.S. Patent Number 5,851,777

Method of Inhibiting Calcification of Aldehyde-fixed Bioprosthetic Materials. U.S. Patent 6,008,292; European Application 98958678.9-2107

Medical Compositions for Intravesical Treatment of Bladder Cancer. US Patent 6,894,071.

Tetrahydroindolone Derivatives For Treatment Of Neurological Conditions. US Patent 7,795,266

Assay for Determination of Compounds Having Anti-Emetic Activity. US Patent 8,637,236

Numerous patents applied for and awaiting office actions.