

## *Curriculum Vitae*

### **CONFIDENTIAL R**

#### **PROFESSIONAL SUMMARY:**

Over **twenty years** of experience in the **biopharmaceutical** industry. Extensive background in regulatory strategy, the drug development process, and project management. Professional highlights include:

- Providing regulatory strategies to drug development teams
- Liaison to corporate partners for global product development
- Project management for Senior Management Team
- Organizing and coordinating submission activities with functions
- Review and approval of all submissions
- **Managing regulatory meetings for INDs and NDAs**
- **Strong CMC** background and experience
- Managing Analytical Research and QC Laboratories and conducting stability, methods development and validation per ICH guidelines
- Overseeing on-site inspections and contract manufacturing site inspections

#### **EDUCATION:**

**Ph. D., Analytical Chemistry**, Indiana University, Bloomington, IN. (1980)  
M. S., Organic Chemistry, Illinois State University, Normal, IL. (1977)  
B. S., Chemistry, Chungyuan University, Taiwan. (1972)

#### **PROFESSIONAL EXPERIENCE:**

##### ***CONFIDENTIAL, Alameda, CA***

1997 - Present, Sr. Director, Regulatory / QA/QC

Managing a team of ten individuals responsible for regulatory submissions and corporate compliance. Serving as project leader. Providing regulatory strategies to development teams for product development in multiple ophthalmic therapeutic areas. Ensuring smooth technology transfer from Product Development to Quality Control and Manufacturing including analytical methods transfer and process scale-up. Overseeing activities in Chemistry Laboratory and Microbiology Laboratory and ensuring stability

programs and methods validation are following GMP/GLP and ICH guidelines. Serving as a liaison to FDA on all submissions and negotiations in regulatory meetings. Managing inspections from FDA, State Agencies, and Corporate partners. Set up quality systems ensuring compliance in GMP/GCP/GLP. Managing departmental budgets and schedules as well as project timelines for company. Also served as the point person in technology transfer to several major pharmaceutical companies.

***CONFIDENTIAL, Alameda, CA***

1994 - 1997, Director, Analytical Research  
1990 - 1993, Manager, Analytical Research

Established Analytical Research Department and managed a staff of ten scientists. Supervised activities in methods development and validation following current regulations including ICH guidelines, and activities in methods transfer to Quality Control and corporate partners. Supported research and development including drug release studies, bioavailability assays, clinical PK studies, pre-formulation activities, formulation stabilities, and trouble shooting for manufacturing activities. Worked with contract analytical labs. Prepared CMC sections for eight INDs and one NDA submission. Worked on several drug master files with corporate partners. Managed projects in various ophthalmic indications.

***ADVANCED POLYMER SYSTEMS, Redwood City, CA***

1986 - 1989, Senior Scientist

Worked with Formulation Development on a polymer based micro sponge delivery system on various topical products in the pharmaceutical therapeutic and cosmetic applications. One of the products was licensed out and is marketed as RETIN-A MICRO by Johnson & Johnson for acne indication. Developed methods for physical and chemical characterizations of the polymer delivery system, and methods for assaying the active drug. Supported research and development including drug release studies, product stabilities, and trouble shooting for manufacturing activities.

***CONDUCTIMER CORPORATION, San Jose, CA***

1983 - 1986, Senior Research Scientist

Major activities were methods development for characterization of conductive polymers, and experiment design for the evaluation of conductive polymers. Techniques such as spectroscopy, separation methods, and electrochemistry were applied to the research and development of conductive materials in the electrode and corrosion applications. Supervised a group of chemists.

**UNIVERSITY OF OKLAHOMA, Norman, OK**

1981-1983, NIH Postdoctoral Fellow

Engaged in research work. Research goals were to understand the reaction mechanisms of some enzyme catalyzed biological reactions, and to compare the biological reactions with electrochemical pathways of reduction/oxidation reactions. In this project, separation methods utilizing techniques such as gel permeation, HPLC, and GC were developed for product identification and purification. Spectroscopy such as IR and rapid-scan UV were used to monitor reaction mechanisms. GC-MS with electron ionization or chemical ionization techniques were used to characterize intermediates and final products. The biological reactions and the electrochemical reactions were concluded to follow similar mechanisms.

**INDIANA UNIVERSITY, Bloomington, IN**

1977-1980, Research Assistant

Participated in research activities including organic synthesis and electrosynthesis of olefins, highly conjugated olefins, allenes, cumulenes, ketones, and iodonium salt. Synthesized isotope labeled compounds to investigate reaction mechanisms. Techniques such as electrolysis, cyclic voltammetry, and polarography were used to perform electrochemical synthesis. A combination of separation techniques such as GC, HPLC, and characterization methods such as MASS, NMR, IR, and UV spectroscopy were used to identify the intermediates and final products.

**ILLINOIS STATE UNIVERSITY, Normal, IL**

1975-1976, Research Assistant

Synthesized high energy organic compounds. Developed a single step synthesis for the nitromethylation of aromatic compounds involving organometallic catalysts. This new process offered better yield, higher purity, and an easier separation step for the synthesis of nitro-aromatics.

**COMPEQ MANUFACTURING**

1974-1975, Quality Assurance Supervisor

Supervised a quality assurance line of 20 people. Major functions were setting product specifications per customer requests, developing analytical procedures for incoming and final product inspections, and monitoring the process to minimize errors and to reduce unnecessary costs.

## PROFESSIONAL MEMBERSHIP:

Regulatory Affairs Professionals Society  
Drug Information Association  
American Association of Pharmaceutical Scientists  
Parenteral Drug Association  
American Chemical Society  
Alpha Omega Chapter, Phi Lambda Upsilon National Honorary Chemical Society

## PUBLICATIONS:

Nitromethylation of Aromatic Hydrocarbons with Nitromethane-Manganese(III) Acetate. Confidential, J. Chem. Soc., Chem. Commun. (1976) 968

Nitromethylation of Aromatics with Nitromethane-Manganese(III) Acetate. Confidential, J. Org. Chem., 43 (1978) 239

Electrochemistry of 1,1,4,4-Tetraphenyl-1,3-butadiene, 1,1,4,4-Tetraphenyl-1,2-butadiene, and 1,1,4,4-Tetraphenyl-1-butene in Dimethylformamide. T.R. Confidential, J. Electroanal. Chem., 197 (1986) 341

Electrochemistry of Phenylpropadiene, Confidential, J. Org. Chem., 52 (1987) 1231

Electrochemical Reduction of 1,1,4,4-Tetraphenylbutatriene. c, J. Electroanal. Chem., 222 (1987) 257

The Second Voltammetric Oxidation Peak of 7,9-Dimethyluric Acid. Confidential, J. Electroanal. Chem., 144 (1983) 191

Electrochemical Oxidation of 7,9-Dimethyluric Acid in Acid Solution. Confidential, J. Electroanal. Chem., 154 (1983) 107

Peroxidase-catalyzed Oxidation of 7,9-Dimethyluric Acid. Confidential, Bioelectrochem. Bioenerg., 156 (1983) 75.

Oxidation Chemistry of 3,7-Dimethyluric Acid, Electrochemical and Peroxidase-catalyzed Mechanisms. Confidential, J. Electroanal. Chem., 177 (1984) 149

Systemic Absorption of PilaSite vs. A Pilocarpine Eyedrop Solution. C.Y. Eto, R. Repass, Confidential, Suppl. to Invest Ophthalmol Vis Sci, 33(4): 1121 (1992)

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**PATENTS:**

Patent Number 5,340,572, Alkaline Ophthalmic Suspensions, Confidential, August 23, 1995.

Patent Number 5,474,764, Alkaline Ophthalmic Suspensions, Confidential, December 12, 1995.