

Wing-Kee Philip Cho, Ph.D.

Summary: Expertise and over 28 years of experience in formulation and process development of solid delivery systems including immediate and controlled release dosage forms for new chemical entities and line extensions. Lead formulator of five marketed products including two products with annual sales over one billion dollars. Extensive experience in regulatory filings, cGMP and quality systems. Recipient of President Award, the highest scientific award given by Schering-Plough. Areas of experience and expertise include:

- Solid Formulation Development
- Solid Process Development
- Regulatory Strategies and IND/NDA Filing
- Cross-Functional Team Management
- Due Diligence Evaluation
- CRO Management

Professional Experience

Private Practice

Consultant: 2011-present

Schering-Plough/Merck

Formulation and Pharmaceutical Sciences Fellow: 1987-2011

Smith Kline & French Laboratories

Solid Formulation Development Associate Senior Investigator: 1983-1987

Education/Certification

1977: B.S., Pharmacy, University of Wisconsin-Madison

1982: Ph.D., Pharmaceutics, University of Michigan

1983: Post-Doctoral Fellow, University of Utah

Drug Development Experience

- Lead formulator of five marketed products (Eulexin®, Temodar®, Clarinex D12®, Zetia® and Victrelis®) including two products with annual sales over one billion dollars (Zetia® and Temodar®)
- Developed drug product manufacturing processes; scale-up and technology transfer of manufacturing processes to commercial sites
- Prepared and reviewed monographs, technical reports, and regulatory documents to support worldwide regulatory submissions
- Chaired cross-functional product development teams
- Prepared and reviewed best practice documents for formulation and process development
- Performed due diligence evaluations
- Managed product development projects outsourced to CROs

Selected Publications

- W.I. Higuchi, E.Y. Cesar, W.P. Cho and J.L. Fox, "Powder Suspension Method for Critically Reexamining the Two-Site Model for Hydroxyapatite Dissolution Kinetics", *J. Pharm. Sci.*, 73, 146, 1984.
- W.P. Cho, J.L. Fox, W.I. Higuchi and P. Pithayanukul, "Influences of Dodecylamine Hydrochloride Adsorption on the Dissolution Kinetics of Hydroxyapatite", in "Adsorption on and Surface Chemistry of Hydroxyapatite", D.N. Misra, Ed., Plenum Press, New York, 51, 1984.
- W.P. Cho, J.L. Fox, P. Pithayanukul and W.I. Higuchi, "Hydroxyapatite Dissolution Rates in Fluoride/Dodecylamine Solution", *J. Colloid Interface Sci.*, 99, 235, 1984.
- W.I. Higuchi, W.P. Cho, J.L. Fox and K. Yamamoto, "Unifying Criteria for Dissolution Kinetics of Various Hydroxyapatite Preparations", *J. Colloid Interface Sci.*, 110, 2, 1986.
- G.H. Zhang, W.A. Vadino, W.P. Cho and I.A. Chaudry, "Factors Affecting Dissolution Testing Using the Flow-Through Cell Method", *Pharmaceutical Research*, 7(9), S79, 1990.
- P. Mojarevian, C. Lin, W.P. Cho, W.A. Vadino and J. Rosen, "Correlation of In Vitro Release Rate and In Vivo Absorption Characteristics of Four Chlorpheniramine Maleate Extended Release Formulations", *Pharmaceutical Research*, 9(4), 450, 1992.
- G.H. Zhang, W.A. Vadino, T.T. Yang, W.P. Cho and I.A. Chaudry, "Evaluation of the Flow-Through Cell Dissolution Apparatus: Effects of Flow Rate, Glass Beads and Tablet Position on Drug Release from Different Types of Tablets", *Drug Dev. Ind. Pharm.*, 20(13), 2163, 1994.

Selected Patents

- "Pharmaceutical Composition Comprising Loratadine, Ibuprofen and Pseudoephedrine". W.P. Cho, W.A. Vadino and I.A. Chaudry, U.S. Patent No. 4990535, issued February 5, 1991.
- "Sustained Release Tablet Comprising Loratadine, Ibuprofen and Pseudoephedrine", W.P. Cho, W.A. Vadino and I.A. Chaudry, U.S. Patent No. 5100675, issued March 31, 1992.
- "Controlled Release Flutamide Composition", E. Stupak and W.P. Cho, U.S. Patent No. 5162117, issued November 10, 1992.
- "Extended Release Oral Dosage Composition", W.P. Cho, U.S. Patent No. 6709676, issued March 23, 2004.
- "Sterol Absorption Inhibitor Compositions", W.P. Cho, U.S. Patent No. 7030106, issued April 18, 2006.
- "Method for Inhibiting Sterol Absorption", W.P. Cho, U.S. Patent No. 7612058, issued November 3, 2009.
- "Pharmaceutical Formulations and Methods of Treatment Using the Same", B. Malcolm, P. Bradley, A. Pavlovsky, W.P. Cho and Z. Qiu, US Patent No. 7772178, issued August 10, 2010.