

CURRICULUM VITAE

GREGORY M. KOCHAK, Ph.D.

647 Woody Drive
Auburn, AL 36832

Telephone: (334) 887-1016
Email: kochagm@charter.net

Affiliation: R&D Services, LLC, 663 N. 132nd Street, Suite 126, Omaha, NE 68154

Telephone: (402) 445-6054
Webpage: www.rdservkc.com

SUMMARY OF SELECTED ACCOMPLISHMENTS

- " 18 Years experience in the pharmaceutical industry including senior management; 8 years in academia.
- " Assembled and managed a multi-disciplinary department at an international pharmaceutical company.
- " Assembled the managing partners and incorporated a start-up product development pharmaceutical company; created the business plan and acquired small business and private capital.
- " Acquired strategic business development partners and clients at a contract research organization.
- " Represented international clients at the FDA leading to successful U.S. NDA registrations.
- " Contributed to the research and development, and successful U.S. NDA registrations of Lotensin[®] (Ciba-Geigy), Tegretol XR[®] (Ciba-Geigy), Habitrol[®] (Ciba-Geigy), Zonegran[®] (Dainippon Pharmaceuticals), Tenormin[®] (Stuart Pharmaceutical), Anafranil[®] (Ciba-Geigy), Voltaren[®] (Ciba-Geigy); international registration of Afema[®] (Ciba-Geigy); and, U.S ANDA of generic pentoxifylline (Biovail).
- " Received federal and industry grant support as an academic researcher.
- " Experience in the clinical development, trial design, and implementation for drugs in the CNS, oncology, rheumatology and cardiovascular therapeutic areas.
- " Experience in preclinical design and implementation of studies for pharmacokinetic, drug formulation, drug metabolism and bioavailability assessment leading to first-dose-in-man protocols.

- “ CMC support including amendments and assessment of stability indicating polymeric packaging.
- “ Ad hoc advisory committee for population biostatistical models and analysis, FDA's Center for Drug Evaluation and Research, Office of Generic Drugs.
- “ Completed industry sponsored training programs in Senior Management, Executive Advisory and Creative Leadership.

AREAS OF EXPERTISE

“ **Clinical pharmacology and therapeutics**

Pharmacokinetics and pharmacodynamics: Includes fundamental analysis, model assessment and simulation; biostatistics and random effect models; dose linearity, bioavailability, biopharmaceutical assessment, mass balance and proof-of-concept therapeutics. Biomarker identification and biochemical clinical surrogate analysis.

“ **Drug metabolism**

In vivo/in vitro drug metabolism, drug-drug interactions, both enzyme kinetic and protein binding interaction; metabolite identification, pharmacokinetics and pharmacodynamics.

“ **Bioanalytical chemistry**

Analytical method development and validation; HPLC, LC/MS/MS, GC, GC/MS, radiometric methods, and bioassays. Large and small molecules.

“ **Drug delivery and biopharmaceutics**

Preformulation, formulation, manufacturing scale-up, and controlled release; physical pharmacy, industrial pharmaceutical technology and manufacturing; bionanotechnology.

“ **Biostatistics/Bioinformatics**

ANOVA, covariate analysis, linear and nonlinear regression, random effects population models, sample size estimation, power, confidence intervals, experimental design.

“ **Product and project management**

Strategic and logistic planning and management. Due diligence and contract development. Regulatory summaries, submissions (IND and NDA), technical reports and scientific manuscripts.

WORK EXPERIENCE

- 2007-Present Independent pharmaceutical consultant, affiliation R&D Services, LLC, Omaha, NE
- 1999-07 Associate Professor, Department of Pharmacal Sciences, School of Pharmacy, Auburn University, Auburn, AL 36849
- 1993-00 Founder and former Chairman, Board of Directors, Innova Pharmaceuticals, Inc., 46 Old Camplain Road, Somerville, NJ 08876
- 1995-98 Vice President, Research and Development, Kansas City Analytical Services, 12700 Johnson Drive, Shawnee, KS 66216-1643
- 1981-93 Director, Clinical Pharmacokinetics and Disposition Section, CIBA-GEIGY Corp., Ardsley, NY 10502, 1991-93; Manager, 1986-91; Senior Research Scientist, 1985-86; Senior Scientist, 1981-1985.
- 1987-Present Adjunct Doctoral Faculty, University of Missouri, Kansas City, Missouri
- 2002-06 Board of Directors, East Alabama Comprehensive Sickle Cell Foundation, 401 South 8th Street, Opelika, AL 36801-1721

EDUCATION

- 1976-81 University of Missouri, Kansas City, Missouri; Ph.D. in Pharmaceutical Sciences.
- 1971-76 Ohio State University, Columbus, Ohio; B.S. in Pharmacy.

PROFESSIONAL ACTIVITIES

American Pharmaceutical Association
Academy of Pharmaceutical Research
American Association of Pharmaceutical Scientists
Fellow, New York Academy of Science

Hudson Valley Pharmaceutics Discussion Group

- X Founding member, 1986
- X Board of Directors 1986 - 1988
- X President 1987

Eastern Regional Group of the AAPS

- X Founding member, 1987
- X General Co-chairman 1987 First Eastern Regional Meeting, Atlantic City, New Jersey
- X Pharmacokinetics, Pharmacodynamics, and Drug Metabolism (PPDM) Section Chairman, 1988 Second Eastern Regional Meeting, Atlantic City, New Jersey

Registered Pharmacist, Ohio State Board of Pharmacy, 1976.

Referee for the Journal of Pharmaceutical Sciences, Biopharmaceutics and Drug Disposition, Pharmaceutical Research, International Journal of Pharmaceutics and Journal of Drug Targeting.