

GREGORY MICHAEL KOCHAK

CURRICULUM VITAE

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SUMMARY

Dr. Kochak's experience includes more than 20 years in the pharmaceutical industry and eight years in pharmacy education. He has experience in discovery, preclinical, and clinical drug development including Phases 0/I, I, and II. Besides working in Pharma, Dr. Kochak was founding partner of a small drug product development company and was an associate professor at a large research university. He received his doctorate from the University of Missouri-Kansas City after completing a pharmacy degree at Ohio State University. Dr. Kochak has published and presented widely in the areas of pharmaceutical technology, pharmacokinetics and clinical research.

EMPLOYMENT

2007-present President at Kochak Consulting, Auburn, AL 36832. Kochak Consulting is also affiliated with R&D Services Pharma Consulting, LLC, Overland Park, KS 66214 (www.rdservkc.com)

Dr. Kochak is an independent consultant for the pharmaceutical and legal-medical industries. Consultant activities have included a wide range of projects and services including preclinical support of IND applications, IND summaries, preclinical pharmacokinetics and toxicokinetics; discovery assessment of HDAC inhibitors; development of active polymeric materials for stability packaging; drug recall avoidance strategy and FDA communications; portfolio development for a biopharmaceutical start-up, clinical study placement with external collaborators and CROs; pharmacometric modeling and simulation; and, a CMC section amendment among other projects.

Provides consulting services to the medical-legal community assessing litigation strategies and analysis on technical issues regarding patents and medical malpractice.

1999-07 Associate Professor, Department of Pharmacal Sciences, School of Pharmacy, Auburn University, Auburn, AL 36849

As a university faculty member Dr. Kochak taught courses in the professional and graduate programs. He mentored several M.S. and Ph.D. candidates.

Research was directed towards the development of hydrophilic nanoparticulate drug delivery systems for the purpose of delivering macromolecules with selective cellular intervention exploiting the Warburg effect. This research resulted in a number of publications and other scientific communications exploring carbohydrate-based polymeric platforms, methods of spatially directed interfacial polymerization and synthesis, the characterization of interfacial and material properties in aqueous fluids, macromolecule loading efficiency, and device performance characteristics with regards to protein mass transfer mechanisms.

His major accomplishments included the completion of three M.S. and Ph.D. students, recognition of outstanding research award by one of these students, successful grant funding, the development and mentoring of professional students, and the development of internal and external collaborations.

1993-00

Founder and former Chairman, Board of Directors, Innova Pharmaceuticals, Inc., 46 Old Camplain Road, Somerville, NJ 08876

Dr. Kochak was a founding partner, Chairman of the Board of Director (1993-1997), and member BOD (1997-2000). Innova Pharmaceuticals, Inc. was incorporated in 1992, and was a research and development company specializing in the development of technically challenging sustained and immediate release drug products for the generic industry. As a founding partner of this start-up company, Dr. Kochak was instrumental in assembling the senior partners' team; acquiring and outfitting a 6,000 sq ft facility complete with laboratories, pilot production, and office space; and acquiring both state and private sector funding. He was involved in all aspects of starting a business including various registrations with governmental agencies, budgeting, staffing, planning and financing the business. He provided technical expertise in formulation development.

In July 1998, the U.S. FDA approved generic pentoxifylline sustained release tablets which was developed by Innova and licensed to Biovail. It is currently marketed in the U.S. by Teva.

1995-98

Vice President, Research and Development, Kansas City Analytical Services, 12700 Johnson Drive, Shawnee, KS 66216-1643

Responsible for all R&D (70-80 direct and indirect reporting personnel) including institutional staffing, fiscal and budget management, program planning, business development and client interactions. Provided leadership and technical expertise in pharmacokinetics, clinical study design, HPLC and LC/MS/MS bioanalytical method development, and statistics. Represented clients at FDA regulatory meetings. Strategically positioned the company and initiated the sale to Applied Analytical, Inc. in 1998.

Accomplishments included consultation services to Dainippon Pharmaceuticals leading to the successful NDA registration of Zonegran[®], recruitment and support of Purdue Pharma clinical drug development, and negotiations leading to the successful completion and sale of KCAS to Applied Analytical, Inc.

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.

Responsible for development and execution of clinical pharmacology and pharmacokinetic plans and supporting bioanalytical methods development across multiple therapeutic areas (Phases I and II). Authored, reviewed and approved study reports, regulatory documents supporting IND, NDA and ANDA submissions. Managed the CPD department which was comprised of 20-30 Ph.D., M.D. and junior level scientists within allocated budgets. Managed study progress and timelines. Provided leadership and technical expertise. Represented the department on project teams. Matriculated through various levels of responsibility within the organization.

Accomplishments included original research and clinical study implementation in the angiotensin converting enzyme program for hypertension and heart failure, aromatase inhibition program for estrogen-dependent breast cancer, and anti-epileptic program for adult and juvenile populations. I pioneered random effects biostatistical models in order to quantify population intersubject and intrasubject variability in clinical research and evaluate statistical covariates. Contributed to the clinical pharmacology and pharmacokinetic sections for successful U.S. NDA registrations of Lotensin[®], Tegretol XR[®], Habitrol[®], Anafranil[®], Voltaren[®] and international registration of Afema[®].

UNCOMPENSATED APPOINTMENTS

1987-present	Adjunct Doctoral Faculty, University of Missouri, Kansas City, MO
2002-2006	Board of Directors, East Alabama Comprehensive Sickle Cell Foundation, 401 South 8th Street, Opelika, AL 36801-1721

ACADEMIC BACKGROUND

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

MANAGEMENT TRAINING

Management Skills, Executive Advisory Skills, and Effective Technical and Business Writing programs sponsored by CIBA-GEIGY Corp.

Creative Leadership Program sponsored by the Center for Creative Leadership, Colorado Springs, Colorado.

PROFESSIONAL ACTIVITIES

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

Hudson Valley Pharmaceuticals Discussion Group
Founding member, 1986
Board of Directors 1986 - 1988
President 1987

Eastern Regional Group of the AAPS
Founding member, 1987
General Co-chairman 1987 First Eastern Regional Meeting, Atlantic City, New Jersey
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.

Ad hoc advisory committee, FDA's Center for Drug Evaluation and Research, Office of Generic Drugs

HONORS AND RECOGNITIONS

Rho Chi Society - National Pharmacy Honors Society
Research Fellow CIBA-GEIGY Corporation

APhA2003 Postgraduate Best Paper Award, APhA -APRS Basic Sciences Section, *A. Basu Sarkar and Gregory M. Kochak*.

Major advisor to *A. Basu Sarkar*, 2005-2006 recipient of the Auburn University Outstanding Graduate Student, doctoral level; awarded by the Graduate Council, Office of the Dean, Graduate School Auburn University.

PUBLICATIONS

Refereed Journal Publications of Original Research

Sarkar, A.B. and Kochak, G.M., "Hydrophilic carbohydrate nanocapsules as a sustained delivery depot of small and macromolecular drugs: Preformulation and mass transfer", *Int. J. Pharm. Sci. Rev. Res.* 13:19-27 (2012).

Sarkar, A.B., Kestur, U. and Kochak, G.M., "Interfacially Assembled Carbohydrate Nanocapsules: A Hydrophilic Macromolecule Delivery Platform", *J. Biomed. Nanotechnology* 5: 456-463 (2009).

Sarkar, A.B. and Kochak, G.M., "HPLC Analysis of Aliphatic and Aromatic Dicarboxylic Acid Cross-Linkers Hydrolyzed from Carbohydrate Polyesters for Estimation of the Molar Degree of Substitution", *Carbohydrate Polymers*, 59: 305 (2005).

Kochak, G.M., and Mangat, S., "Transepithelial Ultrafiltration and Fractal Power Diffusion of D -Glucose in the Perfused Rat Intestine", *Biochim. Biophys. Acta, Biomembranes* 1567:87 (2002).

Kochak, G.M., Page, J.G., Buchanan, R.A., Peters, R., and Padgett, C.S., "Steady State Pharmacokinetics of Zonisamide, An Antiepileptic for Refractory Complex Partial Seizures", *J. C lin. Pharmacol.*, 38:166 (1998).

Morgan, J.M ., Piraino, A.J., Saris, S .D., Graham , C.S ., Hirschhorn, W .L., Kochak, G .M., and Choi, R. L., "Inhibition of Angiotensin-Converting Enzyme with Libenzapril in Normotensive Males ", *J. Clin. Pharmacol.*, 34:1177 (1994).

Choi, R.L., Sun, J.X., and Kochak, G.M ., " Effect of Food on the Relative Bioavailability of Fadrozole Hydrochloride", *Biopharm. Drug Dispos.*, 14: 779 (1993).

Kochak, G.M., Pai, S., Iannucci, R., Honc, F., Kachmar, D., Perrino, P., and Egger, H., "Prinomide Tromethamine Pharmacokinetics: Mutually Dependent Saturable and Competitive Protein Binding Between Prinomide and its Own Metabolite", *Pharm. Res.*, 10: 49 (1993).

Alioth, C., Blum, R.A., D'Andrea, D.T., Kochak, G.M., Teng, L., Ziehmer, B.A., Schentag, J.J., and Chan, K.K.H., "Application of Dual Radiotelemetric Technique in Studying Drug-Drug Interaction Between Diclofenac Sodium and Ranitidine HCl in Volunteers ", *Pharm. Res.*, 10: 1688 (1993).

Kochak, G.M., Choi, R.L., and Entwistle, E.A., "Dose Proportionality and Population Characteristics of Oral Fadrozole Hydrochloride, an Aromatase Inhibitor, in Postmenopausal Women", *Pharm. Res.*, 10: 1760 (1993).

Kochak, G.M., "Population Characteristics of Biological Systems Influenced by Multi-Component Random and Uniform Variation", *Pharm. Res.*, 9: 341 (1992).

Thakker, K.M., Mangat, S., Wagner, W ., Castelanna, J., and Kochak, G.M ., "Effect of Food and Relative Bioavailability Following Single Doses of Voltaren 150 mg Hydrogel Bead Capsules in Healthy Subjects", *Biopharm. Drug Dispos.*, 13: 327 (1992).

Kochak, G.M., Sun, J.X., Choi, R.L., and Piraino, A.J., "Pharmacokinetic Disposition of Multiple-Dose Transdermal Nicotine in Healthy Adult Smokers", *Pharm. Res.*, 9: 1451 (1992).

Thakker, K.M., Mangat, S., Garnett, W .R., Levy, R.H., and Kochak, G.M., "Comparative Bioavailability and Steady State Fluctuations of Tegretol Commercial and Carbamazepine OROS Tablets in Adult and Pediatric Epileptic Patients", *Biopharm. Drug Dispos.*, 13: 559 (1992).

Kochak, G.M., Berner, B., Dewitte, W., and Leal, M., "Variational Analysis of the Transdermal Delivery Rate From Two Prototypical Ethanol-Water Nitroglycerin TTS Devices and Transderm-Nitro 10 in the Normal Population", *J. Pharmacokinet. Biopharm.*, 20: 443 (1992).

Lipton, A., Harvey, H.A., Demers, L.M., Hanagan, J.R., Mulagha, M.T., Kochak, G.M ., Fitzsimmons, S., Sanders, S.I., and Santen, R.J., "A Phase I Trial of CGS 16949A - A New Aromatase Inhibitor", *Cancer*, 65: 1279 (1990).

Kochak , G .M ., Choi, R.L., and deSilva, J.K ., "Pharmacodynamic Dependent Disposition of the Angiotensin Converting Enzyme Inhibitor, Libenzapril", *J. Clin. Pharmacol.*, 30: 138 (1990).

Kochak, G.M., Mangat, S., Entwistle, B.A., Mulagha, M.T., Lipton, A., Santen, R.J., and Demers, L.M., "The Pharmacodynamic Inhibition of Estrogen Synthesis by Fadrozole, an Aromatase Inhibitor, and its Pharmacokinetic Disposition", *J. Clin. Endocrin. Metab.*, 71: 1349 (1990).

Egger, H., Kochak, G.M., Robertson, P., Iannucci, R., Rufino, F.A., and Stancato, F., "Physiological Disposition of CGS 16617 in Rat, Dog, and Man", *Drug Metab. Dispos.*, 17: 669 (1989).

Kochak, G.M., Smith, R.A., Choi, R.L., John, V., Tipnis, V., Honc, F., deSilva, J., and Weidler, D., "Intra-and Intersubject Variability: Mixed Effects Statistical Analysis of Repeated Doses of an Angiotensin Converting Enzyme Inhibitor, CG S 16617", *Pharmaceutical Res.*, 6: 328 (1989).

Kochak , G .M ., Rakhit, A ., Thompson, T.N., and Hurley, M ., "Pentopril-Cimetidine Interaction Caused

by a Reduction in Hepatic Blood Flow", *J. Clin. Pharmacol.*, 28: 222 (1988).

Kochak, G.M., Rakhit, A., Honc, F., and Mahoney C.J., "Pharmacokinetic Disposition of the Novel Atypical Anxiolytic CGS 9896 in the Cynomolgus Monkey", *Psychopharmacology*, 94: 332 (1988).

Choi, R.L., Kochak, G.M., Reydel-Bax, P., and Hurley, M., "Effect of Food on the Bioavailability of CGS 16617, an Angiotensin Converting Enzyme Inhibitor, in Healthy Subjects", *J. Clin. Pharmacol.*, 28: 848 (1988).

Rakhit, A., Radensky, P., Szerlip, H.M., Kochak, G.M., Andet, P., Hurley, M., Feldman, G.M., "Effect of Renal Impairment on the Disposition of Pentopril and its Active Metabolite", *Clin. Pharmacol. Ther.*, 44: 39 (1988).

Rakhit, A., Kochak, G.M., Tipnis, V., and Hurley, M., "Inhibition of Renal Clearance of Furosemide by Pentopril, an Angiotensin Converting Enzyme Inhibitor", *Clin. Pharmacol. Ther.*, 41: 580 (1987).

Kochak, G.M., and Rakhit, A., "Determination of Metabolite Pharmacokinetics for Orally Administered Prodrugs", *Drug Metab. Dispos.*, 15: 456 (1987).

Rakhit, A., Kochak, G., Tipnis, V., Radensky, P., Hurley, M., and Williams, R., "Pharmacokinetics of Pentopril in the Elderly", *Br. J. Clin. Pharmacol.*, 24: 351 (1987).

Kochak, G., Honc, F., and Waldes, L., "Simultaneous Determination of 2-(p-chlorophenyl)-pyrazolo (4,3-c) quinoline-3(5H)-one (CGS 9896) and its 6-, 7-, and 8-Hydroxy Metabolites in Plasma, Urine, and Bile by High Performance Liquid Chromatography", *J. Chromatogr.*, 378: 242 (1986).

Kochak, G.M., and Mason, W.D., "The Pharmacokinetics of Methyldopa in Dogs", *J. Pharmacokin. and Biopharm.*, 13: 405 (1985).

Kochak, G.M., Rakhit, A., Wagner, W. E., Honc, F., Waldes, L., and Kershaw, R., "The Pharmacokinetics of Baclofen Derived From Intestinal Infusion", *Clin. Pharmacol. and Ther.*, 38: 251 (1985).

Rakhit, A., Kochak, G., Dotson, R., and Tipnis, V., "Disposition of Pentopril, a New Orally Active Angiotension -Converting Enzyme Inhibitor, and its Active Metabolite in Rats", *J. Pharm. Sci.*, 74: 947 (1985).

Rakhit, A., Hurley, M., Redalieu, E., Kochak, G., Tipnis, V., Coleman, J., and Rommel, A., "Effect of Food on the Bioavailability of Pentopril, an Angiotensin-Converting Enzyme Inhibitor in Healthy Subjects", *J. Clin. Pharmacol.*, 25: 424 (1985).

Kochak, G., and Honc, F., "An Improved Gas-Liquid Chromatographic Method for the Determination of Baclofen in Plasma and Urine", *J. Chromatogr.*, 310: 319 (1984).

Kochak, G.M., and Mason, W.D., "A Simplified Method of Determining Free Methyldopa in Urine", *Anal. Letters*, 14(B6): 439 (1981).

Kochak, G.M., and Mason, W.D., "Determination of Free Methyldopa in Plasma by High Pressure Liquid Chromatography and Electrochemical Detection", *J. Pharm. Sci.*, 69: 897 (1980).

Mason, W.D., Kochak, G.M., and Winer, N., "Decreased Renal Clearance of Atenolol with Exercise", *J. Pharm. Sci.*, 69: 344 (1980).

Winer, N., Mason, W.D., Carter, C.H., Willoughby, T.L., Kochak, G.M., Cohen, I., and Bell, R., "Effect of Atenolol on Blood Pressure, Heart Rate, Renin, and Norepinephrine During Exercise", *Clin. Pharmacol. and Ther.*, 26: 315 (1979).

Mason, W.D., Winer, N., Kochak, G.M., Bell, R., and Cohen, I., "Pharmacokinetics and Absolute Bioavailability of Atenolol", *Clin. Pharmacol. and Ther.*, 25: 408 (1979).

Refereed Journal Publications of Scientific Abstracts

Sarkar, A.B. and Kochak, G.M., "Synthesis of nanoparticles with hydrophilic core and surface", *The AAPS Journal*, 9:S2 (2007).

Sarkar, A.B. and Kochak, G.M., "Incorporation into and release of model protein lysozyme from carbohydrate nanoparticles", *The AAPS Journal*, 9:S2 (2007).

Sarkar, A.B. and Kochak, G.M., "Carbohydrate platforms for the synthesis of nanocapsules with hydrophilic colloidal cores", *The AAPS Journal*, 6 (2004).

Sarkar, A.B. and Kochak, G., "HPLC Analysis of Aliphatic and Aromatic Dicarboxylic Acids from Carbohydrate Polyesters", APhA Academy of Pharmaceutical Research and Sciences, APhA2003, New Orleans, LA, 2003, *J. Amer. Pharm. Assoc.*, 43 (2003).

Pujari, V., Eley, J., and Kochak, G., "In-Vivo Studies of Polymethacrylate Nanospheres Containing Coumarin-6", APhA Academy of Pharmaceutical Research and Sciences, APhA2003, New Orleans, LA, 2003, *J. Amer. Pharm. Assoc.*, 43 (2003).

Page, J.G., Kochak, G.M., Polvino, W.J., and Buchanan, R.A., "Multiple Dose Zonisamide Metabolism", American Epilepsy Society, 1996, *Epilepsia* 37(Suppl 5): 172 (1996).

Morgan, J.M., Piraino, A.J., Saris, S.D., Graham, C.S., Good, W.R., John, V.A., Kochak, G.M., and Choi, R.L., "Inhibition of Angiotensin I Converting Enzyme with CGS-16617: A Dynamic Study", American Society of Clinical Pharmacology and Therapeutics, Orlando, Fla., 1992, *Clin. Pharmacol. Ther.*, 51: 131 (1992).

Comfort, A.R., Dinh, S.M., Otte, J.H., Shevchuk, I., Kochak, G., and Berner, B., "In vitro and in vivo correlation of ethanol-enhanced nitroglycerin TTS", Controlled Release Society, Orlando, Fla., *Proceedings of the 19th International Symposium on Controlled Release of Bioactive Materials*, 244 (1992).

Kurihara-Bergstrom, T., Nightingale, J., Kochak, G., Tipnis, V., Rubin, P., Wilding, I., and Davis, S., "Transdermal Delivery of Buprenorphine in Man", American Association of Pharmaceutical Scientists, San Antonio, TX, 1992, *Pharm. Res.* 9: S170 (1992).

Kurihara-Bergstrom, T., Kochak, G., Rubin, P., Wilding, I., and Davis, S., "Transition From In Vitro to Clinical Trials: Application of Fillable TTS in Transdermal Formulation Development", American Association of Pharmaceutical Scientists, San Antonio, TX, 1992, *Pharm. Res.* 9: S190 (1992).

Alioth, C., Chan, K., Blum, R., Ziehmer, B., Teng, L., Luders, R., Kochak, G., and Schentag, J., "Application of Dual Radiotelemetric Technique in Studying Drug-Drug Interaction Between Diclofenac

Sodium and Ranitidine HCl in Volunteers", American Association of Pharmaceutical Scientists, Washington, DC, 1991, *Pharm. Res.*, 8: S64 (1991).

Tang, JP., Xu, ZQ., Melethil, S., Douglas, F., Rakhit, A., and Kochak, G., "Osmotic Pressure and Brain Uptake of Libenzapril in Rats", American Association of Pharmaceutical Scientists, Washington, DC, 1991, *Pharm. Res.*, 8: S278 (1991).

Kochak, G.M., "Population Characteristics of Biological Systems Influenced by Multi-Component Random and Uniform Variation", American Association of Pharmaceutical Scientists, Washington, DC, 1991, *Pharm. Res.*, 8: S301 (1991).

Kochak, G.M., Thakker, K.M., Mangat, S., Faleck, H., Cook, T., Garnett, W., Pellock, J., Farwell, J., and Levy, R., "Steady-State Bioavailability and Fluctuations of Carbamazepine Following Crossover Administration of q.i.d. Conventional Tegretol Tablets and b.i.d. Tegretol OROS Tablets", American Epilepsy Society, Philadelphia, Pa., 1991, *Epilepsia* 32: 3 (1991).

Thakker, K.M., Mangat, S., Wagner, W., and Kochak, G., "Absolute Bioavailability, Effect of Food and In Vitro-In Vivo Correlations for Once Daily Controlled Release Voltaren (Diclofenac Sodium) Dosage Form", 4th European Congress of Biopharmaceutics and Pharmacokinetics, Geneva, Switzerland, 1990, *Eur. J. Drug Metab. Pharmacokin.*, Special Ed.: 6(poster abstracts), (1990).

Kochak, G., Furst, D., Iannucci, R., Honc, F., Kachmar, D., and Pai, S., "Prinomide Dose Proportionality", American Society of Clinical Pharmacology and Therapeutics, Nashville, Tenn., 1989, *Clin. Pharmacol. Ther.*, 45: 151 (1989).

Furst, D., Egger, H., Kochak, G., Luders, R., Brunner, L., Mason, D., and John, V., "Multiple Dose Kinetics of Prinomide in Rheumatoid Arthritic Patients", American Society of Clinical Pharmacology and Therapeutics, Nashville, Tenn., 1989, *Clin. Pharmacol. Ther.*, 45: 150 (1989).

Morgan, J., Piraino, T., Good, W., John, V., and Kochak, G.M., "The Pharmacodynamic Effect of CGS 16617", American College of Clinical Pharmacology, Baltimore, Md., 1989, *J. Clin. Pharmacol.*, 29: 841 (1989).

Choi, R.L., Kochak, G.M., deSilva, J.K., and Reydel-Bax, P., "Pharmacodynamic-Dependent Disposition of the Angiotensin Converting Enzyme Inhibitor, CGS 16617", American College of Clinical Pharmacology, Baltimore, Md., 1989, *J. Clin. Pharmacol.*, 29: 843 (1989).

Mason, W.D., Winer, N., Kochak, G., Cohen, I., and Bell, R., "Pharmacokinetics and Absolute Bioavailability of Atenolol in 12 Healthy Volunteers", American Society of Clinical Pharmacology and Therapeutics, Kansas City, MO, 1979, *Clin. Pharmacol. Ther.*, 25: 263 (1979).

PAPERS OR LECTURES

Papers/Presentations at National/International Professional Societies, Conferences, and Meetings

Kochak, G.M., "A Perspective on Variational Analysis in Drug Development", *International Pharmaceutical Federation BIO-International '92*, Bad Homburg, Germany (1992).

Leal, M., Joshi, J., Gaudry, D., Pirano, A., Morgan, J., Kochak, G., Hayes, M., and Powell, M., "Simultaneous GC/MS Analysis of Labeled and Unlabeled Nitroglycerin in Human Plasma for

Determination of Transdermal Flux Rates", *Proceedings of the 39th ASMS Conference on mass spectrometry and applied topics*, Nashville, Tenn. (1991).

Kochak, G.M., "Intra- and Inter- Subject Statistical Variations: Theory and Application to Bioavailability Trials", *Long Island University/Food and Drug Administration Symposia on Bioavailability/Bioequivalency: Scientific and Regulatory Issues*, Brooklyn, NY (1990).

Lipton, A., Harvey, H. A., Demers, L.M., Hanagan, J.R., Mulagha, M. T., Kochak, G.M., Fitzsimmons, S., Sanders, S. I., and Santen, R. J., "A Phase I Trial of CGS 16949A - A New Aromatase Inhibitor", *16th International Congress of Chemotherapy*, Jerusalem, Israel, (1989).

Reydel-Bax, P., Choi, R.L., Kochak, G.M. and Hurley, M., "Effects of Food on the Bioavailability of CGS 16617, an Angiotensin Converting Enzyme Inhibitor, in Healthy Subjects", *First Eastern Regional Meeting of the American Association of Pharmaceutical Scientists*, Atlantic City, NJ (1987).

Honc, F., Kochak, G.M. and Tipnis, V., "Mechanism of CGP 31608 Degradation and Methods of Stabilization", *First Eastern Regional Meeting of the American Association of Pharmaceutical Scientists*, Atlantic City, NJ (1987).

Kochak, G.M., Rakhit, A., Honc, F. and Mahoney, C.J., "Pharmacokinetic Disposition of the Novel Atypical Anxiolytic CGS 9896 in the Cynomolgus Monkey", *Third European Congress of Biopharmaceutics and Pharmacokinetics*, Freiburg, Germany (1987).

Kochak, G.M. and Rakhit, A., "Metabolite Pharmacokinetics for Orally Administered Prodrugs", *First National Meeting of the American Association of Pharmaceutical Scientists*, Washington D. C. (1986).

Kochak, G.M., "Dosing Schedules - Pharmacokinetic Basis of Controlled Release Products Including Newer, Novel Drug Delivery Systems", *University of Missouri-Kansas City Centennial Symposium*, Kansas City, MO (1985).

Kochak, G.M., Honc, F. and Waldes, L., "The Pharmacokinetics of Baclofen in Man", *37th National Meeting of the Academy of Pharmaceutical Sciences*, Philadelphia, PA (1984).

Honc, F., Waldes, L. and Kochak, G.M., "Analysis of CGS 9896 and its 6-, 7-, and 8-Hydroxy Metabolites in Plasma by High Performance Liquid Chromatography", *37th National Meeting of the Academy of Pharmaceutical Sciences*, Philadelphia, PA (1984).

Kochak, G.M., "The Pharmacokinetics of Intravenously Administered Methyldopa in the Dog", *33rd National Meeting of the Academy of Pharmaceutical Sciences*, San Diego, CA (1982).

Kochak, G.M., "Determination of Free Methyldopa in Plasma by High Pressure Liquid Chromatography with Electrochemical Detection", *International Liquid Chromatography Symposium III*, Boston, MA (1979).

Kochak, G.M., Mason, W. D. and Winer, N., "Kinetics and Absolute Bioavailability of Atenolol", *American Society of Clinical Pharmacology and Therapeutics*, Kansas City, MO (1979).

Invited Lectures and Seminars

University of New Mexico, Cancer Research and Treatment Center, Colleges of Medicine and Pharmacy,

“Synthesis of Novel Carbohydrate Platforms and Nanoencapsulation of Proteins: Circulating systems with Hydrophilic Interfaces” (2007).

University of Toledo, College of Pharmacy, “Synthesis of Novel Carbohydrate Platforms and Nanoencapsulation of Proteins: Circulating systems with Hydrophilic Interfaces” (2007).

National Institutes of Health, “Carbohydrate Nanoparticles: A Novel Delivery Platform for the Systemic Route” (2006).

Cleveland Clinic Foundation, Department of Biomedical Engineering, “Advances in Nanotechnology for Drug Delivery” (2005).

University of Alabama at Birmingham, Department of Biomedical Engineering, “Mutually Coupled Convective and Diffusive Drug Transport Through Biological Membranes” (2000).

Auburn University, College of Chemical Engineering, 2000 Seminar Program, “Mutually Coupled Convective and Diffusive Drug Transport Through Biological Membranes” (2000).

University of Maryland, College of Medicine, "Quantitative Analyses of Pharmacokinetic Stability in Clinical Research" (1999).

Long Island University, Arnold and Marie Schwartz College of Pharmacy, "A Molecular Theory of Momentum Transfer in Permselective Convection Streams" (1994).

U.S. Food and Drug Administration, "Variational Analysis and Regulatory Considerations for Bioavailability/Bioequivalence Assessment" (1993).

Hudson Valley Pharmaceuticals Discussion Group, Westchester Co., NY, "Population Characteristics of Biological Systems Influenced by Multi-Component Random and Uniform Variation" (1991).

State University of New York at Buffalo, College of Pharmacy, "Inter- and Intrasubject Variability: Theory and Application to Biological Systems" (1990).

Virginia Commonwealth University, College of Pharmacy, "Convective and Diffusive Permeability in Biologic Membranes" (1989)

Hudson Valley Pharmaceuticals Discussion Group, Westchester Co., NY, "Metabolite Pharmacokinetics" (1987).

University of Missouri-Kansas City, School of Pharmacy, "Pentopril-Cimetidine Interaction Caused by a Reduction in Hepatic Blood Flow" (1988).

GRANTS AND CONTRACTS

Proposals Funded

G. Kochak (PI) and P. Stamm ; A comprehensive sickle cell medication management and education program supporting juvenile patients in the Lee County and Opelika City School Systems. Auburn University Outreach Scholarship Grant, FY 2005/06; \$40,000.

G. Kochak (PI); Hygroscopicity of statins in marketed pharmaceutical products. CSP Technologies, FY 2005; \$10,000.

G. Kochak (PI); Solid state stability of lovastatin and simvastatin in pharmaceutical tablets. CSP Technologies, FY 2005; \$20,000.

G. Kochak (PI); Drug stability in desiccant polymeric packaging. CSP Technologies, 7/6/04; \$52,000.

G. Kochak (PI); Custom manufacturing contract; Department of the Treasury, U.S. Customs Service, 8/5/02; \$71,395.

G. Kochak (PI); Contract to manufacture solid oral tablets; Department of the Treasury, U.S. Customs Service, 9/26/01; \$50,000.

G. Kochak and G. Reid; Pharmaceutical cGMP Manufacturing and Technology Capital Improvement Grant, The Daniel Foundation of Alabama, Birmingham AL, FY 2000; \$500,000.

G. Kochak and W .D. Mason; "HPLC-EC Analysis of Free Methyldopa in Human Plasma", Harris Laboratories, Lincoln NE, FY 1979; \$7,777.

W .D. Mason (PI) and G. Kochak ; "Analytical Determination of Methyldopa and its Potentially Active Metabolites in Plasma", Faculty Research Grant, University of Missouri, Kansas City MO; FY 1978; \$1,965.

GRADUATE STUDENTS AND POSTDOCTORAL SUPERVISION

Umesh Kestur, Ph.D. (2010), Auburn/Purdue Universities. Role: major advisor/co-advisor.
Current position: Research Investigator, Bristol-Myers Squibb.

A. Basu Sarker, Ph.D. (2006), Auburn University. Role: major advisor.
Current position: Associate Professor of Pharmacy (tenured), University of Findlay.

Atresh Tata, M.S. (2006), Auburn University. Role: major advisor.
Current position: Analytical Chemist, Invagen Pharmaceuticals, Inc.

Veena Pujari, M.S. (2004), Auburn University. Role: major advisor.
Current position: CVS pharmacist, greater Cincinnati area.

Priyanka Mathur, M.S., (2002), Auburn University. Role: committee member.
Current position: CVS pharmacist, greater New York area.

Jian-Ping Tang, Ph.D. (1991), University of Missouri, Kansas City. Role: committee member.
Current position: Principal Scientist, Roche Pharmaceuticals.

Bhaskar Shetty, Ph.D. (1988), University of Missouri, Kansas City. Role: committee member.
Current position: Vice President Pfizer Worldwide R & D, La Jolla Laboratories.

Sudhakar Pai, Ph.D., Ciba-Geigy Corporation. Role: postdoctoral supervisor.
Current position: Senior Director Clinical Pharmacology, Akros Pharma, Inc.