

MUKUL A. AGRAWAL, PH.D.



Work

Roxane Laboratories, Inc.
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EDUCATION

1997 **Ph.D.** in Biopharmaceutics and Pharmacokinetics, University of Cincinnati, Cincinnati, OH.

Advisor _____, **MD, PhD.**

Project : Development and *in vivo* evaluation of a novel peroral CRDDS.

Research Experience : Development of formulations for *in vivo* animal studies. Planning, organizing and conducting *in vivo* studies and pharmacokinetic and statistical analysis of data from animal and human pharmacokinetic and bioavailability studies.

1990 B.S. Pharm. Sci., The University of Bombay, India

WORK EXPERIENCE

07/07-present **Associate Director, Medical Affairs.** Boehringer-Ingelheim Roxane Laboratories, Inc., Columbus, OH.

- Manage and oversee the activities of the medical group, consisting of ~~full-time~~ full-time staff, to support the successful filing and approval of ~~ANDAs~~ ANDAs each year.
- Oversee contracts and budgets for the medical group.

Responsibilities include management and oversight of approximately ~~active~~ active projects. Provide biopharmaceutic and pharmacokinetic guidance regarding product development. Ensure filings are on time and within budget and co-ordinate responses to FDA questions for faster approvals. Help maintain average approval times at significantly below industry average.

01/02-06/07 **Clinical Research Manager.** Boehringer-Ingelheim Roxane Laboratories, Inc., Columbus, OH.

- In-house expert on conduct of pharmacokinetic BE studies, *in vitro* BE studies and BCS Class I biowaiver studies.
- Responsible for the bioequivalence program (PK and *in vitro*) for the development and approval of the first ever generic suspension nasal spray product with gross sales _____

Responsibilities include pharmacokinetic reviews and assessments of prospective projects, designing, contracting and supervising clinical study conduct, data analysis and interpretation, quality assurance and auditing. Also involved in the management of Contract Research Organizations activities, negotiating budgets, project supervision, and ensuring compliance with all relevant FDA GCP/GLP requirements. Overseeing the compiling of relevant sections of ANDA, responding to FDA comments and interacting with

FDA for successful review of biopharmaceutics portion of ANDA.

09/99-12/01 **Clinical Research Associate.** Boehringer-Ingelheim Roxane Laboratories, Inc. Columbus, OH.

Duties include pharmacokinetic reviews of prospective projects, and designing, contracting and supervising clinical studies to support ANDA filings for multisource product development. Involves interacting with CRO, overseeing study conduct, quality assurance, data analysis and interpretation, and management of CRO

activities and budgets.

02/98-09/99 **Advanced R&D Chemist.** BFGoodrich Company, Brecksville, OH.

Responsible for the *in vivo*, pharmacokinetic and bioavailability testing program (pre-clinical) for the Drug Delivery Systems group. Involves designing, planning, implementing/coordinating the studies at contract research facilities, data analysis and interpretation, and preparing project reports.

1995-1997 **Graduate Assistant.** College of Pharmacy, University of Cincinnati.

Involved in the Pharmacokinetics aspects of a NIDA/NIH sponsored, multiple investigator/multiple site study

to investigate the pharmacokinetics of cocaine and to develop potential treatments for its dependency. Responsible for preparing study protocols, supervising clinical studies, data analysis and report writing.

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ADDITIONAL QUALIFICATIONS AND ACTIVITIES

- Proficient in use of **WinNonlin** software for pharmacokinetic data analysis.
 - Experienced in the use of **Neural Computing Technology**.
 - Served as the elected representative of the graduate students of the college of Pharmacy, to the Organization of Health Sciences Graduate Students, 1992-93.
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PUBLICATIONS

1. Ritschel, W.A., Paulos, C., Arancibia, A., **Agrawal, M.A.**, Wetzelsberger, K.M. and Lücker, P.W.: Pharmacokinetics of acetazolamide in healthy volunteers after short- and long-term exposure to high altitude. *J. Clin. Pharmacol.* 38: 533-539 (1998)
2. Ritschel, W.A., Paulos, C., Arancibia, A., **Agrawal, M.A.**, Wetzelsberger, K.M. and Lücker, P.W.: Urinary excretion of acetazolamide in healthy volunteers after short- and long-term exposure to high altitude. *Meth. Find. Exp. Clin. Pharmacol.* 20: 133-137 (1998)
3. Ritschel, W.A., Sabouni, A. and **Agrawal, M.A.**: Novel P.O. drug delivery system: Compression-coated hydrogel piston pump. 1. Shell thickness and pore size. *Pharm. Pharmacol. Lett.* 6: 119-122 (1996)
4. Ritschel, W.A., Sabouni, A. and **Agrawal, M.A.**: Novel P.O. drug delivery system: Compression-coated hydrogel piston pump. 2. Design and *in vitro* evaluation. *Pharm. Pharmacol. Lett.* 6: 123-126 (1996)
5. Ritschel, W.A., Paulos, C., Arancibia, A., Pezzani, M., **Agrawal, M.A.**, Wetzelsberger, K.M. and Lücker, P.W.: Pharmacokinetics of meperidine in healthy volunteers after short- and long-term exposure to high altitude. *J. Clin. Pharmacol.* 36: 610-616 (1996)
6. Ritschel, W.A., Paulos, C., Arancibia, A., Pezzani, M., **Agrawal, M.A.**, Wetzelsberger, K.M. and Lücker, P.W.: Urinary excretion of meperidine and normeperidine in man upon acute and chronic exposure to high altitude. *Meth. Find. Exp. Clin. Pharmacol.* 18: 49-53 (1996)
7. **Agrawal, M.A.**: Book Review. *Int. J. Clin. Pharmacol. Ther.* 32: 570 (1994)
8. **Agrawal, M.A.**, Rajan, R. and Subbiah, M.T.R.: Potential role for histones in lipid peroxidation. *Med. Sci. Res.* 22: 175-176 (1994)
9. Subbiah, M.T.R., Kessel, B., **Agrawal, M.A.**, Rajan, R., Abplanalp, W. and Rymaszewski, Z.: Antioxidant potential of specific estrogens on lipid peroxidation. *J. Clin. Endocrin. Met.* 77: 1095-1097 (1993)
10. Bhadra, S., Banavali, S.D., **Agrawal, M.A.** and Subbiah, M.T.R.: Cholesterol peroxidation potential as influenced by dietary fat type. *Int. J. Vit. Nutr. Res.* 63: 223-228 (1993)

PRESENTATIONS

1. Ritschel, W.A. and **Agrawal, M.A.**: Physiologically based novel peroral modified release drug delivery system: Selfdestructing hydrogel piston pump. Presented at the 5th National Congress of Pharmaceutical and Biochemical Sciences, Peruvian Academy of Pharmacy, Trujillo, Peru. May 21-24, 2003
2. **Agrawal, M.A.**, Arancibia, A., Paulos, C. and Ritschel, W.A.: Effect of short- and long-term exposure to

high altitude on the pharmacokinetics of acetazolamide. Presented at the 13th Annual Meeting of AAPS, San Francisco, CA. Nov. 15-19, 1998

3. *Agrawal, M.A.*, and Ritschel, W.A.: Evaluation of a new peroral modified release system in human subjects. Presented at the 12th Annual Meeting of AAPS, Boston, MA. Nov. 2-6, 1997

4. *Agrawal, M.A.*, and Ritschel, W.A.: *In situ* segmental absorbability study of promethazine in rats. Presented at the 11th Annual Meeting of AAPS, Seattle, WA. Oct. 27-31, 1996

5. Ritschel, W.A., Paulos, C., Arancibia, A., Pezzani, M., *Agrawal, M.A.*, Wetzelsberger, K.M. and Lücker, P.W.:

Pharmacokinetics of meperidine in man upon acute and chronic exposure to high altitude. Presented at the 25th Annual

Meeting of the ACCP, Rockville, MD. Sep. 21-23, 1995

6. Ritschel, W.A., Paulos, C., Arancibia, A., Pezzani, M., *Agrawal, M.A.*, Wetzelsberger, K.M. and Lücker, P.W.: Urinary

excretion of meperidine and normeperidine in man upon acute and chronic exposure to high altitude. Presented at the 25th

Annual Meeting of the ACCP, Rockville, MD. Sep. 21-23, 1995

7. *Agrawal, M.A.* and Hussain, A.S.: Correlating protein binding site to chemical structure using the Kohonen network.

Presented at the 9th Annual Meeting of the AAPS, San Diego, CA. Nov. 6-10, 1994

8. Subbiah, R., Rymaszewski, Z., Kessel, B., *Agrawal, M.A.*, Rajan, R. and Abplanalp, W.: Antioxidant effect of estrogens

on human low density lipoprotein (LDL) oxidation. Poster presented at the International Conference on Menopause,

Stockholm, June 1992.

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PATENTS

1. Ritschel, W.A. and *Agrawal, M.A.*: Patent Number 6,365,185, Issued April 2, 2002, "Self-destructing controlled release peroral drug delivery system".

PROFESSIONAL MEMBERSHIPS

Rho Chi Pharmacy Honor Society

American Association of Pharmaceutical Scientists

American College of Clinical Pharmacology

Regulatory Affairs Professionals Society

AWARDS

• Third Prize in the Graduate Student Research Poster Competition organized by Indianapolis/Cincinnati Discussion

Group of American Association of Pharmaceutical Scientists, Feb. 16, 1995

• George Rieveschl-Parke Davis Summer Fellowship, Summer 1994 and 1995

• University Graduate Scholarship, Fall 1991 to 1996