Associate Director, Medical Affairs and Drug Safety; Clinical Safety Officer

AREAS OF EXPERTISE

- **Served as generic industry representative on FDA's Advisory Committee for Pharmaceutical Sciences and Clinical Pharmacology**
- **Standard and complex formulations including oral and ophthalmic products**
- **Protocol development and review for bioavailability/bioequivalence studies**
- **Biopharmaceutical approach to formulation development**
- **Protocol development and review for in vitro testing for complex dosage forms**
- **CRO selection and study management**
- **Represent sponsors as biopharmaceutics and pharmacokinetics expert at FDA meetings**
- **Monitoring of in vivo bioavailability and bioequivalence studies**
- **Development of briefing packages and technical documents for submission to FDA**
- **In vitro and in vivo development of inhalation and nasal spray products**
- **Prepare product development strategy for ANDA filings**
- **Strategy for 505(b)(2) NDA development and filing**

INTRODUCTION

Pharmaceutical Sciences consultant with over 15 years of pharmaceutical industry experience and works with clients to develop strategies for successful development and US FDA approval of various dosage forms utilizing both 505(b)(2) and ANDA approaches. Specializing in the use of a biopharmaceutics based approach, he has successfully led development of complex dosage forms such as injectable formulations including biosimilars, oral modified release formulations, and nasal and inhalation products.

Consultant has worked extensively with FDA and others to develop bioequivalence strategies for products for which no clear guidance was available. He has experience preparing and submitting expert position papers for FDA review. Consultanthas also participated in several FDA meetings such as Pre-IND, NDA and ANDA meetings and has also served on the FDA's Advisory Committee for Pharmaceutical Sciences and Clinical Pharmacology as a representative of the Generic Pharmaceutical Association (GPhA).

Consultant is an active member of the American Association of Pharmaceutical Scientists (AAPS) and is currently serving on the steering committee of the Bioequivalence Focus Group.

Consultant received a Ph.D. in Biopharmaceutics and Pharmacokinetics from the University of Cincinnati, Cincinnati, OH and a Bachelor in Pharmaceutical Sciences from the University of Bombay, India.

WORK EXPERIENCE

09/2012 – Present
Industry Consultant
Duties:

- Areas of expertise include: Regulatory, clinical and product development strategy for ANDA and 505(b)(2) NDA; biopharmaceutical approach to development of various formulations such as oral tablets, oral capsules, oral and injectable suspensions, ophthalmic, nasal, inhalation, rectal suppository and topical dermal products; *in vitro* and *in vivo* development programs for inhalation and nasal spray products; Development of correspondence and submissions to US FDA and representing clients at FDA meetings; Protocol development and review for bioavailability/bioequivalence studies; Protocol development and review for *in vitro* testing for complex dosage forms; CRO selection and study management; Monitoring of *in vivo* bioavailability and bioequivalence studies; Compiling literature based safety and efficacy support for NDA and ANDA.

09/1999 – 09/2012
Roxane Laboratories, Inc., Columbus, OH
Associate Director, Medical Affairs and Drug Safety; Clinical Safety Officer, (07/2009 – 09/2012)
Duties:

- Oversight of approximately 80 active projects and 120+ approved products. Provide biopharmaceutic and pharmacokinetic guidance regarding product development strategies. Ensure filings and reports are on time and within budget while ensuring compliance with applicable regulations. Participate in GPhA, FDA and Industry initiatives in developing and implementing new guidances. Member of BE focus group of GPhA. Successfully manage department's annual budget which includes supporting 75-80 studies including PK, BA/BE, Clinical and in vitro.
- Lead and direct the activities of the medical group, consisting of 7 full-time staff, to support the successful filing and approval of 16-20 ANDAs each year.
- Lead and direct the activities of the drug safety group of 5+ direct and indirect reports that are responsible for the post approval monitoring and reporting of adverse events. Serve as the Clinical Safety Officer (CSO) for company. Ensure compliance with all applicable FDA regulations.

07/2007 – 06/2009
Associate Director, Medical Affairs
Duties:

- Management and oversight of approximately 80 active projects. Provide biopharmaceutic and pharmacokinetic guidance in the development of modified release oral products, inhalation and nasal solution and suspension products. 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.
- Manage and oversee the activities of the medical group, consisting of 5 full-time staff, to support the successful filing and approval of 16-20 ANDAs each year.
- Oversee Contracts and budgets for the medical group.

01/2002 – 06/2007
Clinical Research Manager
Duties:

- In-house expert for pharmacokinetic BE studies, in vitro BE studies and BCS Class I biowaiver studies. Responsibilities include biopharmaceutics and 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.

09/1999 – 12/2001
Clinical Research Associate
Duties:

- Biopharmaceutics and 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. Monitoring and auditing of studies and CROs to ensure compliance.

09/2010 – Present
Ohio Northern University, Ada, OH
Adjunct Professor of Pharmacy
Duties:

- Participate in student educational opportunities in form of lectures, seminar presentations or clinical conferences as appropriate.

06/2008 – 10/2011
FDA'S Advisory Committee for Pharmaceutical Sciences and Clinical Pharmacology.
Generic Industry Representative
Duties:

- Participate in Advisory Committee meetings convened by FDA as representative of the Generic Pharmaceutical Association. Present GPhA opinions to FDA and bring back FDA comments to GPhA for discussion. Participate in discussions with Technical Advisory Committee of GPhA.

02/1998 – 09/1999
BF Goodrich Company, Brecksville, OH
Advanced R&D Chemist
Duties:

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

EDUCATION

1997
University of Cincinnati, Cincinnati, OH
Ph.D. – Biopharmaceutics and Pharmacokinetics
Advisor: W.A. Ritschel, MD, Ph.D.
Project: Development and in vivo evaluation of a novel peroral CRDDS.
Research Experience: Development of formulations for in vivo animal studies using biopharmaceutic and pharmacokinetic approach. Planning, organizing and conducting in vivo studies and pharmacokinetic and statistical analysis of data from animal and human pharmacokinetic and bioavailability studies.

1990
The University of Bombay, India
Bachelor of Science: Pharmaceutical Science

PUBLICATIONS

- 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)
- 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)
- 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)
- 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)
- 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)
- 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)
- Agrawal, M.A.: Book Review. Int. J. Clin. Pharmacol. Ther. 32: 570 (1994)
- Agrawal, M.A., Rajan, R. and Subbiah, M.T.R.: Potential role for histones in lipid peroxidation. Med. Sci. Res. 22: 175-176 (1994)
- 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)
- 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

- Ritschel, W.A. and Agrawal, M.A.: Physiologically based novel peroral modified release drug delivery system: Self-destructing hydrogel piston pump. Presented at the 5th National Congress of Pharmaceutical and Biochemical Sciences, Peruvian Academy of Pharmacy, Trujillo, Peru. May 21-24, 2003
- 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
- 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
- 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
- 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

- 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
- 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
- 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.

PATENTS

- 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 MEMEBERSHIPS

- Rho Chi Pharmacy Honor Society
- American Association of Pharmaceutical Scientists
- American College of Clinical Pharmacology