

CURRICULUM VITAE

Ramakant M. Mhatre, Ph.D.

EDUCATION:

M.Sc. Medical Biochemistry
Ph.D. Pharmacology and Toxicology

EXPERIENCE:

January 1998 - Present

Consultant in Pharmaceutical Sciences
Special Regulatory Experience in Biopharmaceutics, Generic Drugs,
Bioequivalence and Analytical Methodology

Pharmacology and Toxicology Study Reviews and Evaluation from INDs and NDAS

November 1984 - December 1997

(October 1994 -December 1997)

Acting Deputy Director and Acting Director at different times in Division of
Bioequivalence, Office of Generic Drugs in FOOD AND DRUG ADMINISTRATION.

Branch Chief, Division of Bioequivalence, Office of Generic Drugs

- As acting Director supervised the review work of 22 professionals including 19 Ph.D. reviewers. Responsible for approving several first generic drugs, controlled release formulations metered dose inhaler and other dosage forms.
- Planning and staffing of the Division
- Developing and coordinating policies of the Bioequivalence Division for generic drugs, in consultation with the Office of Generic Drugs and the Office of Pharmaceutical Sciences.
- Setting up scientific criteria for bioequivalence determination of immediate and controlled release drug products and transdermal drug products as well as other unique drug formulations.
- Establish standards for in-vitro dissolution testing for immediate and controlled release drug products.
- Prepare position papers or memoranda for resolution of complex bioequivalence issues.
- Prepare responses to the members of the Division of Bioequivalence and to other members of the Divisions in the Center.
- Resolve regulatory issues by coordinating with the industry.

SPECIAL RESPONSIBILITIES:

- ◆ Project Officer for University of Tennessee Research contract from 1975-1997. The contract was for conducting in vivo BE studies to resolve complex issues e.g. resolution of biowaivers, hard shell and soft shell gelatin capsules, theophylline issue, in vivo and in vitro correlation. Several publications resulted from this contract.
- ◆ Project Officer representing FDA at the Indo-US Science and Technology Commission. Workshops and Conferences were held in India to promote scientific cooperation between the two countries (1984-1990).
- ◆ Writing guidances (protocols) for conducting in vivo bioequivalence (BE) studies. These protocols were routinely used by the pharmaceutical industry to conduct appropriate BE studies.

- ◆ Member of the scientific research committee coordinating controlled release biostudies at the University of Maryland. Studied the effects of excipients on the formulations and the release of controlled release products.
- ◆ Member of the SUPAC-MR guidance committee. This committee established standards for SUPAC-MR regulation. Conducted training sessions for the reviewers in the Agency and for the investigators from the industry.
- ◆ Permanent member of the Biopharmaceutics and Bioequivalence Coordination group. This group chaired by Dr. Williams dealt with establishing regulatory policies of the Office of Pharmaceutical Sciences.
- ◆ Member of the gelatin capsule working group. Recommendation of this group led to the BE study of gelatin capsules at the University of Tennessee. The results of this study were presented at AAPS meeting in a symposium.
- ◆ Member of the Biopharmaceutics Classification System (BCS). The group formulated policy to establish BE studies based on solubility and permeability of different drugs.
- ◆ Led groups of chemists and pharmacologists to innovator and generic pharmaceutical firms to study day to day operation of the industry.

February 1979 - October 1984

Pharmacologist Reviewer in the Division of Cardio-Renal Drug Products:

Conducted pharmacology and toxicology reviews of cardio-renal drug products. Provided special expertise in drug metabolism pharmacokinetic area to examine critical data submitted in INDs and NDAs and recommend if the data were acceptable. Toxicology reviews involved evaluation of carcinogenicity, mutagenicity and teratogenicity data submitted by the pharmaceutical industry. Served as consultant to other members of the Division and other Divisions within the Bureau of Drugs.

Specialized in the reviews of calcium channel blocking agents.

August 1978 - January 1979

Special assignment in the **Office of Commissioner of FDA**

Direct assignment with the Associate Commissioner of Medical Affairs.

Participated in the activities of Medical Affairs that included the review of disqualification of Clinical Investigators as proposed by the Bureau of Drugs. Active participation in review of policy decisions initiated by the Medical Affairs staff. Assumed responsibility for the FDA Research involving Human Subjects Committee (RIHSC) and examined the research projects submitted by the Project Officers.

Active participation in inter-bureau staff meetings in which senior policy makers formulated regulatory decisions for consideration.

November 1974 - July 1978

Reviewer in the Division of Biopharmaceutics, Bureau of Drugs, FDA

Reviewed and evaluated bioavailability protocols and bioavailability data submitted by the pharmaceutical industry in INDs, NDAs and ANDAs. Provided special expertise in pharmacokinetics, biopharmaceutics, pharmacology and statistical pharmacokinetic analysis.

Responsible in drafting bioavailability/bioequivalency regulations. Active participation in meetings to explain the regulations with representatives from other government agencies, industry and academia. Assisted the Division Director in resolving difficult and controversial issues.

Prepared guidelines for coronary vasodilators using chemical and radiolabel methods for use in bioavailability studies.

Appointed Project Officer for extramural research program at the University of Tennessee to resolve bioavailability/bioequivalency problems.

SPECIAL ACHIEVEMENTS DURING FDA TENURE:

- Presented research work at professional meetings
 - Represented FDA in special conferences and symposia
 - Publications of scientific work in prestigious Journals
 - Professional development training
 - Several Awards, including cash awards
 - Special Citation
- “ For sustained superior performance of duties for the approval of generic drugs with complex bioequivalence issues”.

MEMBERSHIP IN SCIENTIFIC SOCIETIES:

American Association of Pharmaceutical Scientists (AAPS)
Sigma Xi
American Society of Pharmacology and Experimental Therapeutics (ASPET)
a. Division of Clinical Pharmacology
b. Division of Drug Metabolism

American Association for the Advancement of Science (AAAS)
American Association for Cancer Research---- (discontinued)
Society of Toxicology---- (discontinued)
New York Academy of Sciences---- (discontinued)