

Curriculum Vitae
Fatemeh Akhlaghi, Pharm.D., Ph.D.

Summary: I am a pharmaceutical scientist with expertise in clinical pharmacology, translational sciences, drug metabolism, pharmacogenomics and pharmacokinetic/pharmacodynamic (PKPD) modeling. My research goal is to understand the sources of variability in drug disposition and effect specifically in patients with diabetes mellitus or non-alcoholic fatty liver disease (NAFLD). The long-term goal is to devise personalized medicine these disease state. I am proficient in design and implementation of clinical pharmacokinetic studies, quantification of drug concentration and metabolites using LC-MS/MS and data analysis by standard or population pharmacokinetics methods. Characterization of expression and activity of drug metabolism enzymes and transporters *ex vivo* or *in vitro* is another area of research practiced in my laboratory. diabetes mellitus on drug disposition, drug development in alcoholism and therapeutic drug monitoring of immunosuppressive agents in organ transplant recipients. In addition, I am the director of the graduate program in Pharmaceutics and Pharmacokinetics and Principal Investigator on two NIH grants.

Personal Information

Date of Birth: November 18th, 1966
Marital Status: Married with a 24-year old daughter
Residency Status: Naturalized Citizen of the United States

Work Address

Department of Biomedical and Pharmaceutical Sciences
495A College of Pharmacy, 7 Greenhouse Road
University of Rhode Island
Kingston, RI 02881
Phone: (401) 874 9205 / Fax: (401) 874 5787
Email: fatemeh@uri.edu
Departmental Website URI: <http://web.uri.edu/pharmacy/research/akhlaghi/>
Laboratory Website URI: <http://akhlaghilab.com/>
Website Brown University: <https://vivo.brown.edu/display/fakhlagh>
Google Scholar: <https://scholar.google.com/citations?user=wdnBYOAAAAAJ&hl=en>
Linkedin site: <http://www.linkedin.com/in/akhlaghi>
ORCID ID: orcid.org 0000-0002-3946-7615

EDUCATION

| | | |
|-------------------------|---|---|
| 1984-1990 | University of Mashhad, Iran | Pharm.D. |
| Project title: | Use of CD4 to CD8 ratio as a marker for kidney transplant rejection | |
| Major Professor: | Behrouz Nikbin M.D. | |
| 1992-1997 | University of Sydney, Australia | Ph.D. in Pharmaceutical Sciences |
| Project title: | Cyclosporine distribution in cardiopulmonary transplant recipients | |

Major Professors: Kenneth F. Brown Ph.D. and Anne M. Keogh M.D.

EMPLOYMENT HISTORY

| | | |
|-------------------|---------------------------------|--|
| July 2014- | University of Rhode Island | Ernest Mario Distinguished Chair in Pharmaceutics |
| July 2014- | Brown University Medical School | Adjunct Professor of Medicine |
| July 2011- | University of Rhode Island | Full Professor |
| July 2010- | Brown University Medical School | Adjunct Associate Professor |
| 2006-2010 | University of Rhode Island | Associate Professor with Tenure |
| 2001-2006 | University of Rhode Island | Assistant Professor (Tenure Tack) |
| 1998-2001 | University of Cambridge, U.K. | Senior Clinical Scientist |

(Advisor: Andrew K. Trull Ph.D.; Funded by Novartis, Roche Laboratories and Papworth Hospital Research Trust)

| | | |
|------------------|---------------------------------|----------------------------------|
| 1996-1998 | University of Sydney, Australia | Post-Doctoral Research Associate |
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(Advisors: Kenneth F. Brown Ph.D. and Andrew J McLachlan Ph.D.; Funded by Novartis and Janssen Cilag Australia)

FURTHER TRAINING

March 13, 2016

Design and Analysis of Quantitative Proteomic Experiments: Introduction to Statistical Methods and Practical Examples using Skyline, one-day workshop part of Human Proteomics Organization meeting in Boston, MA

July 6-10, 2015

Model-Based Drug Development: Incorporating Population Variability into Mechanistic Prediction of PK and Modelling PK-PD
A course on Simcyp, Certara Corporation

Aug 5-6, 2014

Transporters in Drug Discovery and Development
University of Rhode Island

Jan-March, 2013

Hands on data manipulation using R
Instructor: Dr. Kaori Ito, Pfizer Groton

May 1-5, 2012

Fisher / Shafer NONMEM Course
An Intermediate to Advanced NONMEM course with PLT tools
Bethesda, MD

March 19-21, 2012

The Introductory GastroPlus™ Simulation and Modeling Workshop
Cambridge, MA.

March 29-31, 2011

Triple Quadrupole System Training using Analyst® Software for Quantitation
AB Sciex, Framingham, MA.

October 4, 2009

Phoenix NLME - A Next Generation Tool for Population PK/PD Analysis
Instructor: Dan Weiner, Pharsight Corporation.

September 16, 2006

Course in Pharmacokinetic/Pharmacodynamic Modeling
Instructors: Drs William J. Jusko and Jogarao Gobburu.

September 12-14, 2005

A three-day hands-on course on “Wings for NONMEM Population Pharmacokinetics Modeling”;
Instructors: Drs Nick Holford and Dianne Mould
Also organized the course with Dr. Sara Rosenbaum.

July 26-30, 2004

A weeklong hands-on course entitled “Molecular Genetic Methodologies for Pharmaceutical Scientists”; Department of Pharmaceutical Sciences, University of Buffalo;
Instructor: Dr. Dan Brazeau.

June 2002

A three full days hands-on course “Operator’s Training on Sciex API2000 Liquid Chromatography Mass Spectrometer” University of Rhode Island, also organized the course.
Instructor: Dr. Bill Sawyers, Applied Biosystems.

September 27-29, 1999

Beginning level short course on “Population Pharmacokinetics using NONMEM Computer Program”
Instructors: Drs Lewis Sheiner and Stuart Beal; Uppsala Sweden.

January 9-15, 1999

“A course in Pharmacokinetic and Pharmacodynamic Modeling using WinNonlin” one credit point; Department of Clinical Pharmacology, Karolinska Institute, Stockholm, Sweden;
Instructor: Dr. Ole Borga.

December 7-22, 1998

“A course in Pharmacokinetic and Pharmacodynamic with Clinical Applications”; four credit points; Department of Clinical Pharmacology, Karolinska Institute, Stockholm, Sweden;
Instructors: Drs Gunnar Alvan, Ole Borga, Johan Gabrielsson, Lars Gustafsson.

HONORS AND AWARDS

- 1992 Levy Mail Pattinson Award, Faculty of Pharmacy, Uni. of Sydney
- 1993-96 Faculty of Pharmacy Postgraduate Scholarship, Uni. of Sydney
- 2002 University of Rhode Island New Faculty Development Award
- 2006 Outstanding Intellectual Property Award, University of Rhode Island
- 2008 Paul-Ehrlich Magic Bullet-Award 2008, Nurnberg Germany
- 2010 Outstanding Intellectual Property Award, University of Rhode Island

PROFESSIONAL SOCIETY MEMBERSHIP

- 1990-present The Medical Council of Iran (Registered Pharmacist)
- 1993-1998 Australasian Society for Clinical and Experimental Pharmacology and Toxicology (ASCEPT)
- 1993-1998 Australasian Pharmaceutical Science Association (APSA)
- 1997-2001 International Society of Heart and Lung transplantation (ISHLT)
- 1998-2001 Transplantation Society
- 1996-present International Association of Therapeutic Drug Monitoring and Clinical Toxicology (IATDM&CT)
- 1997-present American Association of Pharmaceutical Scientists (AAPS)
- 2001-present American Association of Colleges of Pharmacies (AACP)
- 2008-present American Society for Clinical Pharmacology and Therapeutics (ASCPT)

CONSULTING ACTIVITIES

- 1996 Physicochemical characteristics of ingredients of an antacid suspension, consultant for Park Davis Pharmaceuticals in collaboration with Dr. Elizabeth Gipps, University of Sydney
- 1997-1998 Droplet size determination of nebulized solutions of Salbutamol and Ipratropium Bromide using Marple - Miller cascade impactor, in collaborating with Dr. Kim Chan, University of Sydney
- 2001-2003 Pharmacokinetics of intravenous immunoglobulin (IVIG), I have analyzed the pharmacokinetic data from several phase III studies conducted by Bio Products Limited, UK
- 2003 Member of Mycophenolic Acid TDM Advisory Board (Optcept clinical trial, an 800 patient trial conducted by Roche Laboratories to evaluate the need for mycophenolic acid therapeutic drug monitoring)
- 2005 Consulting on a case study conducted at the Department of Emergency Medicine, RI hospital on the elimination of carboxy hemoglobin
- 2005-2007 Expert witness in a personal injury case involving cyclosporine generic substitution and risk of organ rejection
- 2007 Expert witness in a patent dispute case between two major pharmaceutical companies

2008-2009 Pharmacokinetic and pharmacodynamic modeling of bortezomib in cynomolgus monkeys, Millennium Pharmaceuticals

2007-2010 Pharmacokinetic consultant for a clinical trial on the intra-nasal use of ketamine in children with laceration, Department of Emergency Medicine, Hasbro Children Hospital, Providence, RI.

2011 Consultant on concentration–projection of a modified release tablet by two different manufacturers.

2014 Expert witness for a non-infringement trial for two Canadian companies

2014 Consultant on bioequivalence studies on a generic versus a brand name drug

2016-2017 Consultant on a patent dispute case involving a combination anti-hyperglycemic agent

2017- Consultant on a patent dispute case involving projection of pharmacokinetic parameters of controlled release formulations

INVITED PRESENTATIONS

| DATE | PRESENTATION TITLE/LOCATION |
|-------------|--|
| Nov 1999 | “Pharmacokinetics of cyclosporine in patients receiving metabolic inhibitors” Invited speaker at PKUK99 meeting, Oxford, UK. |
| Aug 16 2001 | “Clinical pharmacology of immunosuppressive agents” Lecture to the Nephrology Residents, Department of Nephrology, Brown University Medical School, Providence, RI. |
| Oct 1 2001 | “Novel strategies for monitoring immunosuppressive agents” invited speaker at the Department of Pediatrics Nephrology and Transplantation, the Boston’s Children Hospital, University of Harvard Medical School, Boston, MA. |
| Oct 23 2001 | “Monitoring cardiothoracic transplant recipients” Seminar to the Heart Transplant Group, the Brigham and Woman’s Hospital, University of Harvard Medical School, Boston, MA. |
| Jan 25 2002 | “Novel strategies for monitoring immunosuppressive agents” Seminar to Kidney Transplantation Services, Rhode Island Hospital, Providence, RI. |
| Jul 11 2003 | “Pharmacokinetics and pharmacodynamics of immunosuppressive agents” oral presentation at RI-BRIN annual retreat, Alton Jones Campus, RI. |
| May 20 2004 | Speaker at the workshop “Hot and alternative research funding” Title: How to Get Funding from the Industry, University of Rhode Island, Kingston, RI. |
| Apr 7 2005 | “Pharmacokinetics of immunosuppressive agents in diabetic patients” Presentation to the Transplant Services, RI Hospital, Providence, RI. |
| Jan 25 2006 | “Pharmacokinetics and –dynamics of immunosuppressive agents” Center for the New Stem Cell Biology Visiting Professors Seminar Series, COBRE program, Roger Williams Hospital, Providence, RI. |
| May 24 2006 | Poster Judge at the Joint RI-COBRE symposiums, Providence, RI. |

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