

*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 18<sup>th</sup>, 1966  
Marital Status: Married with a 24-year old daughter  
Residency Status: Naturalized Citizen of the United States

**Work Address**

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Google Scholar: <https://scholar.google.com/citations?user=wdnBYOAAAAAJ&hl=en>  
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**EDUCATION**

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

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

### EMPLOYMENT HISTORY

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

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

<b>1996-1998</b>	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, Karoliniska 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, Karoliniska Institute, Stockholm, Sweden;  
Instructors: Drs Gunnar Alvan, Ole Borga, Johan Gabrielsson, Lars Gustafsson.

## HONORS AND AWARDS

- 1992 Levy Maill 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
- 2017- Expert witness on a patent dispute involving patent “obviousness”

### 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.

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