

MANOJ P. JADHAV (PhD, FCP)

Department of Epidemiology, College of PHHP, College of Medicine, University of Florida, 166 SW Archer Road, Gainesville, Florida, USA, 32610-0274.

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* SUMMARY

- 10+years in Research and Development (combined preclinical and clinical)
- 06+ years in Pharmaceutical Clinical Development including Sponsor experience
- 04+ years in teaching Pharmaceutical Medicines and Pharmacy
- Clinical development in therapeutic area e.g. cardiovascular diseases, infectious diseases, HIV/AIDS and cancer
- Roles performed as Investigator, Co-investigator, Post-doctoral research associate, Assistant Professor Research associate etc.

Capabilities

- Extremely efficient in working independently and as a team player to help generate outstanding scientific research outcomes with **“Team Science”** approach
- Expertise in the conceptualization, planning, designing and conduct of BA/BE, phase III and IV clinical studies
- Contributed in the clinical study design, plan conduct and analysis in multi therapeutic areas e.g. cardiovascular diseases, infectious diseases, HIV/AIDS and cancer
- Experienced in government and industry sponsored, investigator initiated clinical studies
- Involved in clinical study synopsis and protocol development for industry and government sponsored clinical studies and its implementation per ICH- GCP guidelines
- Creation of case record forms, patient information sheet, consent document, SOP's etc.
- Conceptualized, designed, planned and conducted pharmacokinetic clinical study
- Participated in clinical study PI meeting, site selection, inspection, study start visit, monitoring, close out visits etc.
- Involved in prospective, retrospective, observation and or interventional clinical research studies.
- Worked on Quality of Life, clinical prospective as well as retrospective studies in rheumatoid and osteo arthritis.
- Experienced in creating the CSR, summary, interim analysis, review of TLF and final reports per regulatory requirements e.g. DCGI, US-FDA guidelines.
- Handling of Institutional Review Board (IRB) related regulatory paperwork and its submission to the concerned authority
- ADR/SAE reporting, analysis and interpretation for phase III/IV clinical studies
- Thorough understanding on the ANDA, INDA details
- Pharmacovigilance applications and its relevance to Clinical studies
- Exhaustive understanding of concepts in risk based monitoring(RBM), quality management systems in clinical trials
- Clinical database (large and small) creation for retrospective studies using e.g. EPIC, CPRS, Red Cap, Microsoft Excel Microsoft Access etc.
- Well trained and acquainted with federal and regulatory policies and procedures regarding human subject research (phase I-IV)
- Expertise in preclinical research in formulation development for liposomal drug delivery systems, transdermal drug delivery systems.
- Performed scienti-kinetic studies in BALB/c mice

- Performed Immunoassay, ELISA assay development for dengue virus fever
- P-glycoprotein transport studies in-vitro for inhaled corticosteroids
- Analytical method development, validation using LSMS/MS, HPLC etc.
- Teaching and mentoring to the M.S and PhD level Pharmaceutical Medicine and Clinical Research candidates
- Have excellent record of preparation and submission of research grants, manuscript writing and research publications,
- Demonstrated exceptional management, communication and leadership skills
- Founder member of the South Asian Chapter of American College of Clinical Pharmacology, Mumbai, India.

*** PROFESSIONAL EXPERIENCE**

COURTESY FACULTY

Feb 2016- till date

Department of Epidemiology, Univ. of Florida, Gainesville, FL, USA.

RESEARCH SCHOLAR

(June 2015- Feb 2016)

Department of Epidemiology, Univ. of Florida, Gainesville, FL, USA. Involved in writing and planning field based clinical studies on prevention and education of hypertension and its risks in the African American population.

POST DOCTORAL RESEARCH ASSOCIATE

Nov. 2013- May 2015

Current post-doc research is on design, plan and conduct of observational, interventional, retrospective and prospective clinical research studies in patients with CV diseases, as well as appropriate use criteria assessment for radiological investigations for CV patients, at the division of cardiovascular medicine, at Univ. of Florida, Gainesville, FL, USA.

POST DOCTORAL RESEARCH ASSOCIATE

June 2013-Oct. 2013

Studied the effect of oral delivery of ACE2 and Ang-1-7 on pulmonary hypertension, heart failure etc. at the department of physiology and functional genomics, college of medicine, Univ. of Florida, Gainesville, FL, USA.

POST DOCTORAL RESEARCH ASSOCIATE

June 2011- May 2013

Research on P-glycoprotein transport studies, both in-vitro and in-vivo for steroids. Immunoassay development and drug screening for dengue virus at the department of pharmaceuticals, College of pharmacy, University of Florida, Gainesville, FL, USA.

ASSISTANT PROFESSOR

Jan. 2009 –June 2011

Department of infectious diseases, Maharashtra University of health sciences, Seth G.S. Medical College and KEM Hospital, Parel, Mumbai, India.

RESEARCH ASSOCIATE & Ph.D. SCHOLAR

Jan.2006 – Jan. 2009

Thesis title: "Laboratory and clinical studies with liposomal amphotericin B" (Cancer and HIV/AIDS)

Department of clinical pharmacology, Seth G.S. Medical College and KEM Hospital and Bombay College of Pharmacy, Mumbai, India.

COURSE CO-ORDINATOR July 2006 - Aug2008

Post graduate diploma in pharma management-Garware institute of career education and development, University of Mumbai, Mumbai, India.

COURSE CO-ORDINATOR Jan 2007- Jan 2009

Worked as an active team member on the development and implementation of the M.Sc. pharmaceutical medicine course at the Maharashtra Univeristy of Health Sciences, Nasik, India.

RESEARCH OFFICER Nov. 2004- Jan. 2006

SRL Ranbaxy Research Laboratories, Faridabad, Haryana, India. (Currently Fortis Clin. Research)

RESEARCH SCHOLAR (M. Pharm.) Oct.2002 - Oct.2004

Govt. College of Pharmacy, (DIPSAR), New Delhi., India.

LECTURER Aug 2000- Oct 2002

Worked at SCSSS's College of Pharmacy, Shirur, University of Pune, Maharashtra, India.

* **EDUCATION**

Ph.D. (Pharmaceutical Technology-Pharmaceutics 2006 - 2008
(University of Mumbai, India)

Master of Science (Pharmacy- Hospital Pharmacy), 2002 - 2004
(University of Delhi, India)

Bachelor of Science (Pharmacy), University of Pune, India 1996 - 2000

* **PUBLICATIONS**

2015

1. Jadhav PM., **Jadhav MP.** Are we engaged in reproducible research? **J Ayurveda Integr Med.** 2015 Jul-Sep;6(3):209-10.

- Winchester DE, Zhang P, **Jadhav MP**, Beyth R. Myocardial perfusion imaging in veteran patients without symptoms: contributing factors and results of testing. **Medicine (Baltimore)**. 2015;94(32):e1154.
- Anthony A Bavry, Ahmed Mahmoud, **Manoj P Jadhav**, Tianyao Huo, Islam Y Elgendy. Critical appraisal of bivalirudin versus unfractionated heparin for percutaneous coronary intervention: a meta-analysis of randomized trials. **PLoS One**. 2015; 26;10(5):e0127832.

2014

- Jadhav MP**, Shenoy V. Re: "Exposure to Bisphenol A From Drinking Canned Beverage Increases Blood Pressure". In: **Hypertension**. eLetters [Internet]. 2014 Dec 15. Dallas: American Heart Association, Inc. [about 2 screens]. Available from: http://hyper.ahajournals.org/content/early/2014/12/08/HYPERTENSIONAHA.114.04261/reply#hypertensionaha_el_511.
- Prajna Kumar, Jeroze Dalal, **Manoj P. Jadhav**. Risk Based Monitoring-Current Challenges with Implementation. **PostDoc Journal**. 2014;2(11);52-55.
- Jadhav MP**, Kshirsagar NA. Access to antifungal medicines in resource poor countries. **Lancet Infect Dis**. 2014; 14(5):370-1.
- Bavry AA, **Jadhav MP**, Huo T, Limacher MC, Pepine CJ. Early invasive versus selective invasive strategies in women with non-ST-elevation acute coronary syndromes – The lady gator pilot study. (submitted to **JACC**)
- Carsten Schmalfuss , Pamela Woodard, Michael Gitter , **Manoj P. Jadhav**, Raye Bellinger, Steven Rose, Anthony Bavry. Incidence of acute kidney injury after intravenous administration of iodixanol for computed tomographic angiography. **Int J Cardiol**. 2014 Aug 19. Pii: S0167-5273(14)01580-0.
- Jadhav MP**. High Throughput Screening (HTS) for the identification of novel antiviral scaffolds. **Clinical Pharm in Drug Dev**.2014: 3:79–83.

2013

- Jadhav MP**, Jadhav PM. What's ailing India's research funding agencies? **Nature India** 2013; doi:10.1038/nindia.2013.176.
- Jadhav MP**, Bachhav S, Kshirsagar NA. Development of Clinical Pharmacology in India-perspective of a young researcher. **Clinical Pharm in Drug Dev**. 2013;2(3);201-204.(Guest Editorial)
- Jadhav MP**, Tang Y, Hochhaus G. Development and validation of LC-MS/MS method for detection and quantification of flunisolide in tissue culture medium. **Analytical Letters**. 2013; 46(9):1355-1363.

13. **Jadhav MP**, Jadhav PM, Shinde VM, Kadam PS, Kshirsagar NA. Liposomal amphotericin B for the treatment of *cryptococcal meningitis* in HIV/AIDS patients in India – a pilot pharmacokinetic study. **Clinical Pharm in Drug Dev.** 2013; 2(1):48-52.
14. Ingle PB, **Jadhav MP**. CAM and Conventional medicine: Hand in hand" **J Clin Rheumatol.** 2013 Jun; 19(4):227.

2012

15. Jadhav PM, Shah R, **Jadhav MP**. Important advances in Malaria vaccine research. **Chron Young Sci** 2012; 3; 111-20.
16. **Jadhav MP**, Yeola C, Zope G, Nabar A. Aliskirin: The first direct renin inhibitor for treatment of hypertension: the path of its development. **J Postgrad Med.** 2012, 58(1), 32-38.
17. **Jadhav MP**, Vishal Shinde, Jijina FF, Nithya Gogtay, Nilima Kshirsagar et. al., A randomized comparative trial evaluating the safety and efficacy of liposomal amphotericin (Fungisome) versus conventional amphotericin B in the empirical treatment of Febrile neutropenia in India" **Ind. Jr. Cancer**, 2012; 49(1); 107-113

2011

18. **Jadhav MP**., Ingle PB, Shelke SS. Assessment of use of complementary alternative medicine and its impact on quality of life in the patients attending rheumatology clinic, in a tertiary care center in India. **Indian Jr of Med Sci.** 2011; 65(2); 27-34.
19. Ingle PB, **Jadhav MP**. A prospective observational study to assess quality of life and prescription pattern in osteoarthritis patients at tertiary health center in Mumbai. **Indian Jr of Med Sci**, 2011; 65(2); 35-40.
20. **Jadhav MP**, Nagarsenkar MS, Kshirsagar NA, Gaikwad RV, Samad A. Formulation and evaluation of long circulating liposomal amphotericin B, scinti-kinetic study using Tc ^{99m} in healthy BALB/c mice." **Ind. Jr. Pharm Sci.**, 2011:73(1); 57-64.

2010

21. Nilima Kshirsagar, **Jadhav MP**. Nanotechnology –public health perspective. **J. Bionanosci.** 2010; 4, 14-21.
22. **Jadhav MP**, Aabha Bamba, Vishal Shinde, Nithya Gogtay, Nilima Kshirsagar et. al., Liposomal amphotericin B (Fungisome TM) for the treatment of cryptococcal meningitis in HIV/AIDS patients in India: A multicentric, randomized controlled trial. **J Postgrad Med.;** 2010; 56(2), 71-76.

2009

23. Bamba Aabha V, **Jadhav MP**, Prabhu R, Ray S, Gogtay Nithya J, Jijina Farah F, Kshirsagar Nilima A. "Refractory hypokalemia due to conventional amphotericin B in patients with leukemia" **Indian J Cancer**, 2009; 41(1); 76-7.

2007

24. **Jadhav MP** and Milind Parle. Hair analysis: a novel technique for tracing drugs" **Indian J. of Pharm. Educ. & Res.**, 2007; 41(1), 73-77.
25. **Jadhav MP**. Mehta S., Kshirsagar N.A. An editorial on "Looking for new drugs to treat dengue fever" **J. of Gen. Med.**, 2007; Vol.19 (1); 53-56.
26. **Jadhav MP**. Kshirsagar N.A. "Nanoparticles-emerging use in medicine" in **Technical Review Series (TRS)**, an official publication of Maharashtra University of Health Sciences, Nashik, India. 2007; 14, 9-17.
27. **Jadhav M. P.** Aabha Bamba, Kshirsagar N.A. "Invest in health – build a safe future" in **Technical Review Series (TRS)**, an official publication of Maharashtra University of Health Sciences, Nashik, India. 2007; 17; 1-6.
28. **Manoj Jadhav**, Aabha Bamba, Nithya Gogtay, Nilima Kshirsagar. "Avian influenza A (H5N1) infections in humans" in **Technical Review Series**, an official publication of Maharashtra University of Health Sciences, Nashik, India. 2007; 20; 1-9.
29. **Manoj Jadhav**, Aabha Bamba, Nithya Gogtay, Nilima Kshirsagar "Severe acute respiratory syndrome (SARS)" published in the special section on infectious diseases in **Technical Review Series (TRS)** an official publication of Maharashtra University of Health Sciences, Nashik, India. 2007; 20; 21-28.

ABSTRACTS

1. Lucas Burke, **Manoj P Jadhav**, Carsten Schmalfluss, Carl J. Pepine, David E. Winchester. Risk Risk of death in veteran patients with elevated troponin: Type 1 versus Type 2 myocardial infarction. JACC March 17, 2015 Volume 65, Issue 10S.
2. Lucas Burke, **Manoj P Jadhav**, Carsten Schmalfluss, Carl J. Pepine, David E. Winchester. Risk Risk of death in veteran patients with elevated troponin: Type 1 versus Type 2 myocardial infarction. Presented at annual Celebration of Research, Feb. 9-13, 2015, University of Florida, UF, FL.
3. Chetan B. Yeola, Gaurav Zope, Pravita Yadav, Sachin Upasani, Sagar Thakkar, **Manoj Jadhav**, Ashish Nabar. *Evaluation of authenticity and rationality of promotional pharmaceutical drug literatures*. Presented as poster at the 40th annual conference of American College of Clinical Pharmacology held at Chicago between 11-13 September 2011, USA.
4. **Jadhav MP**, Nagarsenkar MS, Kshirsagar NA, Gaikwad RV. "Formulation and evaluation of long circulating liposomes for amphotericin B, tracer kinetic study using Tc ^{99m} in healthy BALB/c mice."

accepted and presented for the 8th International symposium of Controlled Release Society – Indian Chapter, at Mumbai, 26-27 Feb. 2009.

5. **Jadhav MP**, Aabha Bamba, Vishal Shinde, Jijina FF, Nithya Gogtay, Nilima Kshirsagar et. al., “*Liposomal Amphotericin B (Fungisome)TM for the empirical treatment of systemic fungal infections febrile neutropenia in India - multicentric, randomized controlled clinical trial in leukemia (ALL, AML) patients- an interim analysis of a prospective study*”, accepted and presented as oral presentation for the 2nd annual conference of South Asian chapter of American College of Clinical Pharmacology held at, Mumbai, India, between 4-5 October 2008.
6. **Jadhav MP**, Aabha Bamba, Vishal Shinde, Nithya Gogtay, Nilima Kshirsagar et. al., “*Liposomal Amphotericin B (Fungisome)TM for the treatment of systemic fungal infections (cryptococcal meningitis) in India - multicentric, randomized controlled clinical trial in HIV/AIDS patients– interim analysis of a prospective study. (ISRTCN 52812742)*” accepted for the poster presentation for the 36th annual conference of American College of Clinical Pharmacology held at San Francisco, CA, USA, between 8-11 September 2007. Abstract Published in *Journal of Clinical Pharmacology* 2007, *42*, 1183-1211.
7. S. Agrawal, **Jadhav MP**, “*In-vitro-in vivo transdermal permeation of carvedilol from chitosan based matrix-type transdermal patches*” was accepted for poster presentation in National Biotechnology Conference, organized by American Association of Pharmaceutical Scientists (AAPS), June 18-21 2006, at Boston, MA.

BOOK AND CHAPTER EDITED

- Edited a book entitled “**Recent advances in phytopharmaceuticals**” with Dr. Priyanka Jadhav and Prof. NA. Kshirsagar. Published by CBS Publication, New Delhi.

WORKSHOPS AND CONFERENCES

- **Co-Chair-** for the symposium on “Cardiovascular diseases from discovery to recovery” annual conference of the ACCP, in Atlanta, USA. Sep 14-16, 2014.
- **International conferences organized** - 05 South Asian Chapter of American College of Clinical Pharmacology (ACCP), (2007-2011).
- University level certificate courses, symposium organized - 16
- National level conferences - **03**
- **Invited lectures** – **07** at IIT, Mumbai, SAC-ACCP, Serum Institute, Pune, Pharmacy Schools etc.

SKILLS

- Conduct, co-ordination, monitoring of multi-centric, randomized, controlled clinical trials
- Well versed with EPIC access, CPRS patient record systems
- ELISA assay, P-gp transport studies in-vitro, in-vivo, immunoassay development
- Small animal pharmacology/toxicology
- Handling of LC-MS/MS HPLC, HPTLC, UV, submicron particle size analyzer, Buchi RotaVap evaporator, etc.
- Animal models of peptic ulcer, analgesic and anti-inflammatory activity, infectious diseases

- DMPK and Extensive Clin Pharm experience
- Preparation and evaluation of transdermal drug delivery system, liposomes etc.

ACADEMIC AFFILIATIONS

- **Ph.D. Mentor** (clinical research) at the Taxila American University, Guyana, South America (Dec 2013- onwards).
- Adjunct faculty, at the college of pharmacy, Sinhagad, Pune, India.

AWARDS AND HONORS

- 2013- Prof. M.L. Khorana prize for best research paper in pharmaceuticals and bio pharmaceuticals, presented by Indian Pharmaceutical Association (IPA), India.
- 2010 -Honored with the fellow of the American College of Clinical Pharmacology, (FCCP), USA.
- 2009- till date - Chairman of the student outreach committee of the South Asian Chapter of American College of Clinical Pharmacology, Mumbai
- 2009- Won the Best oral presentation award at the third international conference of SAC-ACCP, Mumbai
- Jan. 2006 – Dec. 2008- Research fellowship sponsored by department of Biotechnology, New Delhi, during PhD program.
- 2004- Ranked First in M.S (Pharmacy) first year and awarded with gold medal from University of Delhi, New Delhi, India
- 2002-2004- Recipient of junior research fellowship, during M.S (Pharmacy) course, from University Grants Commission (UGC), New Delhi, India.
- 1996-2000- Ranked among top five students throughout bachelors in pharmacy studies.
- Actively participated and won, in various quiz and competitions at college level

RESEARCH GRANTS AND AWARDS

Effect of ranolazine after deferral of percutaneous coronary intervention by fractional flow reserve (IMWELL3): Funded by Gatorade research funds, College of Medicine, University of Florida, GNV, FL. (Role Co-Investigator, 82,000 USD, for 2014-2016.)

PROFESSIONAL AFFILIATIONS

- 2010- present Member & Fellow of American College of Clinical Pharmacology (*ACCP*)
- Life time Registered pharmacist, Maharashtra State, India

CONTRIBUTION TO SCIENTIFIC JOURNALS AS REVIEWER

1. May 2012- present- Clinical pharmacology in drug development
2. May 2012- present- Journal of clinical pharmacology
3. Oct.2012- present- Drug design, development and therapy
4. Jan 2012- present- Drug development and industrial pharmacy
5. July 2013- present - Journal of Ayurveda and integrative medicine
6. Sept 2015- present Journal of Clinical and Translational Science
7. Sept 2015- present Clinical Pharmacology & Therapeutics
8. Sept 2015- present Pharmacometrics & Systems Pharmacology

