

Vijayalekshmi Nair, Ph.D., DABT, UK ERT

Occupational and Product Quality Toxicologist

Education:

- 2010 – 2014 **Ph.D. Toxicology, College of Veterinary Medicine**, Texas A & M University – College Station, Texas
Advisor: Dr. Stephen H. Safe
Dissertation focus: Studied the role of Metformin in pancreatic cancer through mTOR and Ras signaling pathways and the significance of Sp transcription factor, insulin-like growth factor-1 receptor (IGF-1R) and epidermal growth factor receptor (EGFR).
- 2002 – 2004 **MSc. Biotechnology**, PSG College of Arts & Science – Coimbatore, India
- 1999 – 2002 **BSc. Biotechnology**, University of Kerala – Kerala, India

Work History:

- 02/2021 – Present **Associate Toxicologist**, Affyigility Solutions Inc
Perform Toxicological Evaluation of API including the determination of OEL and ADE/PDE
- 12/2015 – 12/2018 **Post-doctoral Research Fellow (Inhalation Toxicology)**, Department of Cell Biology and Neurosciences, University of California – Riverside, California
Research Focus: Cytotoxicity and molecular mechanisms of e- Cigarette-flavor chemicals in a 3D Lung model through an Air-Liquid Interface Exposure system.
- 03/2015 – 11/2015 **Post-doctoral Research Fellow (Heavy Metal Toxicology)**, Department of Pathology, University of North Dakota – Grand Forks, North Dakota
Research Focus: The toxicity of Arsenic and Cadmium in urothelial cells.
- 05/2010 – 08/2014 **Graduate Research Assistant (Molecular Mechanisms in Cancer)**, Department of Veterinary Physiology and Pharmacology, Texas A&M University – College Station, Texas
Research Focus: Studied the role of Metformin in pancreatic cancer through mTOR and Ras signaling pathways and the significance of Sp transcription factor, (IGF-1R) and (EGFR).

01/2008 – 08/2009 **Volunteered in Cytokine Research Laboratory**, M.D. Anderson Cancer Center – Houston, Texas

Research Focus: Inflammatory pathways in cancer

08/2005 – 12/2007 **Research Assistant**, Regional Cancer Centre – Trivandrum Kerala, INDIA

Research Focus: Single-Nucleotide Polymorphisms in Xenobiotic Metabolizing Genes and DNA-repair genes and their roles in cancer susceptibility.

Certifications:

Diplomate of the American Board of Toxicology (DABT), November 2019

UK Register of Toxicologists (UK ERT), November 2023

Research Abilities and Skills:

Molecular techniques (in-vitro and in-vivo): Involved in the development and standardization of toxicological methods related to two different types of air-liquid interface exposure systems. Mammalian cell culture, 3D lung microtissue culture for air liquid interphase exposure system, Immunohistochemistry, Immunoblotting, Western Blotting, ELISA, Ras activation assay, live cell imaging, qPCR, Lab animal handling (in-vivo animal models like orthotopic model, athymic nude mice), treatment and tissue processing.

Cancer Research on pro-oncogenic pathways: Studied mechanism-based drugs (Metformin) which targets mTOR and Ras signaling pathways and the role of insulin-like growth factor-1 receptor (IGF-1R) and epidermal growth factor receptor (EGFR) in this process.

Toxicology data analysis/review: Proficiency in collecting and analyzing toxicology data, including testing and evaluating toxicity of ingredients. Used proteomics approach and Ingenuity Pathway Analysis (IPA) to study the toxic response of ingredients. Experience in integrating, summarizing, and writing up research results (published over 10 research articles).

Principles of risk assessment: Familiarity and knowledge of general risk assessment through American Board of Toxicology certification.

Collaboration and leadership: Lead and contributed in research teams. Presented case control study protocol for IRB approval with cross functional teams including clinicians and scientific community. Involved in training and mentoring both graduate and undergraduate students in cell culture and molecular techniques.

Publications:

Vijayalekshmi Nair, Malcolm Tran, Rachel Z.Behar, Song Zhai, Xinping Cui, Rattapol Phandthong, Yuhuan Wang, Songqin Pan, Wentai Luo, James F.Pankow, David C.Volz, PrueTalbot. Menthol in Electronic Cigarettes: A Contributor to Respiratory Disease? Toxicology and Applied Pharmacology, 2020 Nov 15;407: 115238. doi: 10.1016/j.taap.2020.115238. Epub 2020 Sep 17.

Stephen Safe, **Vijayalekshmi Nair**, Keshav Karki. Metformin-induced anticancer activities: Recent insights. Biol Chem. 2018 Mar 28; 399(4): 321-335.

Wei Ying, Tyler Brehm, Andrew Morin, Karen Triff, **Vijayalekshmi Nair**, Guoqing Zhuang, Hui Song, Richard Cheng-An Chang Chang, Srikanth Kanameni, Alexander Tseng, Haiqing Wang, Michael Golding, Fuller W. Bazer, Robert Chapkin, Stephen Safe, Beiyang Zhou. MicroRNA-223 is a crucial mediator for PPAR γ -regulated macrophage alternative activation. J Clin Invest. 2015 Nov 2; 125(11):4149-59.

Shruti U. Gandhi, Parisa Imanirad, Un-Ho Jin¹, **Vijayalekshmi Nair**, Eric Hedrick, Yating Cheng, J. Christopher Corton, KyoungHyun Kim, Stephen Safe. Specificity Protein (Sp) Transcription Factors and Metformin Regulate Expression of the Long Non-coding RNA HULC. Oncotarget. 2015 Sep 22;6(28):26359-72.

Vijayalekshmi Nair, Sandeep Sreevalsan, Riyaz Basha, Maen Abdelrahim, Ala Abudayyeh, Aline Rodrigues Hoffman, Stephen Safe. Mechanism of Metformin-dependent Inhibition of Mammalian Target of Rapamycin (mTOR) and Ras Activity in Pancreatic Cancer: Role of Specificity Protein (Sp) Transcription Factors. J Biol Chem. 2014 Oct 3;289 (40):27692-701.

Wei Ying, Srikanth Kanameni, Cheng-An Chang, **Vijayalekshmi Nair**, Stephen Safe, Fuller W. Bazer, and Beiyang Zhou, Interferon tau alleviates obesity-induced adipose tissue inflammation and insulin resistance by regulating macrophage polarization.PLoS One. 2014 Jun 6;9(6).

Stephen Safe, Parisa Imanirad, Sandeep Sreevalsan, **Vijayalekshmi Nair**, Indira Jutooru. Transcription factor Sp1 also known as specificity protein 1 as a therapeutic targets. Expert Opinion in Therapeutic Targets July 2014, Vol. 18, No. 7, 759-769.

Vijayalekshmi Nair, Sathya Pathi, Indira Jutooru, Sandeep Sreevalsan, Riyaz Basha, Maen Abdelrahim, Ismael Samudio, Stephen Safe.2013, Metformin inhibits pancreatic cancer cell and tumor growth and downregulates Sp transcription factors. Carcinogenesis. 2013 Dec;34(12):2870-9.

Satya Pathi, Indira Jutooru, Gayathri Chandalapaka, **Vijayalekshmi Nair**, Lee SO and Stephen Safe, 2012. Aspirin inhibits colon cancer cell and tumor growth and downregulates specificity protein (Sp) transcription factors. PLoS One; 2012, 7(10).

Bharat B. Aggarwal, **Vijayalekshmi R.V.**, Bokyoung Sung., 2009. Targeting Inflammatory Pathways for Prevention and Therapy of Cancer: A Short-Term Friend, Long-Term Foe. Clinical Cancer Research, 15(2) 425-430.

Vani S, Volga S.S., Leelakumari S., Praveenkumar B.R., **Vijayalekshmi RV**, Sheeja V.R., Santhi S., Ratheesan K., Elizabeth K.A., and Ravindran A., 2008. Hereditary breast/ovarian cancer: clinicopathological characteristics and survival of BRCA2 positive and negative cases. *Journal of Experimental Therapeutics and Oncology*, 7 227–236.

Sreeja L., Syamala V.S., Syamala V., Hariharan S., Raveendran P.B., **Vijayalekshmi R.V.**, Madhavan J., Ankathil R., 2007 Oct 19. Prognostic importance of DNA repair gene polymorphisms of XRCC1 Arg399Gln and XPD Lys751Gln in lung cancer patients from India. *Journal of Cancer Research and Clinical Oncology*, 134 645–652.

Awards and Honors:

- **George T. Edds Award 2014** for outstanding scholastic and research abilities in the field of toxicology, College of Veterinary Medicine, Texas A&M University.
- **Graduate Student Presentation Grant**, 2014, funded by the Association of Former Students and the Office of Graduate and Professional Studies, Texas A&M University for attending Society of Toxicology - 53rd Annual Meeting, March 24–27, 2014, at Phoenix, Arizona
- **Third place for Platform Presentation.** 2014 Spring Research Symposium, College of Veterinary medicine, Texas A & M University
- **CVM Outstanding Graduate Student Scholarship**, 2013, College of Veterinary medicine, Texas A & M University
- **First place for poster presentation**, 2013, Student Research Week, Texas A&M University
- **Second place for Poster Presentation**, 2013, Graduate Student Association Symposium College of Veterinary medicine, Texas A & M University
- **Graduate Student Research Trainee Grant award**, 2013, College of Veterinary Medicine, for grant proposal titled “Metformin inhibits Pancreatic Cancer Cell and Tumor Growth by Downregulating Sp Transcription factors”
- **Second place for poster Presentation**, 2012, Gulf Coast - Society of Toxicology Annual Conference at Baylor University
- **Third place for poster Presentation**, 2011, Gulf Coast and Central chapter- Society of Toxicology at New Orleans
- **Third place for Poster Presentation**, 2011, College of Veterinary medicine, Texas A & M University Graduate Student Association Symposium
- **Graduate Student Association Travel Award**, 2011, to present at the SOT 2011 Annual meeting, Washington, D.C.
- **Student Travel Award**, 2010, to present at the Gulf Coast Chapter Society of Toxicology Annual Meet 2010, Houston, TX.
- **Regent’s Fellowship**, 2010, Texas A&M University.

Presentations:

- **Vijayalekshmi Nair** and Prue Talbot. Menthol Induces Oxidative Stress and Inflammatory Responses in Human Lung Epithelial Cells Exposed at the Air-Liquid Interface. Society of Toxicology, March 13—17, 2017, Baltimore, Maryland.
- **Vijayalekshmi Nair**, Seema Somji, Scott H.Garrett, Donald A. Sens. Specificity protein (Sp) transcription factors are downregulated in Arsenite - transformed Human Urothelial Cells (UROtsa), *Society of Toxicology*, March 13—17, 2016, New Orleans, Louisiana.
- **Vijayalekshmi Nair** and Stephen Safe. "Metformin blocks Lipogenesis in Pancreatic Cancer Cells by downregulating Specificity Protein Transcription Factors" *Society of Toxicology, March 23rd 2014, Phoenix, AZ.*
- **Vijayalekshmi Nair**, and Stephen Safe. "Metformin causes degradation of fatty acid synthase and PI3 kinase signaling proteins in pancreatic cancer cells through downregulation of Specificity Protein (Sp) Transcription Factors" *Society of Toxicology, March 11th, 2013, San Antonio, TX.*
- **Vijayalekshmi R. V.** and Stephen Safe. "The Antidiabetic Drug Metformin Inhibits Pancreatic Cancer Cell Growth and Targets Downregulation of Specificity Protein (Sp) Transcription Factors" *Society of Toxicology, March 14-15th, 2012, San Francisco, CA.*
- **Vijayalekshmi R.V.** and Safe, Stephen. "Molecular Mechanism of Action of Insulin Sensitizing Drug- Metformin as Anticancer Agent In Pancreatic Cancer." *Society of Toxicology Annual Meeting, March 6th -10th, 2011, Washington,D.C.*

Leadership and Service:

- General Secretary for Graduate Student Association - College of Veterinary Medicine, Texas A&M University (2011 May – 2012 April).
- Postdoctoral representative – Leadership council for Southern California Society of Toxicology – (2016 May- March 2017).

APPROVALS	
COMPANY: AFFYGILITY SOLUTIONS LLC	
ORIGINATOR: _____	DATE: 2026-05-18
QUALITY _____ 	DATE: 2026-05-18
MANAGEMENT _____ 	DATE: 2026-05-18
EFFECTIVE DATE: _____	2026-05-18

This is to certify that

**Vijayalekshmi Ramachandran
Nair Vasanthakumari**

has been included within the

UK Register of Toxicologists

and is bound by the codes of conduct of the

Royal Society of Biology

and

British Toxicology Society

for the period

26 October 2023 to 25 October 2028



Mr Mark Hosford, ERT
(Panel Chair)



Incorporated by Royal Charter

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CERTIFICATE *of* SIGNATURE

REF. NUMBER
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SIGNER

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