Preveen Ramamoorthy, Ph.D.

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MISSION

- > To develop and deploy rapid molecular diagnostic, molecular prognostic, pharmacogenomic companion diagnostic and molecular genetic tests
- > To catalyze and drive translation of existing/novel biomarkers into clinically useful molecular diagnostics tests
- To innovate by developing/co-developing novel molecular diagnostics technologies
- > To create molecular diagnostics training programs to enable physicians, scientists and students to participate in the era of molecular medicine
- > To partner with drug development, diagnostics and technology companies to enable the development of companion diagnostics and molecular diagnostics

SUMMARY

Professional with fifteen years of combined academic/industry experience in infectious disease, immunology, oncology and genomics and five years of biotechnology industry experience in cancer/viral vaccine/antibody development and molecular assay development. Scientific committee member of Q-PCR symposium (http://qpcrsymposium.com/). Reviewer for the Journal of Asthma.

PROFESSIONAL EXPERIENCE

National Jewish Medical and Research Center, Denver, CO

2007-Present

Director, Molecular Diagnostics, Advanced Diagnostic Laboratories

Assistant Professor, Department of Medicine, Division of Mycobacterial and Respiratory Infections

- Established brand new state-of-the art Molecular Diagnostics facility with capabilities in sequencing, real-time PCR, luminex bead array, liquid handling robotics technology, microarrays and bioinformatics
- Established initial molecular diagnostics test pipeline comprising of rapid molecular diagnostic tests, molecular prognostic tests, pharmacogenomics/companion diagnostics tests and molecular genetic tests
- Established CLIA/CAP compliant process/procedures to develop, validate and deploy molecular diagnostics tests
- Hired three industry trained personnel and integrated them with Advanced Diagnostic Labs (ADx) and Molecular Resource Center (MRC) scientists and faculty into a fully functional R&D Molecular diagnostics program
- Leading efforts to bring in Laboratory Information Management System (LIMS) into the ADx labs to implement the electronic lab notebook concept
- Participating in translational research activities to catalyze institutional wide translation of biomarkers into molecular diagnostic tests
- Guest lecturer for the molecular diagnostics program (MT830) from Michigan State University in conducting their hands on training program at NJMRC.

MedImmune Inc., Mountain View, CA

2002-2007

Scientist II and Manager, New Technology and Innovations Group

Member of Product Development Teams- Viral/Cancer Vaccine and Monoclonal Antibody Research & Development

- Member of product development teams consisting of members from research, clinical research, analytical development, process development, formulations, quality assurance and quality control to develop:
- Live attenuated influenza vaccine (egg derived and reverse genetics derived)
- Live attenuated pandemic influenza vaccine
- Live attenuated respiratory syncytial viral vaccine
- Live attenuated human metapneumovirus vaccine
- Live attenuated Listeria vector cancer vaccine
- Therapeutic monoclonal antibodies

Lead Scientist- New Technology Assessment

• Initiated discussions and proof-of-principle experiments with technology providers to address unmet needs in studying Immune/host response and pathogen/vaccine detection encompassing cellular, nucleic acid and protein technologies.

Site Project Lead- <u>Listeria EphA2 Cancer Vaccine Development</u>

- Developed Identity, Purity, Safety and Potency assays for Listeria EphA2 cancer vaccine candidate for preclinical studies and Phase I clinical development. These assays included microbiology assays, genotyping assays
- Played a lead role in crafting the assay development strategy and identifying, auditing and managing CRO.
- Coordinated activities with research, regulatory and quality assurance departments and between partner company (CERUS), two MedImmune sites and CRO.
- Supervised 3 research associates and a CRO for the assay development activities
- Crafted biomarker discovery strategies to identify efficacy and toxicity biomarkers.

Group Leader- Microbiology

• Implement routine and novel methods of microbial culture and identification to support the needs of process development, quality control and manufacturing departments

Lead Scientist- Biomarker Discovery

- Contracted Expression Analysis Inc (CRO) to conduct biomarker discovery using transcriptomic profiling of the cellular response to respiratory viral vaccines in a GLP environment. Participated in discussions and experimental design
- Evaluated open gene expression technologies to discover biomarkers of vaccine response in ferrets, the in vivo model of choice for flu virus/vaccines.

Lead Scientist- Molecular Assay Development to support drug/vaccine development

- Designed, developed and deployed assays using the following technologies: Resequencing microarrays, microfluidics technologies, whole genome amplification mediated real-time PCR assay, PCR assays and real-time PCR assays.
- Invented novel assay to size/quantify genomic DNA.

Technology Transfer Lead- Clinical Assay Development

- Developed and transferred the application of Agilent Bioanalyzer microfluidics platform technology to the clinical testing department. This technology was successfully applied to genotype influenza virus and Flumist® from clinical samples from one of the largest flu vaccine clinical trials in the pediatric population.
- Trained and mentored two research associates, facilitated the installation of Bioanalyzer systems and IQ/OQ ahead of the deadline

Walter Reed Army Institute of Research (WRAIR), Silver Spring, MD

2000-2002

Post-doctoral Scientist, Department of Molecular Pathology

<u>Project Goal:</u> To build a pathogen specific blood transcriptome signature library by cataloguing peripheral blood mononuclear cellular responses to pathogens and develop a gene chip to identify pathogens using blood transcriptomic signatures. This project was funded by DARPA and U.S army grants.

Project Lead (Industry Collaboration) - Discovery of Immune/Inflammatory Biomarkers in Small Pox Vaccine

- Lead the experimental design, execution and coordination of the project with Acambis (Boston, MA)
- Infected human peripheral blood mononuclear cells with small pox vaccine and profiled the host immune response using microarrays. The objective was to use the results for translational immunology studies in small pox vaccine clinical trials.
- Coordinated and trained Acambis (Boston, MA) personnel in using PAXgeneTM Blood RNA System for clinical studies.

Project Lead/Collaborator- Molecular Diagnosis of Pathogens Using Blood Transcriptomic Signatures

- Profiled the gene expression responses of human peripheral blood mononuclear cells (PBMC) in response to Venezuelan Equine Encephalitis virus (VEE), Dengue virus, Lymphocytic Choriomeningitis virus (LCMV) and Anthrax infections using cDNA arrays.
- Trained, managed and mentored a lab of 2 technicians and 5 gifted student interns for this project.

Lead- Microarray Target Validation Core Facility

- Established real-time PCR protocols and data analysis methods for validating targets derived from microarray data
- Supported the Molecular Pathology department's needs for real-time PCR assays for multiple biomarker discovery projects

Lead/Collaborator- Grant Writing and Review

- Written/Co-written grants for National Institutes of Health (NIH), Department of Defense (DOD and Military Infectious Disease Research Program (MIDRP).
- Reviewed grants for Defense Threat Reduction Agency (DTRA) and Small Business Innovation Research (SBIR).

Lead- Technology Evaluation and Collaboration

- Evaluated a variety of technology platforms to cross-validate and field deploy validated gene markers. Technologies from Gene Logic, Nanogen and Motorala were evaluated
- Established collaboration with the Institute of Human Virology (Baltimore, MD) for clinical biomarker studies and biomarker discovery studies
- Lead the technical evaluation of Nanogen's microfluids microarray
- Evaluated a variety of bioinformatics tools and platforms from Silicon Genetics, Partek, Incogen and Stratagene for data mining

EDUCATION

Ph.D Microbiology 1995-2000

Department of Microbiology and Molecular Medicine, Clemson University, Clemson, SC

<u>Dissertation:</u> A Human Prolactin Antagonist hPRL-G129R Inhibits Breast Cancer Cell Proliferation Through the Induction of Apoptosis

- <u>Project Goal</u>: To therapeutically target the prolactin receptor of breast cancer cells using a novel prolactin receptor antagonist. The hypothesis was to block the autocrine/paracrine growth signals delivered by breast cancer cell secreted prolactin.
- Co-wrote NIH and American Cancer Society grants
- Played a critical role in establishing, managing the lab and mentoring 2 graduate students and 2 undergraduate students

MS Medical Microbiology

1992-1995

Department of Medical Microbiology, University of Madras, Chennai, India

Thesis: Process of Acquiring HBV/HCV Infection by Renal Failure Patients Undergoing Renal Transplantation

- Project Goal: To investigate the etiology behind the morbidity/mortality of renal failure patients due to hepatitis
- Quantified and correlated viral/immune markers of HBV and HCV infection in renal failure patients
- Performed liver enzyme assays and clinical history analysis of renal failure patients.

• MS Medical Microbiology Program: A clinically oriented program that provided a firm grounding in the basic clinical sciences, clinical microbiology and practical hands on experience in translating this knowledge in clinical settings.

PUBLICATIONS

- **Preveen Ramamoorthy**, Rina Das, Niranjan Kanesa-Thasan, Robert Putnak and Marti Jett. *Host Immune Gene Expression Profiling In the Diagnosis of DEN Infection and Application of Nanogen's Microelectronic/Microfluidics Chip to Profile Host Immune Gene Expression Responses.* 23rd Army Science Conference: "Transformational Science & Technology for the Army...a race for speed and precision." Orlando, FL, 2-5 December 2002.
- Rina Das, Roger Neill, George Ludwig, **Preveen Ramamoorthy**, Rasha Hammamieh, Apsara Dhokalia, Sachin Mani, Chanaka Mendis, Christiano Cummings, Brian Kearney, Atabak Royaee, Xiao-Zhe Huang, Chrysanthi Paranavitana, Melody Jensen, Leonard Smith, Niranjan Kanesa-Thasan, David Hoover, Luther E. Lindler, David Yang, Erik Henchal and Marti Jett. *Host Gene Expression Profiles in Peripheral Blood Mononuclear Cells: Detection of Exposure to Biological Threat Agents*. 23rd Army Science Conference: "Transformational Science & Technology for the Army...a race for speed and precision." Orlando, FL, 2-5 December 2002.
- Marti Jett, Boris Ionin, Rina Das, **Preveen Ramamoorthy** and Roger Neill. *Enterotoxins*: Thomas E. Creighton (ed.) Encyclopedia of Molecular Medicine. New York: John Wiley & Sons, 2002, ISBN: 0-471-37494-6.
- Ramamoorthy P, Wagner TE, Chen WY. *In Vitro Effects of a Human Prolactin Antagonist, hPRL-G129R in Breast Cancer Cells*. International Journal of Oncology, January 2001, 18 (1): 25-32.
- Cataldo LA, Chen NY, Qiu Y, Li W, **Ramamoorthy P**, Wagner TE, Chen WY. *Inhibition of the Oncogene STAT3 by a Human Prolactin (PRL) Antagonist is a PRL Receptor Specific Event*. International Journal of Oncology, December 2000; 17 (6): 1179-85.
- Chen WY, Ramamoorthy P, Chen NY, Sticca R, Wagner TE. A Human Prolactin Antagonist, hPRL-G129R, Inhibits Breast Cancer Cell Proliferation through Induction of Apoptosis. Clinical Cancer Research, November 1999, 5:3583-3593.

INVITED TALKS

- Harnessing the Biosensor Capabilities of the Immune System for Molecular Diagnostics and Theranostics Applications- A Transcriptomics Approach. **XDx**, South SanFrancisco, July 26, 2006.
- Evaluation of Agilent Bioanalyzer Technology for DNA Applications- A MedImmune Perspective, Foster City, July 18, 2006.
- Harnessing the Biosensor Capabilities of the Immune System for Molecular Diagnostics and Theranostics Applications- A Transcriptomics Approach. Roche Diagnostics, Alameda, October 2004.
- Comparison of Changes in Host Immune Gene Expression Patterns Induced by DEN-2 and its Vaccine Strain Using Gene Array Technology and Real Time PCR. FASEB April 2002, New Orleans.
- Human Prolactin Antagonist and Breast Cancer Therapy, 18th Southern Biomedical Conference and the 2nd
 International Conference on Ethical Issues in Biomedical Engineeering, Clemson, South Carolina, May 21-23, 1999.
- Process of Acquiring HBV/HCV Infection by Renal Failure Patients Undergoing Renal Transplantation, XVIII National Congress of the Indian Association of Medical Microbiologists, Pune, India, November 13, 1994.

AWARDS

- Presented the MedImmune Vaccines Directors Award in 2003.
- Awarded consecutive travel grants to attend FASEB meetings, 2001, Orlando, FL and 2002, New Orleans, LA.
- Awarded the Albert Krall Memorial Award, 8th Annual South Carolina Statewide Research Conference: *Molecular Approaches to Biological Problems*, January 1999, Wild Dunes.
- Ranked 8th by the University of Madras in BS Zoology.
- Experienced Teaching Assistant- Department of Microbiology & Molecular Medicine- Invited to conduct the Fall 1998 Teaching Assistants training sessions of Clemson University.

TRAINING AND CONFERENCES

- 14th International Molecular Medicine Tri-Conference, San Francisco, Feb 28-March 2, 2007.
- Translational Medicine Workshop, South San Francisco, March 5-9, 2007.
- Personalized Medicine- Scientific, Regulatory and Business Dimensions, UC Santa Cruz, June 15-16, 2006.
- Biomarker World Congress, Philadelphia, May 16-18, 2006.
- Translational Research Course, South San Francisco, April 5-8, 2006.
- Molecular Medicine Tri-Conference, San Francisco, Feb 21-24, 2006.
- Clinical Biomarkers- Beyond Discovery, Cambridge, November 30 December 2, 2005.
- Emerging Technologies for Drug Discovery, South San Francisco, April 5 6, 2005.
- Quantitative PCR- The Validation Tool of Choice, La Jolla, March 21 22, 2005.
- Nucleic Acid Based Technologies Applications Amplified- Profiling PCR and Beyond, McLean, June 2004.
- Scientific Presentations Workshop- MedImmune Vaccines, 2004.
- Chips to Hits Conference- Microarray Technologies and Their Use in Drug Discovery and Development, Boston, October 2003.
- Design of Experiments Training- MedImmune Vaccines, 2003.