Anita Lal, Ph.D.

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Summary

Innovative product development professional experienced at developing Class II and Class III *in vitro* diagnostic products for oncology and infectious diseases under FDA and CLIA regulations

Education

MBA, Class of 2017	Evening-Weekend Program, Haas School of Business, University of California Berkeley
Ph.D.	Biochemistry & Molecular Biology, University of Georgia, Athens, GA
B.S.	University of Delhi, Delhi, India

Notable Skills

- Experience in all aspects of IVD product development from product concept to product launch
- Familiar with FDA and CLIA requirements, and associated quality systems
- Strong leadership and management skills
- Experience at managing scientific collaborations and relationships with an emphasis on development
- Solid understanding of scientific study design concepts and strong technical skills
- Excellent interpersonal skills, and teamplayer
- Outstanding written and verbal communication skills

Professional Experience

Siemens Healthcare Diagnostics

Senior Program Manager, Molecular IVD (October2015-present)

- Project Lead for cross-functional team developing PCR-based Class III *in vitro* molecular diagnostic products for infectious disease

Siemens Healthcare Diagnostics

Staff Biochemist, Molecular IVD (March 2013-September 2015)

- Team Lead and Core Team Member for development of PCR-based *in vitro* molecular diagnostic products for infectious disease
- Technical expert member of Product Health Team supporting customer complaints
- Provide technical support in working with the FDA and other regulatory agencies, including preparation of documents for modular PMA submission and participation in FDA meetings
- Serve on cross-functional teams, and interface with regulatory, quality, operations, labeling, product support, clinical and marketing teams
- Partner with statistical team and successfully develop and execute non-clinical and clinical studies
- Prepare protocols, final reports, policy documents and SOPs in support of ongoing development efforts
- Review clinical protocol and providing support to clinical affairs team for conduct of clinical trials for PMA submission

Clinical Persona

Consultant, Companion Diagnostics Development (July 2013-January 2014)

- Provide product development support to start-up company as they seek companion diagnostic development partners and investor funding

Pathwork Diagnostics

Associate Director, Product Development and Clinical Affairs (April 2012-March 2013)

Manager, Product Development and Clinical Affairs (April 2009- April 2012)

- Technical Lead for development and successful launch of Class II molecular *in vitro* diagnostic products for oncology

- Participate in companion diagnostic development efforts in collaboration with pharma
- Participate in establishing mutation testing for oncology offered as a Laboratory Developed Test
- Experience at all phases of diagnostic product development (from feasibility to product launch) under FDA prescribed design control process and associated quality systems
- Partner with informatics/research teams to effectively transition technology from feasibility to development
- Successfully design, analyze and execute clinical studies for both pre- and post-marketing products/concepts
- Prepare protocols, final reports, policy documents and SOPs in support of ongoing clinical efforts
- Provide product development operational support to meet project timelines
- Provide technical support in working with the FDA and other regulatory agencies, including preparation of documents for 510(k) submission and participation in FDA meetings
- Lead efforts for external site selection and recruitment for product development activities
- Serve on cross-functional teams, and interface with regulatory, operations, software, production and marketing teams
- Identify and evaluate issues that may impact project scope, schedule, performance or budget and propose and implement contingency plans and/or resolutions
- Partner with clinical reference laboratory (with CLIA certification and CAP accreditation) in a technical expert role for troubleshooting, assay optimization and improvements
- Participate in transitioning developed products into commercial operations
- Manage academic and industrial collaborations in support of clinical and post-marketing studies
- Participate in technology assessments and provide recommendations for product pipeline development
- Lead efforts to publish project related abstracts and manuscripts, and present relevant data internally and externally
- Co-authored 4 peer-reviewed publications on diagnostic test validation and test improvements

University of California, San Francisco – Neurological Surgery

Assistant Professor (October 2004-February 2009)

Assistant Researcher (February 2003-October 2004)

- Establish a new research laboratory focused on the genetics of meningioma tumorigenesis (oncology)
- Successfully conceive, plan, supervise and execute diverse research projects including evaluation of biomarkers
- Participate in collaborations with academic scientists and clinical teams internally at UCSF and across institutions
- Frequent presenter at neuro-oncology meetings
- Develop organizational system for laboratory management
- Involvement in professional neuro-oncology society at an organizational level
- Experience investigating and solving technical situations in the laboratory
- Over 6 years of experience supervising scientists
- Obtained 8 research grants from private and federal funding sources
- Co-authored 13 peer-reviewed publications

Duke University – Department of Pathology

Postdoctoral Research Fellow (March 1998-January 2003)

- Use of gene expression technologies and molecular biology bench work to locate genes and investigate their functional role in the development and progression of glioblastomas (oncology)
- Co-authored 12 peer-reviewed publications

Publications and Patents

- 37 peer-reviewed publications
- 3 invited-review publications
- 1 book chapter
- Co-inventor on patent (US Patent No. 7115265)