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LECTURER, UC Davis Graduate School of Management, Davis, CA

DIRECTOR, Biotechnology Industry Immersion

Currently, Director, Biotechnology Industry Immersion program at University of California, Davis, Graduate School of Management (MBA), that is designed to prepare students to manage a Biotechnology business. Taught Entrepreneurship course from 2013-2021 that was designed to teach students to be successful entrepreneurs and manage innovation. In parallel the students learned to analyze new business opportunities before making investment decisions. In addition to teaching, member of the Sacramento Angel Investment group and new investment selection committee and mentor/advisor to several startups.

PRINCIPAL CONSULTANT

*Assess product development strategy, process and technology in IVD industry
and consult for mergers and acquisitions or represent at the board*

Seasoned strategy and product development executive; 24 years' experience with Siemens and its parent companies in the In-Vitro Diagnostics Industry. Experience developing chemistry/Immunochemistry and Microbiology diagnostic products. Participated in creating diagnostics business in India from scratch. Highly successful track record in creating concepts and transforming them into commercial products. As a member of the Microbiology business leadership team, influenced business growth from \$140MM to \$220MM over 10 years. Passion for measuring, monitoring, and implementing continuous process improvements to increase organizational efficiencies.

- **Leadership/Supervision:** 20+ years of increasing responsibility managing up to 100 people, from clinical scientist to product development directors. As VP of R&D for MicroScan, managed all aspects of product development, supported strategy development and created technology road map.
- **Innovative:** Identified novel, customer centric solutions for technical problems.
- **Mentoring/Coaching:** Mentored direct reports and non-direct reports across the organization. Encouraged and supported employee training that led to increased self-confidence, organizational alignment and increased efficiency and communication.
- **Continuous improvement:** Adopted "Kaizen" philosophy for the development process. Assessed, measured and improved development processes to significantly reduce cycle time. Implemented Customer Centered Product Definition (CCPD) and Product and Cycle-time Excellence (PACE) processes.
- **Team work/Collaboration:** Built good relationship with Marketing, Manufacturing and other support functions to improve cross-functional collaboration and trust.
- **Communication:** Ensured clear communication on business strategy and priority throughout the organization for better alignment and success of the business.

EDUCATIONAL AND ACADEMIC BACKGROUND

Education: 1982 - 1988 Post-doctoral fellowship, Clinical Chemistry, Washington University School of Medicine, St. Louis., MO
1978 - 1982 Ph.D., Microbiology, Sardar Patel University, India

Academic Experience: 1976-1978: Faculty at Gujarat College, India
1978-1982: Faculty at Sardar Patel University, India
1982 - 1988 Six years Research Associate at Washington University School of Medicine, St. Louis, MO
2013 Faculty appointment at UC Davis, MBA school to teach "Business Development Clinic"

Healthcare Industry Experience: 1988-2012, 24 years in Industry, from bench Scientist to VP of R&D

SIGNIFICANT CAREER ACCOMPLISHMENTS

- 30 years of successful career growth through a series of increasing technical and management responsibilities in R&D, Clinical and Marketing and Technical Support organizations.
- Track record delivering revenue generating products.
- Four patents and three trade secrets; the most successful patent on CKMB monoclonal antibody fetched significant royalty revenue for Washington University.

- 28 publications in peer reviewed journals.
- 22 abstracts and presentations at national and international professional meetings.
- Member of AACC/ASM/CLSI/PDMA; Chair or member of various subcommittees.
- Member of various "approval" committees and "Emerging Market Strategy" team.

PROFESSIONAL EXPERIENCE (continued)

- Presented workshops on Emerging Antibiotic Resistance, Cardiac markers and Integration of Product Development in the Business Processes at various National and International meetings.
- Mentor students at the Indian Institute of Management, Ahmedabad and MBA students at University of California, Davis.
- Member of Sacramento and Davis Angel groups that fund promising startups.

Consultant, In-Vitro Diagnostics Strategy and Product Development Current

- Expertise in IVD product development from 24 years industry experience.
- Post-doctoral training in Clinical Chemistry from Washington University led to understanding of clinical utility of diagnostic tests.
- Conducted research and patented technologies in the field of immunodiagnostics, monoclonal antibodies and automated immunochemistry and Microbiology systems.
- Can assess and help improve product development processes and strategy based on 15 years of senior management experience at Siemens and its parent companies.
- Available to consult with IVD companies to assess technology for merger/acquisition or represent them at the board.

SIEMENS HEALTHCARE DIAGNOSTICS

Vice President, R&D, Molecular and Microbiology Assay Development 2011 - Feb 2012

Managed all aspects of Molecular (RT PCR) and Microbiology (Microbial Identification and Antibiotic Susceptibility Testing) Assay Development activity in the Siemens Diagnostics Healthcare, Molecular and Microbiology Business Segments. Directed major planning aspects of the R&D department, including an annual operating plan and a long-range strategic plan.

Vice President, R&D, MicroScan Microbiology Systems 1997 - 2011

Managed all aspects of Microbiology R&D organization of up to 80 to 100 people. Directed major planning aspects of the R&D department including an annual operating plan and a long-range strategic plan.

- Involved in creating and implementing hardware, software and biologics development strategy.
- Involved in the evaluation of new technologies in automation and molecular diagnostics.
- Organized the department for increased efficiency by hiring and retaining individuals with the requisite skills and implemented product development process to increase productivity such as PACE, Siemens PDP (Product Development Process) and CCPD.

DADE CHEMISTRY / IMMUCHEMISTRY SYSTEMS

1996 - 1997

Director, Clinical and Scientific Affairs,

Technical and administrative responsibility for clinical Affairs function, including supporting development of product specifications and Design Validation. Directed 15 individuals with Clinical Chemistry background.

- The group collaborated with marketing and customers to define design input requirements for general chemistry and immunochemistry test being developed for the aca, aca® plus Stratus CS and Dimension analyzers. The group also conducted clinical trials in hospital laboratories.
- Helped develop the cardiac marker (creatin kinase MB, troponin I and Myoglobin) strategy for Dade Behring analyzers. Established a cross-functional rationale based customer focused requirement gathering process.

- Was part of the team that conducted Chemistry/Immunochemistry market research on opportunities in China and India, especially M3/M4 market segment.

E I DUPONT DE NEMOURS & CO., Wilmington, DE

1988 - 1996

Group Leader, Clinical Studies Group, Marketing and Technical Support Organization (1995- 1996)

Technical and administrative responsibility for overall direction for clinical studies and development of product specifications. Directed 10 individuals with Clinical Chemistry background.

- The group conducted clinical trials in hospital laboratories and collaborated with customers and the Marketing organization to define design input requirements for general chemistry and a immunochemistry test being developed for the aca, aca® plus Stratus CS and Dimension analyzers.
- Provided technical support to the Western Zone Marketing organization for six months.
- Led the team to conduct Market research in India for the DuPont Chemistry/Immunochemistry products. Visited 20-25 labs and around 10 potential distributors. This is now a significant revenue generator for Siemens (that acquired DuPont products).

Senior Clinical Scientist / Clinical Science Associate (1993 – 1995)

Responsible for developing design input requirements for immunoassay for hemoglobin A1c.

- Developed design-input requirements and conducted clinical trials for a Prostate Specific Antigen immunoassay, a method that required a PMA submission to the FDA.
- Chaired the American Association for Clinical Chemists (AACC) CKMB standardization Subcommittee. The subcommittee, consisting of eminent Clinical Chemists, developed a recombinant CKMB reference material that is now commercially available through AACC.

Senior Development Biochemist (1990 – 1993)

- Collaborated with scientists and engineers (from the concept development to final product release) to develop the aca® plus immunoassay system.
- Developed basic bi-chromatic technology that allowed for performance of immunoassay in presence of suspended chromium dioxide particles. The technology has since been patented and is also being used on Dimension® analyzers. Also developed the CKMB immunoassay for the aca® plus.

Development Biochemist (1988 - 1990)

Joined DuPont's IVD business to work on an ongoing new immunoassay platform development project.

- Developed T4 and TU immunoassays for Vista® immunoassay analyzer.
- Contributed to development of fundamental technology.
- Identified and help resolve critical system integration issues to improve analytical sensitivity of the system.
- Identified anti-microbial agents compatible with all Immunoassays on Vista® in a way that the signal to noise level is not impacted and is compatible with a wide range of immunoassay reagents.
- Conducted extensive studies to identify the cause and eliminate human anti-mouse antibody interference in all two-site immunoassays. The approach is now being used in all two-site immunoassays on aca® plus and Dimension® RxL analyzers.

WASHINGTON UNIVERSITY SCHOOL OF MEDICINE, St. Louis, MO

1982 - 1988

Research Associate / Chief Fellow (1983 – 1988)

- Obtained post-doctoral training in clinical chemistry. Two years extensive training in laboratory medicine, including human pathophysiology. Rotated through Barnes, Jewish and Children's hospital clinical chemistry laboratories.
- Discovered first unique monoclonal antibodies to creatine kinase MB and Lactate dehydrogenase. Developed Immunoassays for CKMB, LD1 and LD5.
- Patented monoclonal antibody to CKMB. Antibody is now widely used in most commercial CKMB Immunoassays from various manufacturers and brought millions of dollars of royalty to the university.

Research Associate (1982 – 1983)

- Conducted post-doctoral research in the processing of E.coli ribosomal RNA with two RNA processing enzymes Ribonuclease III and Ribonuclease E.

ACADEMIC WORK EXPERIENCE

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|---|---------------|
| SARDAR PATEL UNIVERSITY, Vallabh Vidyanagar, India Adjunct Faculty, Instructor, Department of Biosciences | 1978 – 1982 |
| <ul style="list-style-type: none">• Taught courses in Medical Microbiology and Immunology to under-graduate students.• Obtained Ph.D. in Microbiology.• Maintained and managed the centralized instrument laboratory. | |
| GUJARAT COLLEGE, Ahmedabad, India Demonstrator in Microbiology | 1976 – 1978 |
| <ul style="list-style-type: none">• Primary responsibility included teaching Microbiology and Immunology to undergraduate students | |
| LECTURER, UC Davis Graduate School of management, Entrepreneurship Clinic | 2013 -2021 |
| LECTURER and DIRECTOR, Biotechnology Industry Immersion program | 2021- current |

SUPPORTING INFORMATION

Technical and Management Courses:

- Hybridoma. Organized by the Center for Advance training in Cell and Molecular Biology, The Catholic University of America, Washington DC at Rosemont ILL, May 31-June 1, 1984.
- Regulatory Mechanism in Immunity, organized by the American Association of Immunologists at the Lindenwood College, St. Charles, MO, June16-23, 1985.
- Strategy of Experimentation, organized by E.I. DuPont, Wilmington DE, 1989.
- Interpersonal Skill development. Organized by Forum, June 21, 1995.
- Project Management Program. Organized by Integrated Project System. June 27, 1995.
- QSR/ISO training. Organized by MicroScan. Aug 1997.
- European IVD Directive. Organized by MicroScan April 1999.
- Global Leadership Forum. A senior leadership development program developed by Dade Behring Inc. Sep.1999.
- Managing Technical Professionals and Organizations. Organized by MIT Cambridge MA March, 2000.
- Software Verification and Validation Strategies. Organized by Noblitt and Rueland, June 2000.
- Negotiation Skills for Senior Management. Harvard Business School, October 2001.
- Center for Creative Leadership, San Diego, CA, 2005.
- Board Certification: Eligible for the American Board of Clinical Chemistry.

Professional Activities:

- Chaired a roundtable on “Myoglobin” at the 1991 AACC meeting in Washington DC.
- Chairman of the AACC subcommittee to “Standardize CKMB mass Immunoassay” 1992-1996.
- Presented a workshop at the 1992 CAMLT meeting in Los Angeles CA on “AMI Markers”.
- Presented a workshop at the 1992 North West Medical Laboratory Symposium in Tacoma, WA on “AMI Markers”.
- Member of the Clinical Laboratory News (AACC publication) Advisory Board.
- Reviewer for Clin. Chem. and BBA.
- Chairman of a roundtable on “Myoglobin as an early biochemical marker for the diagnosis of myocardial infarction” IFCC 1993, Melbourne, Australia.
- Advisor and delegate of the NCCLS since 1997.
- Vice President Indian Alumni for Clinical Chemistry 1996-1997.
- Active member of local social and cultural organizations.
- Conduct Seminars on "Nuts and Bolts of Product Development" at various MBA schools in India (Sardar Patel University, Amity University, Indian Institute of Management) and at Sacramento Sate University, Sacramento, CA (Prof Seung Bach).
- Mentor students at the Indian Institute of Management, Ahmedabad and MBA students at University of California, Davis.

AWARDS / PATENTS / PUBLICATIONS / PRESENTATIONS

AWARDS:

- Received NIH training award from Grant T32 ES07066-09 from November 1985 to June 1988.
- Recipient of the student travel award to attend the joint meeting of AACC and CACC in Chicago, 1985
- Recipient of the Young Investigator Award at the ACLPS meeting in Philadelphia, 1987.
- Accomplishment Award for identifying anti-microbials for the Vista® immunoassay reagents, E.I. DuPont de Nemours and Co. Inc. 1990.

PATENTS AND TRADE SECRETS:

- The United State Patent “Creatine kinase MB determination method”, serial no. 4,912,003. Issues in 1990. International patents were also filed.
- The United States patent application for the development of a LD-1 assay with the use of M-subunit specific monoclonal antibody (not pursued)
- The United States patent application for the development of an approach to eliminate interference due to human anti-mouse antibody (HAMA) in two-site Immunoassays. 1992 (later turned to trade secret).
- The United States patent “Assay with signal detection in presence of a suspended solid support”. Serial no. 5,454,051, 7/18/95.
- The United States patent; “Assays with signal detection in presence of suspended solid support. Serial no. 5,654,159, 8/5/1997.
- The United State patent application for the development of Random Access Microbiology System, Serial no. 6,573,088 B2, 6/3/2003
- High through-put Automated WalkAway Microbiology Analyzer. Memorandum of Invention (MOI) submitted to Siemens. 2011.

RESEARCH INTEREST:

- Management of New Product Development
- Diagnostic and biochemical application of monoclonal antibodies
- Automation in clinical instruments using interdisciplinary approach
- Molecular diagnostics in clinical Microbiology
- Rapid testing in Microbiology

AWARDS / PATENTS / PUBLICATIONS / PRESENTATIONS

PUBLICATIONS:

1. Dissertation for MS degree: Induction of beta-galactosidase in *Lactobacillus* spp. 1976
2. Ph.D. thesis: Alkaloid production by submerged *Claviceps* sp. strain SD58: physiology of phosphate effect. 1982.
3. Kachhy AN, VV Modi and **HC Vaidya**. Induction of beta-galactosidase in *Lactobacillus* spp. *Ind. J. Exp. Biol.* 15, 112, 1977.
4. **Vaidya HC** and JD Desai. Cell differentiation and alkaloid production in *Claviceps* sp. Strain SD 58. *Ind.J. Exp. Biol.* 19, 829, 1981.
5. Desai JD, AJ Desai and **HC Vaidya**. A new method for isolation of saprophytic cultures of *Claviceps fusiformis* from sclerotia. *Folia Micorbiol.* 27,182,1982.
6. **Vaidya HC** and JD Desai. Effect of phosphate on growth, carbohydrate catabolism and alkaloid production in *Claviceps* sp. SD 58. *Ind. J. Exp. Biol.* 20, 475, 1982.
7. **Vaidya HC** and JD Desai. Alkaloid production by *Claviceps* sp. SD 58: involvement of phosphatase isoenzymes *Folia Microbiol.* 28,12,1983.
8. **Vaidya HC** and JD Desai. Alkaloid production in *Claviceps* sp. SD 58: physiology of phosphate effect. *Ind. J. Exp. Biol.* 20,222,1983.
9. J. Szeberenyi, MK Roy, **HC Vaidya** and D Apirion. 7S RNA, containing 5S ribosomal RNA and the termination stem, is a specific substrate for the two RNA processing enzymes RNAase III and RNAase E. *Biochemistry*, 23, 2952, 1984.
10. **Vaidya HC**, DN Dietzler and JH Ladenson. Purification of five Creatine kinase MM variants from human heart and skeletal muscle. *Biochem. Biophys. Acta* 790,230,1984.
11. **Vaidya HC** DN Dietzler and JH Ladenson. Inadequacy of traditional ELISA for screening hybridoma supernatants for murine monoclonal antibodies. *Hybridoma*. 4,271,1985.
12. **Vaidya HC**, Y. Maynard, DN Dietzler and JH Ladenson. Direct measurement of Creatine kinase MB activity in serum after extraction with a monoclonal antibody specific to the MB isoenzyme. *Clin. Chem.* 32, 657, 1986.
13. **Vaidya HC**, DN Dietzler and JH Ladenson. Quantitation of serum lactate dehydrogenase 5 with monoclonal antibodies. *Clin Chim Acta.* 161,315,1986.
14. **Vaidya HC** and R. Kanan. Porphyria cutenea tarda: an under diagnosed entity. Eds. KM Chan and JH Ladenson. *Clin. Chem.* 33, 1113, 1987.
15. Landt Y., **HC Vaidya** SE Porter et.al. Semiautomatic direct colorimetric measurement of CKMB activity after extraction from serum by CKMB specific monoclonal antibody. *Clin.Chem.* 34, 575, 1988.
16. **Vaidya HC**, SE Porter, Y. Landt et.al. Quantification of Lactate dehydrogenase 1 in serum with the use of M-subunit specific monoclonal antibody. *Clin. Chem.* 34, 2410, 1988.
17. Landt Y, **HC Vaidya** et.al. Immunoaffinity purification of Creatine kinase MB from human, dog and rabbit heart muscle with the use of monoclonal antibody specific for CKMB. *Clin.Chem.* 35, 985, 1989.
18. **Vaidya HC** BA Wolf et.al. Extremely high values of prostate specific antigen in the patients with adenocarcinoma of prostate. Demonstration of hook effect. *Clin Chem.*34, 2175, 1988.
19. Hauptfeld-Dolejssek V. **HC Vaidya** and DC Shreffler. Immune response gene control for the mouse antibody responses to human CKMM and LDH-1 enzymes. *Immunogenetics* 30, 128, 1989.
20. **Vaidya HC** and IL Kothari. Influence of inorganic phosphate on the ultrastructure of submerged hyphae of *Claviceps*. *Ind. J. Exp. Biol.* 27, 532, 1989.
21. **Vaidya HC** Creatine kinase MB. *Clin Chem. News* 14,11,1988.
22. **Vaidya HC**. Myoglobin. *Lab Medicine.* 23,306,1992.
23. **Vaidya HC** and BG Beatty. Eliminating interference from heterophilic antibodies in a two-site immunoassay for CKMB by using F(ab)'2 conjugate and polyclonal mouse IgG. *Clin Chem.* 38, 1737, 1992.
24. Landt M, GL Hortin, C. Smith Pashos G and **HC Vaidya**. Rapid measurement of serum pancreatic amylase. *J.Clin. Lab Anal.* 8,10,1994.

25. **Vaidya HC**. Myoglobin: an early biochemical marker for the diagnosis of acute myocardial infarction. *J. Clin Immunoassays*. 17, 35, 1994.
26. **Vaidya HC**, PJ Zuk and RA Ballas. aca Plus® accessory for the aca® discrete analyzer. P131, in the "Immunoassay Automation: An updated guide to systems". Ed. Daniel Chan. Academic Press, New York, 1996.
27. Fritche FA, CP Kamm, **Vaidya HC**. Measuring prostate specific antigen. *Advance laboratory*. Jan, 63, 1997.
28. **Vaidya HC** and HK Vananen. Myoglobin and Carbonic anhydrase III. Chapter in the book entitled Cardiac markers. In the series "Contemporary Pathology and Lab Medicine" 1998.

ABSTRACTS AND PRESENTATION (only unpublished presentations included)

1. **Vaidya HC** DN Dietzler et al. Studies on the catalytic mechanism of lactate dehydrogenase with the use of monoclonal antibody. Annual meeting of the Academy of Clinical Laboratory Physicians. Philadelphia 1987.
2. Kassai MM, DM Obzansky **HC Vaidya** et.al. Performance characteristics of magnetic particle technology on the DuPont's Vista® Immunoassay system. *J Clin. Immunoassays*, 13, 52, 1990.
3. **Vaidya HC** WJ Allard et.al. Colorimetric and Immunoenzymetric assays for the measurement of TSH, hCG, CKMB on the aca Plus® Immunoassay System. Oakridge conference. April 1992.
4. **Vaidya HC**, JE Loyd et.al. Colorimetric immunoassay for CKMB on the DuPont's aca Plus® immunoassay system, *Clin Chem*. 38, 1100, 1992.
5. **Vaidya HC**, F Apple et.al. Preparation of preliminary standards for the CKMB mass immunoassays. *Clin Chem*. 39, 1256, 1993.
6. Green D, A Wu, **HC Vaidya** et.al. Use of proposed CKMB standardization material for calibration of mass measurements. Clinical correlation of patient sera. *Clin Chem*. 39, 1269, 1993.
7. Pierson-Perry JF, **HC Vaidya** et.al. Analytical performance of a method for ferritin on the DuPont aca® plus immunoassay system. *Clin Chem*. 40, 1020, 1994.
8. Ballas B, **HC Vaidya** et.al. Analytical performance of a method for prostate specific antigen on the DuPont aca® plus immunoassay system. *Clin Chem*. 40, 1026, 1994.
9. Green S., **HC Vaidya** et.al. Standardization of CKMB mass assays. *Clin Chem*. 40, 1032, 1994.
10. **Vaidya HC**, JF Pierson-Perry et.al. Evaluation of ferritin method for the aca Plus® immunoassay system. *Clin Chem*. 41, 580, 1995.