Hemant C. Vaidya, Ph.D.

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DIRECTOR, Biotechnology Industry Immersion

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

From 2013 to 2021, I taught an Entrepreneurship course at the UC Davis Graduate School of Management (MBA), equipping students with the skills to launch successful ventures and manage innovation. The curriculum emphasized critical analysis of new business opportunities prior to investment decisions. Since 2021, I have served as Director of the Biotechnology Industry Immersion program, preparing students to lead and manage in the dynamic biotechnology sector. Beyond teaching, I participate in the Sacramento Angel Investment Group and serve on the new investment selection committee. I have been mentoring several entrepreneurs. One of them (EnlitenAI) recently won second prize at the Elk Grove Economic Council pitch competition. I also serve as an Advisor for Melio, a biotechnology startup, and Ground Truth Genomics and a UC Davis startup.

PRINCIPAL CONSULTANT

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

Experienced strategy and product development executive with 24 years at Siemens and its parent companies in the In-Vitro Diagnostics Industry. I am skilled in developing diagnostic products in chemistry, immunochemistry, and microbiology. Played a key role in building the diagnostics business in India from the ground up. It has a proven track record of transforming concepts into commercial products. As a member of the Microbiology business leadership team, I helped grow the business from $140MM to $220MM over 10 years. Passionate about measuring, monitoring, and implementing continuous process improvements to boost organizational efficiency.

- **Leadership/Supervision:** 20+ years of increasing responsibility managing up to 100 people, from clinical scientists to product development directors. As VP of R&D for MicroScan, I managed all aspects of product development, supported strategy development, and created a 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 led to increased self-confidence, organizational alignment, and increased efficiency and communication.
- **Continuous improvement:** Adopted the "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.
- **Teamwork/Collaboration**: Built good relationships 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 as a Research Associate at Washington University School of Medicine, St. Louis, MO
	2013 Faculty appointment at UC Davis, MBA school, to teach "Business Development (Entrepreneurship) 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, Marketing, and Technical Support organizations.
- Track record of delivering revenue-generating products.
- Four patents and three trade secrets; the most successful patent, the 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 the "Emerging Market Strategy" team.

PROFESSIONAL EXPERIENCE (continued)

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

Consultant, In-Vitro Diagnostics Strategy and Product Development Current

- Expertise in IVD product development with 24 years of industry experience.
- Post-doctoral training in Clinical Chemistry from Washington University led to an understanding of the 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.
- I have been mentoring several entrepreneurs. One of them (EnlitenAI) recently won second prize at the Elk Grove Economic Council pitch competition.
- I serve as an Advisor for Melio, a biotechnology startup.

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 the 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 a product development process to increase productivity, such as PACE, Siemens PDP (Product Development Process), and CCPD.

DADE CHEMISTRY / IMMUNOCHEMISTRY SYSTEMS 1996 - 1997

Director, Clinical and Scientific Affairs,

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

- The group collaborated with marketing and customers to define design input requirements for general chemistry and immunochemistry tests 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 (creatine kinase MB, troponin I, and Myoglobin) strategy for Dade Behring analyzers. Established a cross-functional, customer focused requirement gathering process.
- Was part of the team that conducted Chemistry/Immunochemistry market research on opportunities in China and India, especially the 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)

Assumed both technical and administrative leadership for clinical studies and the development of product specifications, overseeing a team of 10 professionals specializing in Clinical Chemistry.

The team conducted clinical trials in hospital laboratories, working closely with customers and the Marketing division to establish design input requirements for general chemistry and immunochemistry assays being developed for the aca, aca® plus, Stratus CS, and Dimension analyzers. Additionally, I provided technical support to the Western Zone Marketing group for six months.

I also led a market research initiative in India focused on DuPont's Chemistry and Immunochemistry products, visiting 20-25 laboratories and approximately 10 prospective distributors. This strategic effort contributed significantly to what has now become a significant source of revenue for Siemens, following its acquisition of DuPont's product lines.

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

- Responsible for developing design input requirements for immunoassays measuring hemoglobin A1c.
- Created design-input requirements and conducted clinical trials for a Prostate Specific Antigen immunoassay, which required a PMA submission to the FDA.
- Chaired the American Association for Clinical Chemistry (AACC) CK-MB Standardization Subcommittee. The subcommittee, composed of leading Clinical Chemists, developed a recombinant CK-MB reference material, now commercially available through AACC.

Senior Development Biochemist (1990 – 1993)

- Collaborated with scientists and engineers from concept development to final product release to develop the aca® plus immunoassay system.
- • Developed a basic biochromatic technology that enabled immunoassay performance in the presence of suspended chromium dioxide particles. This technology has since been patented and is also being used on Dimension® analyzers. Additionally, 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 the development of fundamental technology.
- • Identified and helped resolve critical system integration issues to improve the analytical sensitivity of the system.
- • Identified antimicrobial agents compatible with all immunoassays on Vista®, ensuring the signal-to-noise ratio is unaffected and compatibility with a wide range of immunoassay reagents.
- • Conducted extensive studies to identify and eliminate human anti-mouse antibody interference in all two-site immunoassays. This approach is now 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 of extensive training in laboratory medicine, including human pathophysiology. Rotated through the Clinical Chemistry laboratories of Barnes-Jewish and the Children's Hospital.
- Discovered the 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 has brought millions of dollars in royalties 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

SARDAR PATEL UNIVERSITY, Vallabh Vidyanagar, India 1978 – 1982
Adjunct Faculty, Instructor, Department of Biosciences

- Taught courses in Medical Microbiology and Immunology to undergraduate students.
- Obtained Ph.D. in Microbiology.
- Maintained and managed the centralized instrument laboratory.

GUJARAT COLLEGE, Ahmedabad, India 1976 – 1978
Demonstrator in Microbiology

- 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 State University, Sacramento, CA (Prof Seung Bach).
- Mentor students at the Indian Institute of Management, Ahmedabad, and MBA students at the 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 States 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 an 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 the presence of a suspended solid support". Serial no. 5,454,051, 7/18/95.
- The United States patent: "Assays with signal detection in the presence of suspended solid support. Serial no. 5,654,159, 8/5/1997.
- The United States patent application for the development of Random-Access Microbiology System, Serial no. 6,573,088 B2, 6/3/2003
- High-throughput 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 an 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 is 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-Dolejsek 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.