



Robert L. Stoy

Curriculum Vitae

PROFESSIONAL EXPERIENCE:

Senior Advisor

CA, 2006 - 2008

Enterprise Analysis Corp.

Provide product development expertise and consulting services to clients, including several of the largest medical diagnostic companies. Worked with senior and middle management to improve strategic business choices, acquisition strategies and implementation of third-party development agreements.

Vice President, Quality Systems and Regulatory Affairs

Brea, CA, 2002 - 2003

Beckman Coulter

Member of executive staff responsible for worldwide leadership of all Quality System and Regulatory Affairs operations, both pre-market and post-market. Successfully launched multiple 510(k) and PMA registrations under aggressively lean resource conditions. Created successful organizations to manage the European IVD Direction initiative for the corporation. Merged the regulatory functions of multiple, large, acquisitions. Successfully overcame several post-market product complaints that had potential major impact on the business. Retired from this position in 2003.

Vice President, Laboratory Systems Architecture

Brea, CA, 2000 - 2002

Beckman Coulter

Responsible for connecting all diagnostic systems into workcell environments using automation and information technology solutions. Combined internal development skills and resources with those of external partners (Japanese) to speed time to market. Delivered the LXi725 system to market in 2002, the industry's first fully integrated and automated system for chemistry and immunochemistry.

Vice President - Director, Clinical Systems Development and System Engineering

Brea, CA, 1997 -2000

Beckman Coulter

Provide leadership to chemistry, engineering, software, system engineering and project management groups in the Clinical Systems Development Center. Delivered to market the IMMAGE protein analysis instrument system and the Synchron LX-20 chemistry instrument system, along with data management systems and sample automation systems. Member of acquisition team that integrated the Beckman and Coulter operations during 1998.

**Vice President, Product Development
Medical Laboratory Automation**

Pleasantville, NY, 1996 – 1997

Responsible for development of coagulation systems in a partnership alliance with Ortho Diagnostics. Restructured development group to be responsive to alliance needs; realigned work on new system utilizing closed tube sampling to complete development work more quickly; organized project management and system engineering groups.

**Vice President, Product Development and Information
Technology**

San Jose, CA, 1991 - 1996

Becton Dickinson Immunocytometry Systems

Substantially modified the development organization for focus on time-to-market and the creation of quality flow cytometry products, with restructuring for leaner operation. Reduced time-to-market by 30% for some products and significantly improved software quality measured by post-market complaint system. Brought to market three successful systems for the research customer, the clinical research market, and the AIDS clinical market.

**Director, New Product Development
Beckman Instruments**

Brea, CA, 1985 - 1991

Responsible for development of clinical and immunochemistry instrumentation in the Diagnostic Systems Group (annual sales \$400 million). Responsible for meeting all regulatory requirements in the worldwide medical device industry. Products developed for use in hospitals and laboratories of all sizes.

Led project engineers and project leaders who matrix managed the R&D projects. Directed activities of additional 150 staff dedicated to a single project, the Synchron CX5. Successfully brought product from concept to manufacturing during 1985-1988; achieved largest market share of all worldwide competitors. Led successful division-wide effort to implement programs to reduce development cycle by 30% and decrease after-sales cost by 50%. Created systems and processes for rapid prototyping, and full electronic design and documentation of electronic and mechanical systems.

**Director, Engineering
Baker Instruments**

Allentown, PA, 1981 - 1985

Successfully led project teams that developed hematology, clinical chemistry and flow cytometry products for small hospital and doctor's office markets.

**Manager, Engineering
Erika, Inc. (div. National Medical Care)**

Rockleigh, NJ, 1978 - 1981

Developed disposable products for hemodialysis, ran clinical trials at hospital labs, directed mechanical process design and developed injection mold process for coil and flat plate dialyzers used in national dialysis centers.

**Senior Scientist
Technicon Instruments**

Tarrytown, NY, 1973 - 1978

Responsible for R&D project direction of new generation of hematology instrument; successfully brought instrument through feasibility development. All systems marketed to medium and large hospitals and clinical labs, both domestic and international.

**Associate Professor of Mechanical and Aerospace Engineering
University of Connecticut**

Storrs, CT, 1967 - 1973

**Consultant - Aerodynamics and Heat Transfer
Raymond Engineering**

Hartford, CT, 1972 - 1974

**Consultant/Assistant Project Engineer
Pratt and Whitney Aircraft**

Hartford, CT, 1968 - 1970

**Senior Engineer
United Aircraft Research Laboratories**

Hartford, CT, 1966 - 1967

EDUCATION:

1959 - 1963 B.S.: School of Aerospace Engineering, Georgia Institute of Technology

1963 - 1966 M.S. and Ph.D.: School of Aerospace Engineering, Georgia Institute of Technology
(NASA fellowship for 3 years)

DIRECTORSHIPS:

Member, Board of Directors Beckman Laser Institute, University of California Irvine,
1998 – 2003

Member, Biomedical Engineering Advisory Board, Georgia Institute of Technology, 2000-2003.

PROFESSIONAL SOCIETIES:

Member, Project Management Institute, 1999-2003

Chair, PDMA International Conference, Monterey, California, Oct 1997

Co-Chair, PDMA Frontier Dialog on Fuzzy Front End, May 1997

Member, NCCLS Subcommittee on Data Management, 1993

Member, International Society for Analytical Cytology, 1991-2002

Member, Clinical Cytometry Society, 1991-2002

Member, Clinical Ligand Assay Society, 1990-2001

Member, Product Development and Management Association, 1989-2002

Member, Society for Analytical Cytology, 1982-1985

Member, American Association for Clinical Chemistry, 1981-2002

Member, American Physical Society, 1967-1985

Chairman, Connecticut Section AIAA 1972-1973

Associate Fellow, American Institute of Aeronautics and Astronautics, 1966-1978

PUBLICATIONS AND PRESENTATIONS:

Related to product development:

Snyder, L., Levine, J., Stoy, R.L., and Conetta, A. 1976. "Automated Chemical Analysis: Update on Continuous Flow Approach," *Anal. Chem.*, 48, pp. 942A-956A.

Stoy, R.L., McDonald, D., and Naughton, J. 1990. "Introducing QFD into an Organization," presented at Second Symposium on Quality Function Deployment, Novi, Michigan, June 1990, *Transactions*, pp. 159-196.

Stoy, R.L. 1993. "Infrastructure Requirements for Effective Teams," presented at PDMA 17th Annual International Conference, San Diego, California, October 1993.

Stoy, R.L. 1994. "Implementing ISO 9000 in the Healthcare Industry: Challenges and Practical Strategies," presented at Medical Marketing Association Annual Meeting, Palm Springs, California, June 1994.

Stoy, R.L. 1994. "Promoting Multifunctional Teamwork," presented at The Executive Workshop on Improving the New Product Development Process, Houston, Texas, June 1994.

Stoy, R.L. 1995. "Changing From Functional to Project Oriented Teams," presented at New Product Strategies: Lessons on Developing the Right New Products in the Right Way, Seattle, Washington, June 1995.

Stoy, R.L. 1995. "Product Development: Where's the Process?," invited lecture presented at School of Marketing, University of San Francisco, San Francisco, California, October 1995.

Stoy, R.L. 1995. "The Management of Product Development," invited lecture presented at the Management of Technology Seminar Series, Georgia Institute of Technology, Atlanta, Georgia, October 1995.

Stoy, R.L. 1995. "Role of Senior Management in Concurrent Product Development," presented at the Society of Concurrent Engineering Fall Conference, Tufts University, Cambridge, Massachusetts, October 1995.

Stoy, R.L. and Roberts, W., "Competitive Analysis in Technology Organizations," presented at the Defining New Products and Services for On-Target, On-Time Results conference, Management Roundtable, Orlando, Florida, April 1996.

Stoy, R.L., "Mastering Critical Elements of the Product Development Process," presented at the Executive Development Program for Accelerating Corporate Growth with Innovative New Products, University of Houston, Houston, Texas, April 1996.

Stoy, R.L. 1996. "Assembled Product Development," chapter 19 of *The PDMA Handbook of New Product Development*, John Wiley & Sons, New York, pp. 271-285.

Related to gas dynamics research:

Huang, A.B., and Stoy, R.L. 1966. "Rarefied Gas Channel Flows for Three Molecular Models," *Phys. of Fluids*, 9, pp. 2327-2336.

Stoy, R.L. 1970. "Rarefied Gas Channel Flow Using the BKG Model," *ZAMP*, 21, pp. 17-26.

Stoy, R.L. 1970. "The Method of Weighted Residuals Applied to Free Shear Layers," *AIAA Journal*, 9, pp. 1527-1528.

Stoy, R.L., and Ostrowski, P.P. 1973. "Analysis of Gas Bubble-Liquid Coflow Systems," *Journal of Hydronautics*, 7, pp. 46-48.

Stoy, R.L. 1973. "High Speed Cinephotography of the Microcirculation," presented at ASME Symposium on Biomechanics at Applied Mechanics and Fluids Engineering Conference, Atlanta, Georgia, June 1973.

Stoy, R.L., Stenhouse, M.H., and Hsia, A.H. 1973. "Vortex Containment of a Submerged Jet Discharge," *American Society of Civil Engineers, J. Hydraulics*, 99, No. HY9, pp. 1585-1597.

Stoy, R.L., and Ben-Haim, Y. 1973. "Turbulent Jets in a Confined Crossflow," presented at ASME Applied Mechanics and Fluids Engineering Conference, Atlanta, Georgia, June 1973.

Stoy, R.L., and Ben-Haim, Y. 1973. "Turbulent Jets in a Confined Crossflow," *J. Fluids Engineering*, 95, No. 4, pp. 551-556.

Dabora, E.K., and Stoy, R.L. 1973. "Variable Energy Blast Waves," presented at Conference on the Mechanism of Explosion and Blast Waves, Naval Weapons Station, Yorktown, Virginia, Nov. 1973.

Stenhouse, M.H., and Stoy, R.L. 1974. "The Calibration and Use of a Conical Hot Film Anemometer in Recirculating Water Flow," *Rev. Sci. Instruments*, 45, No. 3, pp. 368-370.