

MICHAEL MARCHLIK

Vice President Quality Assurance and Regulatory Affairs
McKesson Technology Solutions
5995 Windward Parkway
Alpharetta, GA 30005
(404) 338-3966

Over thirty years quality and risk management experience across a broad range of regulated industries. Fourteen years quality management experience in the medical device industry. Knowledgeable in ISO, FDA, CMDR, and PAL requirements related to medical devices and IVDs. Strong software quality assurance and requirements analysis experience. Certified TQM facilitator and Six Sigma Black Belt. Worked with multiple government agencies on risk based standards development including:

- US EPA (High Level Nuclear Waste Program)
- US Coast Guard (Oil Spill Contingency Modeling)
- California Energy Commission (Municipal Solid Waste Air Toxics Regulation)
- New York State Energy Development Authority (Low Level Nuclear Waste Siting)
- New York City DEP (Process Safety / Risk Analysis)
- US Department of Energy (Tokamak Fusion Reactor Risk Analysis / Savannah River Site Risk based project portfolio management / METC Low Permeability Gas Sands Resource Estimates / High Level Nuclear Waste Program)
- US Army (Rocky Mountain Arsenal Risk Based Cleanup Standards)
- EPA Superfund (Risk Based Cleanup Standards)

Experience

2011 – Present McKesson Technology Solutions

Alpharetta, GA

Vice President, Quality Systems and Regulatory Affairs

Accountable for conformance of McKesson's Health IT portfolio to applicable medical device regulations world wide and establishing effective and efficient quality systems. Working with senior business and quality leaders, established a quality vision and strategy for the organization. Facilitated the development of a quality and regulatory project portfolio, identifying high impact opportunities to leverage activities across the organization.

Represented McKesson as an active collaborator on the Bipartisan Policy Center health project, An Oversight Framework for Assuring Patient Safety in Health Information Technology. Currently working with other industry collaborators to establish a patient safety reporting pilot and a quality systems working group.

1999 – 2011 Becton Dickinson
Worldwide Quality Director, Preanalytical Systems
Quality Systems Director, Corporate Quality

Franklin Lakes, NJ

Senior Quality and Regulatory Affairs executive for \$1.7 billion device business that manufactured over 7 billion devices per year. Accountable for compliance to worldwide medical device standards including all pre-market and post-market activities. Member of executive leadership team with oversight of the design center and five large manufacturing sites in the US, Europe and Puerto Rico. Responsible for an organization of over 100 quality and regulatory professionals.

- Managed a Quality Benchmarking study with McKinsey and Company to benchmark BD's quality performance and efficiency at BD plants compared to peer companies. Worked with the operating committee and VP, Strategic Planning to develop, pilot and implement a BD company scorecard including the definition of quality process objective and metrics.
- Established enterprise membership with ASQ and represented BD at the ASQ Executive Roundtable and on the ISO / ANSI Quality Management standards committees.
- Conducted Six Sigma project with Department of Defense and Distributors/GPOs for GS1 product data synchronization pilot to address FDA Unique Device Identifier initiative.
- Member of corporate task force to meet Japan's PAL and Canada's Medical Device Regulation requirements including ISO registration of Corporate offices. Member of team tasked with harmonizing field action policies and procedure.
- Led multiple corporate software implementation initiatives that met FDA Part 11 and software validation requirements.

1997– 1999 Duke Engineering & Services, Inc.
Project Manager

Charlotte, NC

Managed business practice for quality and risk management services involving high risk processing facilities.

- Staffed and managed a high visibility compliance project for the New York City DEP for a fast track review and improvement of critical business processes for EPA mandated risk management programs for disinfection operations. Successfully submitted regulatory documents on schedule to the EPA that demonstrated adequate risk management controls of liquid chlorine facilities throughout New York City.
- Conducted risk management program review and plan preparation for a chemical manufacturer. Reviewed operating procedures, maintenance practices and process documentation. Identified potential hazards and conducted computer simulation models for accidental releases of highly hazardous materials.
- Prepared quality plan for environmental sampling efforts for nuclear power plant decommissioning projects.

1995–1997 S. Cohen & Associates
Project Manager

Reston, VA

- Developed ES&H audit software application for Digital Equipment Corporation.
- Conducted technical review of computer simulation models for EPA high-level nuclear waste licensing program.
- Led cross-functional project team as team facilitator to develop innovative business process re-engineering effort for portfolio management of real estate assets at Pennsylvania Power & Light. Assisted PSE&G with developing an improved process to prioritize and manage contaminated real estate

holdings using risk based criteria and developed software applications to support efforts.

1994 – 1995 TRC Environmental, Inc. Lyndhurst, NJ

Manager, Safety and Environmental Management

- Developed methodology and software to manage a portfolio of hazardous waste site remediation efforts at major utility client. Result saved client significant costs through improved project management and improved relations with regulatory agencies.
- Supported industry efforts to influence evolving EPA risk management regulations through participation in industry groups and provided testimony during regulatory hearings.
- Conducted air permitting audits across multiple industries.

1990 – 1994 Ebasco Services, Inc. New York, NY

Manager, Safety Management

- Assisted client in evaluation of information technologies to manage engineering changes.
- Assisted clients in assessing risk from accidental releases of hazardous materials at industrial and government facilities. Responsible for preparation of detailed risk analysis study used to obtain Department of Energy approval for use of tritium in the Tokamak Fusion Test Reactor.
- Successfully established new process safety management practice to assist clients in meeting emerging OSHA and EPA regulations. Organized and facilitated a Process Safety Management workshop for the gas processing industry attended by representatives of thirty gas companies. Worked directly with OSHA inspectors to identify key compliance issues and inspection criteria for the industry workgroup.

1989 – 1990 Arthur D. Little, Inc. Cambridge, MA

Senior Consultant

Conducted risk management studies to analyze financial business interruption risk and fixed facility and transportation accidents.

- Conducted business interruption risk analysis for critical IT operations of a major telecommunication company. Managed study that quantified hazards from power failure, HVAC interruption, and loss of utilities, weather related disasters and hazardous material spills. Quantified financial risk and presented clients with analysis of risk reduction measures. Conducted business interruption risk analysis for critical operations of a Fortune 50 consumer products manufacturer. Developed risk ranking of wide spectrum of business interruption risks.
- Worked with state regulators on siting of low level waste facilities. Supported development of US Coast Guard oil spill regulations and US DOT rail safety regulations.
- Worked with industry clients to optimize the selection of air emission control technologies.

1984 – 1989 Ebasco Services, Inc. New York, NY

Project Manager

- Procured and led management consulting assignment at Savannah River Site when site was shutdown for safety and regulatory issues. Directed business process re-engineering effort to substantially improve portfolio management and project controls for a \$6 billion capital project backlog utilizing risk based project prioritization methods. Interacted directly with Department of Energy headquarters staff to review and obtain approval of risk based methods.

- Developed commercial software application to conduct probabilistic cost-benefit assessments of proposed engineering changes. Developed stochastic risk based cleanup models for hazardous waste sites to optimize cleanup levels and minimize costs at the Rocky Mountain Arsenal site. Worked with state and federal regulatory agencies to accept and endorse this approach. Assisted California Energy Commission in development of risk based emission standards for municipal solid waste incinerators. Conducted safety and reliability studies of nuclear plant systems.

1982 – 1984 Lewin & Associates, Inc.

Washington, DC

Senior Research Associate

- Created innovative computer simulation model for estimating supply of natural gas from low permeability gas sands. Leveraged efforts of National Petroleum Council study to create a model for exploring effects of financial, technical and regulatory changes on national gas supply.

EDUCATION

1977 – 1981 Washington University St. Louis, MO
B.A., Biology

- National Merit Scholar

1981 – 1983 Washington University St. Louis, MO
M.S., Engineering

Graduate Research Associate

PROFESSIONAL AFFILIATIONS

- Member, Association for the Advancement of Medical Instrumentation (AAMI)
- Member, American Society for Quality – Past member of Executive Roundtable and contributor to ASQ Future of Quality Study
- Member, American Health Information Management Association (AHIMA)
- Member, EHRA Patient Safety and Public Policy Work Groups
- Member, Medical Imaging Technology Association (MITA) Technical and Regulatory Affairs Committee
- Member, Corporate Executive Board Quality Leadership Council
- Voting Member, U.S. TAG to ISO/TC215 Health Informatics
- Past Voting Member, U.S. TAG to ISO/TC 176 on Quality Management
- Past Voting Member, ASC Z1 Subcommittee on Quality Management
- Past Voting Member, U.S. TAG to ISO/TC 262 Risk Management
- Past Member, American Institute of Chemical Engineers – contributor to Center for Chemical Process Safety Hazard and Risk Analysis Guidelines
- Past Member, Society of Petroleum Engineers
- Past Member, Society for Risk Analysis

SELECTED PUBLICATIONS AND PRESENTATIONS

Marchlik, M., “Deploying a Global CAPA Solution”, Advamed Webinar, March 19, 2009

Marchlik, M., Chumas, J., Kopecky, M., “CAPA in a Global Medical Device Organization”, Trackwise 7th Annual User Conference, San Diego, CA., (October, 2008)

- Marchlik, M., "Understand and Implement EPA's Final Risk Management Rule", Chemical Engineering Progress, pp 64-73, Vol. 92/NO. 8, August, 1996
- Marchlik, M., "A Practical Approach to Risk Management Programs", Paper #110b, presented at AIChE Spring National Meeting, New Orleans, La., (February 25-29, 1996)
- Marchlik, M., "Risk Management Planning, Hazard Assessment and Accident Prevention under 112(r)", presented at Government Institutes Clean Air Compliance Institute, Annapolis, MD., (November 28 - December 1, 1995)
- Marchlik, M., "Implementing a Cost-Effective Risk Management Program", Workshop conducted at American Institute of Plant Engineers Annual Meeting, Portland, OR., (October 14-18, 1995)
- Marchlik, M., "ISO 14000, Trends in Global Environmental Management", presented at Mid-Atlantic States Section, Air & Waste Management Association, 41st Anniversary Conference, Atlantic City, NJ (September 21, 1995)
- Marchlik, M., "Update on 112(r) Rulemaking Effort", presented at CIC/NJ Spring Regulatory Conference, New Brunswick, NJ, (June 28, 1995)
- Villaume, J., Marchlik, M., "Development of a Five Year Remediation Plan", Paper # 95-WP95.01 presented at 88th Annual Air & Waste Management Association Meeting, San Antonio, Texas, (June, 1995)
- Marchlik, M., Sahni, N., "Managing the Avalanche of Process Safety Action Items", Paper # 95-TA147.03 presented at 88th Annual Air & Waste Management Association Meeting, San Antonio, Texas, (June, 1995)
- Marchlik, M., Polito, R., "Implementing a Cost-Effective Risk Management Program", Journal of American Institute of Plant Engineers.
- Marchlik, M., Polito, R., Stabile, P., "Implementing a Cost-Effective Risk Management Program", presented at 1994 Chemical Industries Week Conference, Philadelphia, PA., October 18-20, 1994
- Marchlik, M., Costello, J., "Using a System Engineering Approach to Design for the Environment", Paper # 94-RA121.03 presented at 87th Annual Air & Waste Management Association Meeting, Cincinnati, OH, June, 1994
- Marchlik, M., Takacs, J., Marnicio, R., "An Automated Approach for Risk Integration", presented at 1992 Process Plant Safety Symposium, Houston, TX, February, 1992
- Marchlik, M., Paradies, M., "Development of an Integrated Safety Management Program for a DOE Facility", presented at the Probabilistic Safety Assessment and Management Conference, Beverly Hills, CA, February, 1991
- Marchlik, M., "Analysis of Uncertainties in Health Risk Estimates for Municipal Waste Combustors", Health Effects of Municipal Waste Incineration, Hattener-Frey, H. A., Travis, C., Eds, CRC Press Boca Raton, 1991, 201.
- Marchlik, M., "Risk Assessment as a Policy Tool", presentation to Forum on Environmental Issues, Boston, MA, 1990
- Tyler, R., Odoemelam, O., Shulec, P., Marchlik, M., "Uncertainty Analysis: An Essential Component of Risk Assessment and Risk Management", presented at the EPA/ORNL Workshop on Risk Assessment for Municipal Waste Combustion: Deposition, Uncertainty and Research Needs, June, 1989
- Marchlik, M., Anderson, S., "Municipal Solid Waste Management - Evaluating the Options", Risk Analysis Prospects and Opportunities, C. Zervos, Ed, Plenum Press New York, 1988, 687.
- Anderson, S., Marchlik, M., "Development of an Air Toxics Health Risk Model", presented at Sixth International Conference on Mathematical Modeling, St. Louis, Mo. (August, 1987)
- Marchlik, M., Schaffer, S.A., and Pavlou, S., "Assessing the Impact of Uncertainties on Developing Acceptable Concentration Limits of Hazardous Materials in Soil and Sediments", presented at the Sixth Annual Meeting of the Society of Environmental Toxicology and Chemistry, St. Louis, Mo. (November, 1985)
- Rish, W.R., Schaffer, S.A., Marchlik, M. and Amdurer, M., "A Risk Analysis Approach to 'How Clean Is Clean?'" presented at the National Conference and Exhibition on Hazardous Wastes and Environmental Emergencies, Cincinnati, Oh (May, 1985)
- Rosenberg, J.I., Morra, F. and Marchlik, M., "Future Gas Contributions from Tight Sand Reservoirs", presented at the 1984 International Gas Research Conference, Washington, DC. (October, 1984)
- Brashear, J.P., Morra, F., Marchlik, M., Rosenberg, J.I. and Mercer, J., "Tight Gas Resource and Technology Appraisal: Sensitivity Analyses of the National Petroleum Council Estimates", SPE/DOE/GRI Paper #12862, presented at the Unconventional Gas Recovery Symposium, Pittsburgh, Pa. (May, 1984).

Darby, W. P., Shultz, E. B., Marchlik, M., "Regulation of Air Oxidation Processes within the Synthetic Organic Chemical Manufacturing Industry: Background Information and Analysis", Center for Technology Development Report CDT 81/1, Washington University, 1981