Q9 Consulting, Inc.

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Summary of Leadership Qualifications

Applies experience in information systems management, project management and quality management to guide clients to the best strategic solutions for their business. Delivers training to clients using clients' projects as a case study to deliver value to an existing project.

- Managed development and implementation of Amgen's corporate quality risk management procedures and standards (member of Quality Engineering Leadership Team)
- Managed global Information Systems projects to standardize IS governance and processes (Amgen)
- Improved drug commercialization process by building cross-functional risk management model
- Saved $3MM using a strategic risk and decision analysis approach to solve complex problems
- Saved $1MM implementing a business continuity/disaster recovery solution
- Developed private and public sector client base across North America and Europe
- Succeeded at implementing $3.5MM worldwide data quality project where predecessors failed
- Reduced costs by $2MM and production time from two days to two hours for loan processing

Core Competencies

- Innovative ideas
- Risk and Quality Management
- Project/Program Management
- Strategic Thinking
- Matrix Management
- Leading & Developing People
- Process Reengineering
- Team Building
- Decision analysis

Professional Experience

Adjunct Instructor University of Redlands   **Redlands, CA**
 Instruct the Project Management Certificate program   **2014 – present**

Adjunct Instructor University of California at San Diego   **San Diego, CA**
Project management for international students   **2012 – 2013**

Adjunct Instructor Bellevue University   **Bellevue, NE**
On-line Graduate classes information systems project management   **2012 – 2013**

Principal Quality Engineer   **Temecula, CA**
Abbott Vascular   **2008 – 2012**

- Developed and implemented cross-site (USA and Europe) risk management process
- Wrote and delivered cross-site product quality risk management training in USA and Europe
- Worked with product teams to develop risk assessments and implement risk management processes
- Wrote and delivered one-day hands-on project risk management course to managers and above
- Saved $50,000 on software licenses including free continued maintenance and a $25,000 software license negotiated for $5,000
- Recommended project management training vendor

President / Sr. Consultant
Q9 Consulting Inc.   **Temecula, CA   2007 - present**

- Management consulting and training focused on risk based quality implementation of products, processes, and projects in biotechnology, pharmaceutical and medical device companies
- State and Federal Court qualified forensic document examiner
- Instructor in computer information systems project management graduate school Bellevue University
- Instruct project management to international business students at University of California at San Diego

Sr. Project Manager/Principal Quality Engineer/   Thousand Oaks, CA   2002 - 2007
Senior Manager Amgen Inc.
- Member of Quality Engineering leadership Team
- Improved time-to-market by managing implementation of common Quality Risk Management processes across the company
- Managed development of a risk management model for commercializing new biotechnology products and delivery devices based on ICH Q8, ICH Q9, ISO 14971, 21 CFR 820, 21CFR 210, 21 CFR 211
- Used risk modeling software (@Risk) to develop cost models, budget projections and project schedules
- Managed global team of seventeen managers/senior managers to develop and implement common IS governance corporate wide
- Managed cross-functional, multinational team to procure and implement $3.5MM data quality software
- Created process for capturing and ranking qualitative and quantitative metrics
- Represented my business unit as manager for capacity/workforce management project
- Negotiated an $800,000 software purchase for a $3.5 million dollar project with 18 month ROI

Senior Partner/VP
Project Management Consulting and Training, Inc   Moorpark, CA   1995 - 2002

Clients included:

- Farmers Insurance Group
- Countrywide Financial
- Home Savings of America

- Metropolitan Water District
- Project Management Institute
- Los Angeles World Airports

- PriceWaterhouseCoopers
- Amgen Inc.
- SONY Pictures

- Saved more than $3MM and reduced loan processing time from two days to two hours
- Developed IT risk management plan for 911 upgrade and police dispatch system at Los Angeles Airport
- Improved time and results for client by reviewing audit processes and train auditors on best practices
- Saved customer $1MM by implementing disaster recovery and business continuity planning
- Developed process improvement methodologies and workflow reengineering
- Developed and presented more than 150 two- to four-day project management, risk management, software management, and quality management seminars

President/Co-founder
Procyon Computer Systems, Inc   Westlake Village, CA   1984 - 1995
- Founded company
- Software design and development for interactive, shared graphics software products
- Developed customer base in North America and Europe
- Managed quality initiative for software development
- Software was nominated by DR Labs for best business graphics software for VAX computers
- Participated with U.S. Department of Commerce in Matchmakers program in Italy

Education and Certifications —————————————————————————

M.S. **Technology Management**	University of Denver
B.S. M**athematics, Minor: psychology**	State College of New York at Buffalo
Graduate certificate in Forensic Document Examination	East Tennessee State University
Graduate level Applied Mathematics and Computer Science	San Jose State University
Introduction to CMMI	Carnegie Mellon University
Six Sigma Green Belt Training, ITIL, Catalyst Facilitation, Management training	Amgen Inc

Professional Certifications (all are active)
- Project Management Professional (PMP, 1997)
- Certified Quality Engineer (CQE, 2006)
- Certified Information Systems Auditor (CISA, 1999)
- California Real Estate Broker license (1992)

Professional Organizations ───────────────────────────

American Society for Quality, Senior Member
- Former Programs Chair, FD&C Division discussion group for Southern California
- Former Membership Chair, Temecula Valley Section

Information Systems Audit and Control Association

Project Management Institute
- President, California Central Coast Chapter 2003 & 2004
- Contributing author Risk Management ANSI Standard ANSI/PMI 99-001-2000 (PMBoK Guide)
- Project manager for 2002 multinational risk management conference in Long Beach, CA
- Board of Directors, Los Angeles Chapter (1997-1999)

National Speakers Association

Toastmasters International – Advanced Communicator Silver

ASTM International

National Association of Document Examiners – Chair of the 2012 conference

Forensic Expert Witness Association – Vice President San Diego Chapter

Scientific Association of Forensic Examiners – Vice President

Forensic Consultants Association

Publications Authored and/or Presented (A representative sample)

Wakshull, M. N. (2013, July). The Role od Clearly Communicated Requirements in Project Success. Project Management Institute, California Inland Empire Chapter, Temecula, CA.

Wakshull, M. N. (2012, November). The Use of Control Charts to Assist With Writer Identification. American Society for Quality Quality Day Symposium. Pomona, CA.

Wakshull, M. N. (2012, October). The Effects of Motivational and Cognitive Bias in Forensic Science. Association of Forensic Document Examiners Conference. Phoenix, AZ.

Wakshull, M.N. (2012, April). A statistical approach to defining variability in handwriting. National Association of Document Examiners Conference. San Diego, CA.

Wakshull, M. N. (2011, November). An overview of the World Congress of Forensics. Forensic Consultants Association, San Diego, CA.

Wakshull, M. N. (2011, October). The effects of bias on managers' decisions. American Society for Quality. Temecula, CA.

Wakshull, M. N. (2011, October). The use of statistical process control to assist writer identification. World Congress of Forensics. Chongqing, China.

Wakshull, M. N. (2011, March). Introduction to forensic document examination. California Association of Handwriting Analysts. Buena Park, CA.

Wakshull, M. N. (2010, May). Cognitive bias and the document examiner: Or - what you don't know about your attitudes can hurt your client. National Association of Document Examiners Annual Conference. Portland, OR.

Wakshull, M. N. (2010, January). Do your biases affect your expert opinion? Forensic Expert Witness Association. San Diego, CA.

Wakshull, M. N. (2009, September). Risk management in production and post-production. Project Management Institute Risk SIG Conference. Santa Clara, CA.

Wakshull, M. N. (2009, April). Determining authorship of handwritten documents through examination of microscopic features in writing. National Association of Document Examiners. Boca Raton, FL.

Wakshull, M. N. (2008, March). Managing risk using ICH Q9 and ISO 14971:2007. American Society For Quality Tri-division Conference. Alexandria, VA..

Wakshull, M. N. (2006, May). How cognitive biases affect risk and decision analysis in managers. Proceedings of PMI Risk Management SIG Conference. Houston, TX.

Wakshull, M. N. (2005, April). Applying predictability and stability to identify the most effective project metrics. Proceedings of PMI Pharmaceutical SIG Conference. Dallas, TX.

Wakshull, M. N. (2004, September). Review of *Managing Risk In Organizations*, by J. Davidson Frame. Project Management Journal.

Wakshull, M. N. (2002, October). "The use of even swaps to normalize quantitative and qualitative risk rankings." Proceedings of PMI International 2002 Symposium. San Antonio, TX.

Wakshull, M. N. (2002, March). "Project risk management: a partnership between auditors and project managers." Proceedings of Information Systems Audit and Control Association Conference. Los Angeles, CA.

Wakshull, M. N. (2002, March). "Review of book *Risk and Decision Analysis In Projects*." Project Management Journal. (32)1.