

# MARYDAWN M. MEEDER

MBA • PMP • Professional Engineer (PE) • BS and MS Mechanical Engineer • MS Software Engineer

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## IT Expert for Healthcare and Quality Management Systems

ISO 13485 & FDA Compliance • Lab Information Systems • Life Sciences • Genomics • Pharma  
Six Sigma / TQM • Change Mgm't • Restructuring & Turnarounds • Team Building • M&A Integration  
Led teams up to 300 with \$15M OPEX • PM for Systems Exceeding 25 Million Daily Transactions

*Employers and clients say everything runs better when I am on the job. I bring order out of chaos, organize companies, and set up systems that accelerate achievement of worthy goals. Known for a positive attitude, organized mind, and clear speaking style. Among all the engineers you'll ever meet, I am one of the few who can speak in complete sentences. I answer tough questions in simple language that all understand, and look forward to applying my talents for your company:*

- **Interim Executive:** On short notice – for industries as diverse as genomic medicine and heavy industry – I've stepped into emergency assignments as acting CIO, CFO, QA Manager, or Project Manager.
- **Quality Management:** Starting from scratch – especially for healthcare and medical-device companies – I set up FDA-compliant systems that automate logistics, lab reports, and QA documentation.
- **Project Management & Finance:** If necessary, I can analyze project financials at a deeper level than most PMPs, for example: budgets, forecasts, cash flow, breakeven analysis for capital-intensive projects.

## PROFESSIONAL EXPERIENCE

### CYBERSONICS, Erie, PA

April 2015–Present (Contract)

Manufacturer of ultrasonic devices for diverse sectors – from industrial cleaning to surgery – privately held, 35 employees.

#### Manager of Operational and Quality Processes

*Automated quality management for Cybersonics: selected, customized, and implemented an FDA-compliant, off-the-shelf system that stopped emerging problems with regulators and reduced expensive overtime. Redesigned processes, trained employees, and led two FDA audits that resulted in "no findings" – perfect scores – for the first time company history.*

- **Background:** Cybersonics introduced a product that flooded the company with new business. The existing quality-management system – antiquated, manual system based on Excel – could not scale up to handle the load, so FDA audits created problems that threatened future viability of the company.
- **Actions and Results:** Interviewed management and staff. Gathered requirements and obtained agreement on business parameters. Surveyed the market, identified over 100 potential candidates, and narrowed the field to 2 optimal vendors. Presented options to executive team and implemented system.
  - ✓ Led two highly successful audits. Improved processes so well that the system will pay for itself.
  - ✓ Now implementing additional improvements (identified during requirements-gathering phase).

### DIRECT ALLERGY, Erie, PA

May 2014–Sep 2014 (Contract)

Startup med-services firm • Provides physicians with customized immunotherapy treatments for on-site allergy and asthma testing.

#### Director of Corporate Operations & Acting Chief Financial Officer (CFO)

*Set up "big company" systems for a fledgling startup that struggled to meet its sales forecast. Took charge as Interim CFO – leveraged MBA in finance – and ran finance as well as operations.*

### CMI ENERGY, Erie, PA and Seraing, Belgium

May 2012–July 2013

Mechanical engineering group – HQ Belgium – produces machinery for steel plants, industrial heat recovery equipment, and boilers.

#### Senior Project Manager for Large Capital Projects

*Led massive projects in Russia and Bangladesh. Relocated to CMI's HQ in Belgium for 4 months.*

- **Challenge:** Emergency repair for boiler baffles – part of a Heat Recovery Steam Generator (HRSG) – located 90 miles north of Moscow. A specially qualified team of welders was needed, but hiring qualified personnel – either US or local – was problematic due to legal and tax regulations. Repair window was exactly 4 days, during planned maintenance for the main plant.

- **Solution:** Contacted former mechanical-engineering colleagues at various companies – especially in GE supply chain – and assembled a team of qualified engineers and welders from Ireland.
  - ✓ Flew the team into Moscow, transported them to the Power Plant site, and relayed repair instructions from CMI's engineering team in Erie, PA.
  - ✓ Hired a translator: Site supervisor spoke only Russian and final inspection was done in Russian. Transported construction materials to the job site – exactly when needed for repairs.
  - ✓ Completed the job on time and within budget.

**FOUNDATION MEDICINE, Cambridge MA****Feb 2011-May 2012***Startup firm, privately held • Provides patients with genomic profiles that predict probability – and best remedy – of certain cancers.***Vice President, Information Technology**

**Hired to run a selection process and lead implementation of a Lab Information Management System (LIMS). Hired by FM based on experience with similar systems at Quest and Neogenomics. As a startup, FM urgently needed LIMS to scale up in order to accommodate explosive growth.**

- **CHALLENGE:** Existing LIM systems were designed to track samples through chemical-testing process. FM approach is based on mathematical algorithms and software analysis of person's genetic code.
  - ✓ Foundation Medicine had to creatively adapt an existing "off the shelf" system to track samples. FM was just starting – scaling up from zero thousands of customers.
- **ACTIONS AND RESULTS:** Set up a vendor-selection process that resulted in a contract with Thermo Fisher. Configured the system for FM's state-of-art algorithmic approach to lab testing – a unique application of the Thermo Fisher's LIMS. Delivered a fully operational system – from original concept through user acceptance testing – and achieved full regulatory compliance with CAP, CLIA, and 21 CFR.

**NEOGENOMICS (NASDAQ NEO), Ft. Myers, FL****Jul 2010-Aug 2011***Operates a 6-site network of highly complex, CLIA-certified clinical labs that specialize in diagnostic testing via cancer genetics.***Director of Information Technology**

**Stepped out of my traditional IT role. Applied MBA and Six Sigma Green belt skills. Led a process improvement team that significantly cut turnaround time for Cytology and Cancer Diagnostics.**

**LIMS PROJECT:** purchased, customized, and implemented new LIMS in record time. Managed all aspects of IT including infrastructure, telecom, custom software dev, vendor management, and project management. Cut processing-and-delivery time for cancer tests from 24 days to 4 days.

**EXIQON (NASDAQ: EXQ), San Juan Capistrano, CA****Sept 2009–July 2010***Hospital Services – global supplier of products to biotech and pharma for microRNA R&D (genetics-based cancer research).***IT Director for Regional HQ**

**Managed all aspects of IT – data and call centers, infrastructure, call center, LIMS & software dev.**

**MAJOR PROJECT – BUSINESS ANALYSIS:** Worked closely with ops to analyze costs of testing, which identified the specific costs of California labor, equipment, and materials for the Lab's primary test.

- ✓ Calculated true costs of Exiqon's primary cancer-diagnostics test, and discovered the costs exceeded the govt reimbursement. Presented results to executive management in Denmark, which led to closing of CA location. Shut down the site, including preservation & security of patient data.

**QUEST (NYSE: DGX), San Juan Capistrano, CA****Jan 2006–Sept 2009***World's leading provider of diagnostic services • \$7.1 billion revenue and 41,000 employees • HQ in Madison, NJ.***IT Director for Regional HQ – Hospital Services**

**Hired to lead the transformation to new technology. Recruited into quest based on personal reputation as a change agent with IT expertise and pharmaceutical background.**

- **SCOPE:** Reported to SVP Diagnostic Systems and Services: Managed 10 direct and 300 indirect reports and all IT: operational, financial, HR, tech strategy, software development life cycle, and infrastructure. Managed 3 budgets: \$15M operating / \$9.5M capital / \$2.3M projects.
- **BACKGROUND:** Quest's systems were so outdated that vendors stopped supporting. Completed the overhaul under budget, on schedule, and with no interruption to business operations.

- **ACTIONS & RESULTS:** Most significant goal achievement was change management, because the daily work of every lab employee was dramatically changed by introductions of new systems.
- ✓ **M&A Integration:** Devised and executed migration strategies for 4 large-scale, multi-location acquisitions. Met all cost-savings targets, including \$22M merger with largest clinical laboratory. Standardized 1,200-test code database across 33 regional labs.
- ✓ **Transformed and Reorganized the IT Department** as part of enterprise-wide restructuring. Cut an entire layer of management and identified areas for outsourcing. Negotiations with foreign & domestic government for call and data centers, which saved 40% over 2 years. Deployed software development platform that allowed code re-use, which cut development time and OPEX by 31%.
- ✓ **Cut Development Time More Than 50% (From 9 Months to 16 Weeks)** by introducing project management discipline, Six Sigma, and structured SDLC methodology (PEP3).
- ✓ **Ensured Regulatory Compliance** with ISO, Sarbanes-Oxley 21 CFR Part II, and CLIA. Fixed numerous audit findings, which led to satisfactory results for 6 major audits (no findings in 2007).

**SANOFI / GENZYME GENETICS, Santa Fe, NM****Jan 2002–Jan 2006**

Genzyme: biotech company based in Cambridge, MA • Acquired by Sanofi in 2011.

**Senior Director, Information Technology**

*Recruited by previous boss (Smith-Kline) to overhaul a stagnant IT department that failed to scale up and meet standards during high growth that was driven by breakthroughs in prenatal testing.*

- **SCOPE:** Reported to SVP/COO, controlled budgets (\$5.5M ops / \$7M capital) and directed IT for 5 labs in US & Japan: software development, help desk, call management, network & database admin, vendor relations, software license agreements, technology strategic planning, and genetics-testing operations.
- **TURNAROUND:** Transformed IT into a strategic business partner by upgrading 10-year-old technologies and retooling department for 100X growth. Led numerous, large-scale projects on time and on budget.
- **PROCESS IMPROVEMENT, EFFICIENCY, AND COST SAVINGS:** Saved \$12M y-o-y by reducing average call time 30%. Increased availability from 90% to 99.9% with 30% cost savings. Renegotiated contracts for data/telephony. Cut overhead \$250K by renegotiating contracts and reducing headcount.

**ADDITIONAL EXPERIENCE (MAY 1983–JAN 2002) | GE MANUFACTURING PROGRAM | HEALTHCARE IT**

**TACIT**, Palo Alto, CA (Jan 2001–Jan 2002): DIRECTOR OF CONSULTING SERVICES AND PROJECT DIRECTOR: Led deployment of “Knowledge Mail” software for clients in life sciences, pharmaceutical, and aerospace. Completed major projects for Northrop Grumman, Lockheed Martin, and Sanofi.

**EMAX SOLUTIONS / SCIQUEST**, Newtown Square, PA (Jan 1999–Dec 2001): Consultant and Program Director for application development and consulting firm: Managed \$2.5M project budget and led team of 5 direct & 15 indirect reports. Ran project mgmt & planning, process reengineering, and client development.

**SMITHKLINE BEECHAM**, Collegeville, PA (May 1991–Jan 1999): Advanced through four roles: Decision Support Manager, Manager of Operations, Manager Of Process Engineering, And Manager of Process Improvement. Automated processes, saved millions (\$USD), and supported international laboratory ops.

**GENERAL ELECTRIC**, Valley Forge, PA (May 1983–May 1991): Began career in GE’s ELITE MANUFACTURING MANAGEMENT PROGRAM. Completed intensive training in Management, Leadership, Project Management, and Proposal Development. Advanced through roles as Program Manager, & Supervisor of Industrial Engineering.

**EDUCATION, P.E. LICENSE, AND CERTIFICATIONS**

MS Software Engineering, PENN STATE UNIVERSITY, 1990

MBA, Finance, VILLANOVA UNIVERSITY, 1989

BS, Mechanical Engineering, CLARKSON UNIVERSITY, 1983

Professional Engineer, Licensed New York State, 1983

Agile, Project Management Certification, Software Development Life Cycle, 2012

Program Manager Professional (PMP), PMI Certified, Quest Diagnostics, 2006