

Lisa K. Simone

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R&D Technical Manager / Individual Contributor

Product development leader with experience in medical, consumer, telecommunications, single-patient-use, and automation fields. Organized international teams from marketing, R&D engineering, operations and procurement to beat deadlines developing products from concept through product launch. Led fire-fighting teams solving time-critical customer software and hardware issues. Developed proprietary medical testing algorithms and IRB clinical and FDA testing protocols for research and high profit margin products. Led value engineering to reduce cost on 6 medical products, coordinating RA, QA, operations and process improvement initiatives. Publications, patents and international presentations.

PhD Biomedical Engineering, **BS** Electrical Engineering, Rutgers University
MBA technical (MOT) The Wharton School and University of Pennsylvania Engineering, Executive Masters in Management of Technology (EMTM)

Author, technology mystery book: [If I Only Changed the Software, Why is the Phone on Fire?](#) exploring effective analytical and problem-solving methods in CSI-like mystery format.
LinkedIn Profile: www.linkedin.com/in/lisasimone

PROFESSIONAL EXPERIENCE

Imaging Sciences International, a Danaher Subsidiary 2009-present

PROJECT MANAGER

Value analysis value engineering (VAVE), LCM and product delivery for 2D and 3D real-time dental imaging systems using Kaizen-based lean manufacturing and continuous process improvement.

- Single point of contact for over 90 engineering change requests for 2 Danaher medical device subsidiaries. Replaced reactive project selection process with a method based on engineering assessment and cross-functional prioritization that balances budget, quality, risk and resources.
- Identified issues preventing release of 4 product lines to China; coordinating multi-site engineering, manufacturing, QA/RA, vendors and offshore resources to improve delivery time 3 months.
- Managed emergency release of 2D image quality correction feature to address customer field complaints. Risk minimized with concise but robust test plan verifying image processing accuracy.

Simone Concepts LLC, Bridgewater, NJ 1995-2008

R&D PRODUCT DEVELOPMENT CONSULTANT

Consulting for start-up and specialty projects; on the side.

- Go-to person for startup industrial/robotics manufacturer (Spadix Corporation). Designed initial strategy/marketing campaign. Developed product architecture, HW/SW interface for motion control products. Increased US market share from 0% to 16% for insulated glass windows produced; increased machine product offerings by 150% with average net profit margin 30%. Patent awarded.
- Conceived, designed, co-manufactured virtual reality simulator to assess driving ability after brain injury. 200% reduction in driver retraining costs (over current on-the-road methods) being validated in clinical trials. Simulator improves safety for both relicensed and currently licensed drivers.

New Jersey Institute of Technology (NJIT), Newark, NJ

2006-2008

DIRECTOR OF ENGINEERING DESIGN, RESEARCH PROFESSOR

Continuing R&D collaboration with Kessler Medical (below); revamped senior design program.

- Organized and led teams to create wearable medical diagnostic tests which assess physical function after brain injury. More effective and lower-cost treatment is supported by initial clinical testing. Developed/executed all phases from technology assessment through device testing; technical strategy, planning and finances. Awarded over \$800K in NIH and corporate funding.
- Redesigned senior biomedical engineering design program to integrate *real-life* product development and business standards to engineering curriculum. Strong customer focus to develop effective requirements through design and testing. Based on M-GATE, FDA, process improvement.
- Project manager for over 50 projects, e.g., signal processing, visualization, dental x-ray, biomechanics, biomaterials and scaffoldings, medical diagnostics.

Kessler Medical Rehabilitation Research and Education Corporation, West Orange, NJ

2003-2006

SENIOR RESEARCH SCIENTIST, PRINCIPAL INVESTIGATOR

- Led portfolio analysis of funding strategies and resource allocations of new rehabilitation engineering department. Consolidated lines by 25% resulting in \$1M first funding within one year. Two previously rejected grant proposals totaling \$700K dollars awarded.
- Managed multi-site teams of clinicians, researchers, engineers and patients developing/deploying medical device research protocols to assess daily functional needs of individuals with disabilities.
- Established and maintained compliance and quality documentation for federal (NIH) and state funded human subjects clinical trials. Trained teams on IRB and FDA guidelines.

Motorola, Lucent/Philips Joint Venture, South Plainfield, NJ

1996-2003

DISTINGUISHED MEMBER OF TECHNICAL STAFF

International technical manager for conventional and fire-fighting teams for mobile phones. Extensive embedded design and systems engineering. Resource planning, architecture, development and field testing. Bridged cross-functional product teams, organized technical, industry/academic, and professional development forums.

- Organized and led 5 international teams in a world-wide congress to deliver architecture for first 3G cell phone in 90% of allotted time; cross-functional team formed by tearing down geographic silos.
- Led 5 teams to attack highest-severity technical and integration problems from customer interface through manufacturing acceptance. Reduced time to identify field-failures by 85% with custom root-cause analysis tools. Saved \$1M in DSP and FPGA prototyping costs.

International Technidyne Corporation (a division of Thoratec), Piscataway, NJ

1994-1996

SENIOR BIOMEDICAL R&D ENGINEER

Managed and led system design for cardio intervention point-of-care and electronic QC products; led development in 4-person multidisciplinary team (electrical/mechanical, software, biochemistry).

- Defined/led experiments to identify critical product failure; created proprietary blood clot detection algorithm. Negotiated with FDA reviewers; 510(k) submission. Annual sales of Hemochron Jr at thousands of devices with millions of disposables; profit margin 70%.
- Co-managed aPTT clinical trials with marketing director, developed blinded and encrypted Hemochron Jr for randomized studies enrolling over 5000 patients internationally.

ISO 9000, Design for Manufacturing, Six Sigma Green Belt certifications. Lean manufacturing, UL, FDA, IRB clinical testing, SEI/CMM, product development continuous process improvement. Volunteer for activities to increase student interest in science and technology careers from K-12 through graduate school (competition judge, mentor, panelist, invited speaker).