DON PETERS

2440 Willamette Street; Suite 101 E
Eugene, OR 97405
(408) 348-3540
dpets@comcast.net

SUMMARY

An industrious and technically skilled engineering leader, with extensive experience in product development for the medical device industry, including all phases of the product development life cycle, from conceptualization and definition through realization, service, and retirement. Consistently leverages science and engineering skills along with robust leadership competencies to develop and mentor diverse, cross-functional teams in meeting their goals.

Key Strengths Include:

- Class I, II, & III Medical Devices - Definition, Realization & Post-Market
- Program Management - Phase-Gated Product Development
- Development Processes: Agile, Vee, Waterfall & hybrids
- QMS: Design Control/Risk Management – Training, Mentoring, Deployment, Improvement and Remediation
- Regulatory Submissions: 510(k), PMA, IDE, CE, and IVD
- Quality Management – 21 CFR 820 & ISO 13485
- Risk Management – ISO 14971 (including ISO 80001 & TIR 57)
- Software Development – IEC 62304

EXPERIENCE

dPeters Consulting - LLC, Eugene, OR
President, April 2016 - Current

Providing R&D leadership and product development continuity through cohesive interfaces with Regulatory, Quality and site leadership specifically for software embedded platforms.

Multiple global clients including regions in USA; Japan and EU

- Services provided include:
  - Interface between R&D teams and multi-site leadership to distill complex technical information into action-oriented deliverables.
  - Provide: software documentation for FDA submissions; R&D process improvements in PDLC/SDLC methods and tools utilization (eg Jira; Team Center; TFS; DOORS; etc); develop training and pilot programs to meet current trends in industry standards and FDA guidance including cybersecurity threat analysis, risk management; pre/post market lifecycle improvements.
  - DHF/RMF implementation, improvement and remediation
  - In depth training/mentoring in processes that are efficient and compliant to industry standards. This includes customized SOP's, Work-Instructions, Templates and Forms that are appropriate for a client's current state and yet, extensible for future maturity.
  - Audit support (internal, FDA, MDSAP)
- Example of client results include:
  - Six IVD 510(k) device clearances and subsequent product launches including a CLIA Waived device and cybersecurity documentation
  - Complete Design Control & Risk Management overhaul and deployment.
  - Better understanding internal procedures/workflows that satisfy regulatory requirements. This in turn has led to successful product deliveries and improved compliance demonstration during audits.

ABBOTT MEDICAL OPTICS, Milpitas, California
Director, Research and Development, 2010-2016

Provided multi-site leadership, driving development of products for ophthalmic diagnostic instrumentation and laser refractive surgical equipment.

- Leadership across two sites (California and New Mexico) and five functional domains, including Software, Hardware, Electrical, System Integration, and Verification and Validation (V&V). Total staff size included 41 engineers plus 32 contract engineers with various disciplines.
- Effective management of project and functional budgets upwards of $10,000,000 and $2,500,000, respectively.
- Successfully released various on-market product updates and launched New Product Introductions (NPIs). This included the development, execution, submission, and launch of the iDesign® corneal diagnostic system for refractive surgeons. This product incorporated wavefront and refraction aberrometry, keratometry, topography, and pupilometry. Key Launch Dates: EU – September 2012 and U.S. – June 2015.
- Garnered broad cross-functional collaboration in definition and development of a "next-generation" refractive laser for LASIK surgery.
- Functional R&D representation for domestic and foreign regulatory site visits, including ISO and FDA planned and unplanned QSR audits.
- Face-to-Face FDA Pre-Market Approval (PMA) updates, submissions, and other meetings during the filing process.
- Co-led cybersecurity corporate initiative in standardizing risk management and strategy for compliance with CDRH/CBER guidelines.
- Led division-wide refresh of PDLC/SDLC including design control process. Received Abbott's 2015 Corporate - President's Award for "leadership and courage" in recognition for successful implementation.

BD BIOSCIENCES, San Jose, California
Senior Manager, Systems Engineering Research and Development, Immunocytometry, 2006-2009

Built new department subsequest to significant business reorganization for the purposes of improving NPI quality and timeliness. Products included flow cytometer equipment, reagents and software used for cellular analysis or sorting for Research Use Only (RUO) institutions and Clinical In-Vitro Diagnostics (IVD).

- Quickly recruited and tripled department size to meet growing product demands. Staff included 12 multidisciplinary scientists and engineers.
- Effectively prioritized and directed resources under a tightly-matrixed organization though a very broad, phase-gated product portfolio with numerous product deliveries. Products ranged from very complex cell sorters, with up to five laser sources, including up to 15 color detectors, to less complex Point of Care (POC) single assay systems, using imaging technology.
- Delivered seven USA & Outside-USA product launches on time and within budget. These products included: LSR Fortessa® (2009); FACS SPA III® (2009) and FACS ARIA III® (2010).
- Effectively facilitated and moderated the cascading process of translating the Voice of the Customer, to Product Requirements, continuing to Design Specifications. This includes the effective utilization of a variety of Six Sigma tools and processes.
- Led the definition, implementation and usage of DOORS for product requirements and traceability.
- Developed "mentored internship" program in collaboration with California State University (CSU) System and Professional Science Masters (PSM) Programs, with focus on STEM education. Inducted two PSM students; shaped model for future internships and leadership development.

ABBOTT DIAGNOSTICS DIVISION, Santa Clara, California

Led research and development activities through various roles and positions. Significant contributions made toward several global product launches of world renowned hematology analyzers, based on flow cytometry principles. These included the Cell Dyn® product line: CD1800®, CD3000®, CD3500®, CD4000®, CD4000®(CD61 – Platelet Count), CD4000®(CD3/4/8 T-Lymphocyte Subset Counts), Cell Dyn Sapphire, and Cell Dyn Ruby.

Senior Manager Systems Engineering, 2002-2006
- Leadership for multidisciplinary staff. Developed and successfully launched two next-generation hematology systems, Cell Dyn Sapphire & Ruby.
- R&D interface to US/EU customers, marketing, sales, field service, including oversight of research studies and University co-development efforts.

Software Manager – Algorithm Development, 1997-2002
- Led a software team in developing neural networks, fuzzy logic, and other algorithm methods for cellular classification and morphology.
- Program Manager (ProChain® Critical Chain management) providing leadership for U.S. and OUS CD4000® software launches including automated CD3/4/8 T-Lymphocyte and CD61 Platelet enumeration which earned commercial recognition as marketplace leaders in innovation.

Lead Software Engineer, 1994-1997
- Led the development and implementation of novel algorithms for cellular classification of human peripheral blood cell types and morphology. These were applied to a new Argon laser hematology flow-cytometer, the CD4000®. The successful global launch of that product promoted Abbott reputation from number-ten to number-three market leader in clinical hematology. Developed under both UNIX and Windows: C/C++/Java.
- Received Abbott's prestigious Volwiler - Outstanding Research Team Award plus Abbott's Diagnostics Division Entrepreneurial Award.

Manager, System Integration, 1989-1994
- Led subsystem integration team, final test verification and launch support for the CD3000® and CD3500® HeNe laser hematology cytometers.

SMITHKLINE BECKMAN, San Jose, California, 1981-1988
Manager, Product Support, 1987-1988
- Leadership for customer technical support and sales force training. Provided assessments on new products and potential acquisition/licensing.

Principal Research Scientist, 1981-1986. Invented novel approach for attaching monoclonal antibodies to solid support (ie printed reagent technology).

E D U C A T I O N

SAN JOSE STATE UNIVERSITY, San Jose, California
B.S., Chemistry, Emphasis on Computer Science and Mathematics, 1980

P A T E N T S , P U B L I C A T I O N S , L E C T U R E S

Mass-Producible, Biologically-Active Solid Phase Devices: Patent #5013669.

Cell Viability, a Clinical Useful Parameter to Monitor Therapy Response in Hematology. Blood 88(10):3376, November 15, 1996.

Hypoxia and Erythroid Response Monitored by Automated NRBC Counts. Blood 88(10):2785, November 15, 1996.

Invited Panelist: National Conference of State Legislatures (NCSL): July 2008.
"Higher Education's Role in Meeting Emerging STEM Workforce Needs."

Invited Panelist: Bio-International: May 2009.
"Developing Highly Effective Partnerships with University Workforce Development Programs."