PAUL HOLLENDORFER

5045 Cliff Point Circle East
Colorado Springs, CO 80919

phollendorfer@outlook.com
719-684-6180
www.paulhollendorfer.com
www.linkedin.com/in/paulhollendorfer

ENGINEERING AND OPERATIONS LEADER

Accomplished engineering leader whose strong analytical skills, problem-solving mindset, and business acumen have delivered measurable growth and profitability in the medical device industry. Excels in high-profile roles, making high-stakes decisions, and overcoming complex business challenges. Technical background includes the development and manufacture of medical devices including lasers and fiber optic catheters, mechanical and electro-mechanical products, precision control devices, software controls and related systems. Fluent with documentation requirements in FDA, ISO, and GMP environments. Valued as a primary contributor in medical device and site-change audits by regulating bodies. Forged strong, successful business relationships as a result of teamwork, open-mindedness, and collaboration. Applauded for the vision to launch and sustain new initiatives while simultaneously prevailing in attention to detail and critical analysis.

AREAS OF EXPERTISE

- Leadership
- Strategic Planning & Execution
- Team Performance Optimization
- Regulatory Auditing
- Cost Optimization & Control
- Process Analysis & Reengineering
- Validation (IQ/OQ/PQ/ PPQ)
- Change Management
- Manufacturing Transfer
- Supply Chain Management
- Sales and Operations Planning
- Technical Writing & Communication
- CAPA
- Data Collection & Analysis
- Organizational Design & Development
- Project Management (Agile)

PROFESSIONAL EXPERIENCE

THE SPECTRANETICS CORPORATION, Colorado Springs, CO **1990-2017**
www.spectranetics.com
Spectranetics designs and manufactures a medical laser and fiber optic catheters for use in a variety of procedures in the vasculature. The company also develops and manufactures a range of mechanical tools for use in the cardiac and lead management spaces.

Senior Director: Manufacturing Engineering and Supply Chain, 2012-2017
Reported to the vice president of operations. Led and developed a team of 60 engineers, specialists, and technicians across two departments. Primary responsibilities included production engineering support and supply chain management for the company's entire product portfolio including disposable devices and capital equipment. Cultivated a customer-first culture for internal and external stakeholders. Managed budgets in the $15M range. Created strategic plans and departmental priorities and integrated corporate goals and objectives into department activities. Participated in cross-departmental technical solution teams.

Director: **Manufacturing Engineering,** 2009-2012
Reported to the vice president of operations. Led a team of 30 engineers and technicians with budget oversight of $4M. Provided engineering support for the company's product portfolio, including disposable devices and capital equipment. Led product development activities for the company's capital equipment line. Other duties included communication of goals and status to the company's Leadership Team, transfer of new products into the manufacturing environment, and project management.

Director: Laser Manufacturing, 2008-2009
Reported to the vice president of operations. Led a team of 20 engineers, technicians, assemblers, and support personnel with budget oversight of $2M. Responsible for the company's capital product line, the CVX-300 Excimer Laser System, including production, engineering, and support. Duties included manufacturing planning and prioritization, ownership of production line output, and project management.

Manager: Laser Manufacturing Engineering, 2006-2008
Responsible for engineering support of the CVX-300 Excimer Laser System, including supervision of engineering and other technical personnel. Led change control processes to introduce product changes and enhancements into manufacturing.

Manager: Manufacturing Engineering, 2004-2006
Led a team of ten engineers, technicians, and support personnel. Responsible over engineering support for the company's disposable and capital product lines. Managed introduction of product changes and enhancements into manufacturing.

Systems Engineer, 1998-2004
Responsible for sustaining the CVX-300 laser system product. Acted as the primary engineering subject matter expert on design, manufacture and compliance testing. Managed all continuous improvement projects, including End of Life (EOL) issues.

Laser Engineer, 1994-1998
Responsible for development and sustaining engineering support for the CVX-300 Excimer Laser System.

Mechanical Design Engineer, 1990-1994
Mechanical designer for the CVX-300 Excimer Laser System, responsible for system and component design for various aspects of the product.

ENGINEERING AND OPERATIONS CAREER HIGHLIGHTS

- Key contributor in increasing the company's gross margins from 72% to 76% in 18 months through process flow and application of theory of constraints philosophies.
- Led the rapid reshaping and expansion of team capabilities in two departments to support the company's double-digit growth.
- Deployed a $1M plastic tubing extrusion system into production. This new system significantly advanced the consistency of plastic tubing products and cut material costs by $600k/year.
- Expanded the company's fiber optic draw capacity to 1.5x previous rates with no corresponding increase in labor or overhead.
- Successfully moved the company's capital and disposable product lines to a new facility without interruption to service or revenue. Final site-change audits by FDA and BSI had zero observations.
- Developed the company's strategic plans and project outlines for re-envisioning the CVX-300 Excimer Laser System. Project was multiyear and incorporated new technology introduction, mechanical design, software and hardware design, validation, and compliance.
- Developed and implemented a variety of process equipment for the company's disposable product lines saving $400k/year.
- Reengineered the company's capital equipment line to deliver 3rd Edition IEC 60601 compliance, as well as numerous reliability and manufacturing enhancements. A successful FDA PMAS was delivered.
- Developed the layout, validation, and move strategies for a relocation of the company's capital product lines to a new facility with no production down-time.
- Forged ongoing relationships with regulatory bodies for ongoing factory inspections related to the maintenance of safety labeling (NRTL).
- Ramped up production capacity from 30 lasers per year to 150+.
- Redesigned and implemented a new pulse forming network for the CVX-300 laser system resulting in a complete halt of failures in the assembly.
- Converted the company's CAD software to SolidWorks including benefits analysis, training, and translations into the new format.
- Responsible for successful modifications and subsequent FDA approval to PMA released software for the CVX-300 to support the continued development of disposable devices and their use on the system.
- Numerous updates and partial re-writes of CVX-300 system software which include the implementation of new customer features as well as reliability enhancements.
- Primary contributor on the design for a next generation laser vessel with substantially improved firing rate and manufacturability.
- Developed and maintained numerous supplier relationships to allow consistent and economical manufacture in a low volume production environment.
- Developed and executed various testing regimens for numerous laser sub-systems, including a harsh-environment longitudinal fan system, energy measurement circuitry, and optical couplers.
- Drove the adoption of 3D CAD systems to better understand design tolerance and manufacturability.

EDUCATION

Metropolitan State College of Denver, School of Engineering, 1987-1990: **Bachelor of Science, Mechanical Engineering Technology**

University of Colorado at Boulder, School of Engineering, 1984-1987: Aerospace Engineering

---

PATENTS

INTELLIGENT CATHETER US 10,092,363 and US 9,757,200

Issued October 9, 2018 and September 12, 2017

"A system includes a microprocessor executable verification module in a base unit and a microprocessor readable identifier of an endovascular device in a memory of the endovascular device. The microprocessor executable verification module, based on the identifier, at least one of configures the endovascular device for use and determines whether the endovascular device can be enabled for use."

JOINT DEVICE US 5,547,464

Issued August 20, 1996

"An apparatus for use in bracing or exercising a knee joint in a manner that allows bending of the joint only along a predetermined path which approximates the natural bending of the joint. On at least one side of the joint are upper and lower struts that run along and are attached to the upper and lower leg and are attached to one another near the joint by a connecting mechanism which includes a set of linkage arms and telescoping elements that allow the struts to pivot relative to one another along the prescribed pivot line. The amount of joint flexing or extension is adjustable by use of spacers placed in the telescoping portions or by the activation of a releasable lock. The apparatus may be used as a brace or, alternatively, may be used with or without a cycling mechanism to flex and extend the joint."

TRAINING

Sales and Operations Planning Bootcamp, CEB

Design Controls for Medical Devices, AAMI

Validation Design, AAMI

Optics for Scientists and Engineers, Engineering Technology Institut