

STEVEN L. HENDERSON, CPM
Product Design / Project Management

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Accountable Leadership. Value-Based Optimization through Design Effectivity

Semi-retired project engineering professional with creative, resourceful and organizational skill sets in Research & Development, Product Development and Product Life Cycle management for the medical and consumer markets. Experiences range from successful startup businesses to contributing to Fortune 100 companies which have prepared me for most challenges at any production and sales volumes. Reputation as a passionate driven leader for product realization and project completion while promoting quality system compliance and business value as priorities.

Core Competencies:

Leadership	Design	Manufacturing & Operations	Quality
<ul style="list-style-type: none"> - Project Management - Team Player, lead by example - Cross Functional Leadership - Problem Solving - Action Plan Development / Milestone Definition - Professional Mentoring 	<ul style="list-style-type: none"> - DFM&A - GD&T (ASME Y14.5M-1994) - Dimensional Stack-up Analysis - Prototype Creation - SolidWorks - Pro/Engineer - Adobe Illustrator 	<ul style="list-style-type: none"> - Equipment and Process Qualifications (IQ, OQ, PQ) - Manufacturing Flowcharts - Supplier Relations (International and Domestic) - Configuration Management - Manufacturing and Inspection equipment development and qualifications 	<ul style="list-style-type: none"> - Design Controls - Quality Plan Development - Design Verification & Validation Requirements - FMEA Risk Analysis/ Mitigation (Application, Design, and Process) - IEC 60601 Medical Device Safety Standards - Six Sigma Green Belt Trained

PROFESSIONAL EXPERIENCE

Enable Injections Inc., Cincinnati, Ohio

2017-2022

Associate Director, Research & Development

- Led Research and Development efforts to generate new technologies and product platforms to enhance company's product catalog and IP portfolio.
- Established and executed Feasibility agreements with Pharmaceutical partners to evaluate unique configurations of Enable's devices to determine performance characteristics and compatibility with partners' drug products and/or mimic solutions.
- Directed and managed priorities for team of R&D staff members, including Engineers, Industrial Designers, Lab Technicians and consultants (internal and external) assuring department's activities are aligned with corporate objectives.
- Supported Business Development and Program Management departments' activities to promote concept models and designs to external customers to advance products towards commercialization.

AtriCure Inc, (Previously ENABLE Medical) West Chester, Ohio

2005 - 2017

Sustaining Engineering Project Leader

- Responsible for leading engineering efforts for developing, analyzing, executing and supporting new product development and design changes. Responsibilities ranged from creating Quality Plans, CAD Design, Protocol and test plans, Inspection strategies, Design Verification/Validation and process development.
 - o Position Highlights
 - Released new product codes for extending company's product catalog to meet market needs.
 - Identified and qualified material or component replacements due to supply chain disruptions.
 - Provided technical assistance to customers and field associates' inquiries.
 - Conferred with Surgeons to review therapeutic impacts of design changes and risk mitigation.
 - Provided technical support for Regulatory Engineering to obtain submissions in new International markets.
 - Directed company Biomedical Engineering cooperative education program with University of Cincinnati.
 - Led the planning and implementation of FDA mandate for Unique Device Identification (UDI) for Class III and Class II Implant products.
 - Identified and implemented companywide initiatives such Quality System upgrades to accommodate business dynamics due to substantial business growth.

- Identified opportunities to improve manufacturing capacity and cost savings of existing products, such as product redesign from arduous assembly to insert-molded device, saving many hours of labor and scrap and to promote improved product performance repeatability.

Contract Consulting, Cincinnati, Ohio

2003 - 2005

Engineering Design Consultant

- Developed creative solutions for automotive industry component logistic trays (transport, storage, and process) and generated injection molding bases and cores utilizing SolidWorks.
- Collaborated with Proctor and Gamble researchers, marketing and industrial design team for development of electronic consumer cleaning device by generating 3D computer models to produce SLA models for marketing review.
- Developed automated packaging production equipment for Proctor and Gamble feminine hygiene products division.
- Designed electronics packaging for a high power digital television transmitter for Harris Corporation in Mason Ohio.

E-PRIME LLC, Blue Ash, Ohio

2001 - 2003

Principal Designer

- Developed new tendon repair device by creating 3-D database models that were used by mold makers to create components. Using SolidWorks and generating neutral 3D files, rapid prototype parts were developed to prove form, fit, function, and manufacturing feasibility.
- Worked as a collaborative group to develop innovative medical products from the conceptual and FMEA (Failure Mode & Effect Analysis) stages to product development design, testing, and packaging.
- Provided design solutions to Surgeons to develop their Intellectual Property for new devices to be used for inventive surgical techniques by taking their base concepts from a feasibility stage to market-launch preparedness. New product concepts have included endoscopic and orthopedic devices.

ENABLE MEDICAL CORPORATION, West Chester, Ohio

1996 - 1999

Designer

- Contributed to the development of RF energize surgical scissor product line, allowing surgeons to cauterize blood vessels while cutting tissue to promote bloodless surgical procedures with an emphasis on saphenous vein harvesting during heart bypass surgery.
- Provided design and engineering support, patent research, lab product testing, prototype development, 3-D iges files for rapid prototyping parts, mechanical components testing, and materials research.

BELCAN ENGINEERING SERVICES, Cincinnati, Ohio

1993 - 1996

Designer (D2) (Assigned to BGP Services)

- Led design development of encapsulation conveyor for Procter and Gamble International diaper lines.
- Performed supplier inspections and provided construction field support for fabrication and installation of web splicing delivery equipment.

Designer (Assigned to Liebel Flarsheim)

- Completed Assembly drawings of Hydradjust Urology X-Ray Table to meet FDA requirements for market release.
- Designed accessories for aforementioned surgical table.

ETHICON ENDO-SURGERY, Blue Ash, Ohio

1991 – 1993

Product Development Designer

- Designed and detailed market dominating Endoscopic hernia repair instrument.
- Implemented, directed, and instructed 3D CAD training courses for manufacturing employees providing company savings worth several hundred thousand dollars in outsourcing design and drafting resources.
- Developed proficiency in creating 3-D wire frame, NURB surfaces, and Solid models of plastic and stamped metal components.

CAMPBELL HAUSFELD, Harrison, Ohio

1988 - 1991

Layout Draftsman

- Created layouts, stack-ups, and details of consumer air compressors.
- Studied and completed Boothroyd-Dewhurst Design for Assembly (DFA/DFM) training seminars.
- Completed advanced applications of ANSI Y14.5M – 1982, Geometric Dimension and Tolerancing.

EDUCATION

Xavier University – Xavier Leadership Center, Cincinnati, Ohio

Project Management Certificate Program

University of Cincinnati - College of Applied Science, Cincinnati, Ohio

Continued education towards a Bachelor of Applied Science in Mechanical Engineering Technology.

Cincinnati Technical College, Cincinnati, Ohio

Associates of Applied Science- Mechanical Engineering Technology.