

Medical device CEO with track record of growing and selling companies

BIO

20+ years of experience in senior medical device management, assembling and driving multi-disciplinary teams in product development, manufacturing, quality assurance, regulatory approval through marketing, and direct and distributor sales successes.

Successfully contributed to multi-billion dollar, multi-million dollar and startup companies.

Managed, participated in and executed multiple Business Development agreements for sale, acquisition or license of IP and medical products, to and from start-up and established large companies.

20 years of hands-on design engineering experience with over 110 issued US medical device patents and over 100 more still pending. These 110 US patents led to 300 medical device patents worldwide.

Experienced Expert Consultant and Expert Witness.

Knowledgeable and fluent in many medical device specialties including:

- Cardiac and vascular surgery implants and devices.
- Interventional cardiology and radiology implants, optical imaging, tissue ablation and other devices.
- General, laparoscopic, robotic and minimally invasive surgical devices.
- Orthopedics including spinal fusion and carpel tunnel procedures and devices.
- Oncology including breast, liver, kidney and bowel treatment devices.

CONTACT

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PATENTS and AREAS OF EXPERTISE

Listed "Inventor" on over 110 US issued medical device patents, totalling over 300 patents worldwide:

- General surgery instruments
- Laparoscopy instruments
- Hand surgery treatment devices
- Spine surgery implants and devices
- Cardiac surgery treatment devices and implants
- Vascular surgery implants and devices
- Interventional radiology treatment and implant devices
- Interventional cardiology implants and devices
- Oncology treatment devices
- Breast biopsy/lumpectomy devices
- Bowel surgery devices
- Kidney dialysis treatment devices

PASSIONS

- Growing, positioning and selling technology companies.
- Creating and building teams to develop and sell new technologies in the highly regulated medical device space.
- Turn-around activities for large and small divisions or companies using my deep knowledge and experience in all areas of my medical device development career.
- Family, Travel, Food and Film.

PERSONAL

US and UK Passport holder currently residing West Yarmouth, MA



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EXPERIENCE

Medical Device Consulting and Services through www.peterhinchliffe.com

MedLumics S.L.

CEO April 2024 to Aug 2025

Start up company developing Unique AF ablation catheter system.

- Driving product build and completion of FIM.
- Successful FIM with follow-on conference presentation and publication
- Setting development and regulatory strategy and plans
- Fund raising (Private and non-delutive public)
- Building staff and capabilities for DFM and V&V
- Driving toward FDA regulatory clinical trials for approval

Calon Cardio-Technology Ltd.

CEO Sept 2022 to June 2024

Startup company developing a Fully Implantable Left Ventricular Assist Device.

- Driving product development.
- Setting development and regulatory strategy and plans
- Fund raising (Private and non-delutive public)
- · Building staff and capabilities

Navigate Cardiac Structures Inc.

President and CEO Jan 2022 to August 2022

Startup company developing trans catheter heart valves.

- Re-started operations after COVID shutdown.
- Setting development and regulatory strategies and plans
- Fund raising
- Building staff and consultant teams
- Driving toward FDA regulatory clinical trials for approval

Radius Innovation (part of Jabil)

Senior Global Business Development Manager

March 2021 to Dec 2021

Contract research, development and manufacturing organization with over 100 facilities worldwide.

- Focused in Med Device and using my extensive contacts in my business network to develop relationships.
- Secured extensive Med Device relationships with Jabil for research through manufacturing opportunities



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EXPERIENCE (cont'd)

Jarvik Heart Inc.

President and COO Nov 2015 to Dec 2020

Jarvik Heart, founded and still chaired by Dr. Robert Jarvik, inventor of the first artificial heart, designs, manufactures and sells ventricular assist devices worldwide.

- Raised non-dilutive working capital toward continued growth. More than \$6M.
- Negotiated unique FDA strategy for FDA PMA trial cutting number of patients required in half.
- Won a \$1m international Grant with Leviticus-Cardio to develop a fully wireless implantable system.
- With Leviticus-Cardio successfully implanted first in human wireless Jarvik LVAD as bridge to transplant.
- Increased global distribution by adding key international regional distributors.
- Doubled potential manufacturing volume without increased headcount.
- Outsourced manufacturing bottleneck processes.
- Brought multiple triple digit offers to the board for acquisition.

Peterhinchliffe.com

Founder March 2015 to present

Consultancy created to:

- Mentor, develop and grow skilled and functional teams speeding development and approval of medical technology.
- Strategic Advisor and Board Member.
- Accepted "Medical Device Development Expert Witness" in United States court.

Maquet Cardiovascular (GETINGE)

President and CEO Cardiac Systems

Dec 2010 to March 2015

- (Cardiac Surgery and Cardiac Assist)

President and CEO Cardiac Surgery

Vice President, R&D Vascular Interventions

Maquet Cardiovascular is part of a multi-billion-dollar medical device group (GETINGE) with products for, among others, cardiac and vascular surgery as well as interventional cardiology and radiology.

- Awarded promotions multiple times in 5 years to increasingly critical and senior roles over 4 manufacturing facilities in the US.
- Cardiac Surgery, Vein Harvesting, Intra-Aortic Balloon Pump businesses Created 5-year strategic plans for each business unit including organic growth and acquisition targets.



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EXPERIENCE (cont'd)

- Analyzed, proposed and executed cost reduction plans including facility moves and staff reductions.
- Optimized two of the highest margin business units grossing over \$400M sales annually.
- Positioned and sold product line to streamline business unit offering (e.g., Safeguard femoral and radial artery closure device to Merit Medical).

Deep Vein Medical

Founder April 2009 – Nov 2015

Medical device start-up, spun out of ISI, LLC, to focus on a percutaneous venous valve for chronic venous insufficiency. (Funding for DVM from ISI below)

- Awarded multiple patents.
- Secured multi-million-dollar partnership offers from large strategic partners including W.L.Gore and Covidien.

Interventional and Surgical Innovations, LLC (ISI, LLC)

Founder Jan 2007 – Nov 2015

Venture funded medical device incubator (over \$5m raised from Trevi Health Ventures NYC) that accelerated development of multi-technologies in general and for cardiovascular surgery. Awarded multiple patents supporting the continued development of many concepts.

- Drove contract design and manufacturing toward US and European regulatory approval of unique Guidewire product (Parodi Guidewire) FDA 510k and CE Mark. (FIM in Argentina)
- Attracted interest and proposals from multiple large strategic partners including Abbott, Boston Scientific, etc.
- Spun out venous valve product due to significant development successes and market interest.

Datascope Corp. 2002-2006 (part of GETINGE)

Group President IPD & IV divisions;

Feb 2002 - Dec 2006

President IV division

Vice President, R&D & Operations (IPD) and Vice President, R&D (IV)

Group Vice President, R&D – IV & Interventional Products divisions (IPD)

Vice President, R&D for InterVascular Division (IV)

Datascope was a multi-million-dollar public medical device company providing products to cardiac and vascular surgeons, interventional cardiologists, radiologists.

• Awarded multiple promotions in 5 years to increasingly critical roles over 2 manufacturing facilities, one in the US and one in France.



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EXPERIENCE (cont'd)

- Created 5-year strategic plans for each business unit including organic growth and acquisition targets.
- Executed business development and organic development plans expanding product offerings.
- Analyzed, proposed and executed cost reduction and process improvement plans including staff reductions.
- Optimized two of the highest margin businesses grossing over \$200M sales annually.
- Part of senior management team supporting company sale.

Rex Medical (1999 – 2002)

Founder - Vice President, Research and Development March 1999 – Feb 2002 Medical Device "start-up" focused initially on interventional radiology and cardiology products.

- Started and built the initial infrastructure and development team.
- Awarded multiple patents for:
 - Interventional radiology products
 - Interventional cardiology products
 - General surgery products
 - Oncology products
- Secured \$10M+ sale for Thrombectomy device in first 14 months. (Boston Scientific)

United States Surgical Corporation (then Covidien, now Medtronic)

Director, Research and Development
Program Manager (minimally invasive Coronary Artery Bypass Graft program)
Program Manager (Trocar systems)
Senior Design Engineer (orthopedic products)
Design Engineer (laparoscopic products)

1992 - 1999