

DANIEL F. WALSH JR.

Medical Technology Industry Executive

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Successful Senior Leadership within the Medtech Sector as...

MEDTECH CONSULTING / VP R&D / COO / CTO / VP MFG/ VP QUALITY

- *Expert in Delivering Groundbreaking Medical Device Products to Market*
- *Passion for Driving the Commercial Launch of Life-Saving Medtech*

Accomplished medtech industry executive with a distinguished career amongst global/F500 and mid- to late-stage start-ups as a leader of product development and operations scale-up solutions. Focused on managing and mitigating risk to deliver results.

Respected leader of multidisciplinary teams, projects, programs, and initiatives focused on delivering breakthrough medical products, rapidly achieving scale, enhancing the quality, cost-effectiveness, and effectiveness of patient care. Backed by an executive-level understanding of budgetary constraints, healthcare reform, and the ever-changing regulatory landscape.

Expertise

- ✓ MedTech & Combination Prod Development
- ✓ Manufacturing Operations/Scale-up
- ✓ Regulatory Compliance & Remediation
- ✓ Cost-Reduction & QA Improvement
- ✓ PMA and 510(k) Submission Management
- ✓ Organic & Acquisitive Growth Strategies
- ✓ Time-to-Market Acceleration
- ✓ M&A Structuring/Due Diligence
- ✓ IP Assessment/Protection/Evergreening

Career Highlights

Healthcare Executive Leadership:

Fulfilled interim leadership roles for client companies to propel completion of strategic, high-priority initiatives:

- VP Operations at Therakos leading a combination product/drug outsourced manufacturing operation achieving 6 sigma performance while doubling capacity.
- Interim President for a dental restoration technology company, developing go-to-market strategy for their first product launch. Led 25-member operations staff and provided strategic planning support to CEO/founder.
- Interim VP of R&D (six-month assignment) for a women's health diagnostic technology company (\$175M in annual revenue). Managed final development, production scale-up, and commercial product launch for entire NPD and sustaining portfolio.
- VP of R&D for continuous Neurological Monitoring company. Led Operations, R&D, Quality teams (18 staff)

Product Development, Scale-Up & Launch:

Helped clients deliver more than 20 new medical devices and systems to market, with lead roles in R&D, commercial scale-up, regulatory approvals, manufacturing, and market launch of innovative solutions advancing patient care and disease treatment/prevention:

- Redesigned a breakthrough patient-monitoring device for a leading medical device company
- Designed a radical new approach to combat HIV/AIDS that deployed in Africa.
- Led de novo design and development of a novel deep brain drug delivery system

Education

Drexel University

Philadelphia, PA

MS, Biomedical Engineering

BSEE, Electrical Engineering

Valued for expertise in multiple disciplines:

Cardiovascular

Neurology

Women's Health

Endocrinology

Orthopedics

Telehealth/eHealth

MIS & General Surgery

Gastrointestinal (GI)

In Vitro Diagnostics

Dental

Ophthalmology

Hematology

Record of technology and product development leadership for:

Johnson & Johnson

Philips

Bill & Melinda Gates

Foundation

PTV Healthcare

Capital

Revival Healthcare

Capital

The Catalyst Group

Apollo Endosurgery

Tryton Medical

Idev Technologies

Pfizer

Caligor Rx

Boston Scientific

Convatec

Hologic



Product Development, Scale-Up & Launch:

- Led and co-authored two 510(k) submissions that were successfully cleared (in calendar 2018)
- Redesigned Product Development, Launch and Scale-up processes for a recently restructured and revitalized medtech company
- Led production modeling that synchronized scale-up and market development for a groundbreaking cardiac diagnostic technology.
- Prepared IDE (Investigation Device Exemption) and PMA (Pre-Market Approval) submissions for a novel peripheral vascular interventional technology company
- Developed manufacturing scale-up strategy for a unique hematological analysis system, subsequently included as due diligence for a \$125M trade sale.
- Created product launch and cost-reduction strategy for a novel endoscopic product line that accelerated Round C financing and product launch by six months.
- Directed manufacturing risk assessment/reduction, root cause analysis, and quality assessment for a novel vascular closure device and stent system for bifurcated lesions.

Mergers & Acquisitions:

Led data room management for Therakos acquisition by Mallinckrodt medical

Led technology due diligence and assessment engagements valued at \$1.5B+ in deal flow.

Examples:

- Directed a carve-out exercise for a franchise of a multifranchise global business. This included managing multiple external advisors and client leaders in an extremely confidential exercise to define, attribute and value the business.
- Managed acquisition of insulin pump technology for a multinational medical technology company, analyzing R&D, manufacturing operations, QA, and customer service activities for strengths and risks
- Oversaw divestiture of specialized wound management technology by a large medical company
- Led competitive assessment of powered and unpowered minimally invasive surgery (MIS) companies
- Completed over a dozen target assessments of neuromodulation solutions for obesity, depression, pain, Parkinson's Disease and other indications
- Led Technology and Manufacturing Operations Due Diligence for a heart-failure solution moving to IDE studies in the US
- Led Technical Due Diligence for novel Endometrial Ablation technology

Advisory Services:

Provided strategic, consultative advisory services including:

- *PTV Healthcare Capital:* Strategic Advisor and main technical reviewer of deal flow
- *Private Equity (3 firms-confidential):* Technical Due Diligence and post deal
- *BioAdvance & Pittsburgh Greenhouse Incubator:* Acted as primary reviewer and/or review board panelist assessing medtech proposal submissions
- *Leading Surgical Technology Company:* Developed technology strategy that defined client's technology surveillance portfolio for the next decade.
- *Bill & Melinda Gates Foundation:* Delivered acclaimed HIV-reduction technology strategy, device concepts, and invention disclosures.

Industry-pioneering medical devices and other products include:

Fetal, Neurological & Portable Patient Monitors

Drug Delivery Systems

Cardiovascular Implants (active and passive)

Neuromodulation Systems – Peripheral Nerve and Brain stimulation

Minimally Invasive Surgical Instruments

Advanced Endoscopy Solutions

Coronary & Peripheral Stents/Stent Delivery Systems

Automated Microsurgical Equipment

Structural Heart

Advanced Wound Care

Cardiovascular Intervention

Diagnostics Assays & Systems

HIV/AIDS Protection

Hematology, Oncology & Photopheresis



Professional Experience

DW Medtech Advisory LLC — Operates Worldwide **Principal/Founder, Current**

Founded consultancy firm providing strategic/operational advice and execution support to medical technology companies. Provide leadership of mission-critical product development, commercialization, and launch activities focused on strengthening QA while accelerating R&D timelines, streamlining scale-up operations, and minimizing manufacturing risks to achieve compliant, commercially successful new product introductions.

- Developed and Authored V&V strategy, protocols and 510(k) submission for a novel vascular imaging system
- Provided Independent technical advisory for relaunch of a previously withdrawn Class III structural heart product
- Developed and Technical Risk Assessment Tools in support of a Class III active implantable system PMA submission
- Developed and Executed Second-sourcing strategies for Class II and Class III devices and drug-device-capital combination products
- Conducted technical due diligence for 3 \$100MM+ acquisitions
- Developed risk-based improvement program for a specialist pharmacy specializing in named-patient and orphan drugs
- Process and Quality Improvement planning for OEM orthopedic manufacturer

Revival Healthcare Capital — Operates Worldwide **Operating Partner, Current**

- Provides Executive Leadership and Advisory Services to Portfolio Companies in New Product Development, Product Launch, Quality Assurance, Manufacturing and Regulatory
- Conducts detailed due diligence in Product Development, Technology, Quality Assurance and Quality Systems as well as Regulatory Compliance and Risk Management for target companies

Sanara MedTech Inc — Operates Nationwide **Chief Commercialization Officer, 2020-21**

Sanara is a provider of science-based Wound Care and Surgical products. Serving both clinical institutions and large-scale distributors who want differentiated products for the OR and Wound Care environment.

- Oversight of all contract manufacturing, Supply Chain, Quality Assurance and Regulatory Compliance, including outsourcing critical, but non-core processes to value-added partners.
- Business Development – Identification and Engagement with prospective product development partners for complimentary, value-added products
- New Product Development – Working with product partners, clinicians and technologists to develop and bring to market novel, evidence-based, value-added wound healing technologies. Project management and where appropriate regulatory submission management for NPD projects
- Process Development and Delivery – responsible for compliant processes for all aspects of the above, including SOP development, training and training record maintenance
- Provide technical, scale-up, regulatory and commercial expertise to product partners, on request

Committees

Served in numerous leadership roles for Drexel University BIOMED, including:

Coulter Foundation
Translational
Medicine Oversight
Committee

BIOMED "Ecosystem"
Strategic Advisory
Committee

ABET Accreditation
Curriculum Advisory
Committee

Volunteer Charitable
Positions

Leukemia &
Lymphoma Society
Light the Night Walk
- Greater BucksMont
Regional Board
Member

Hobbies

Kayaking, Bicycling,
Alpine Skiing,
Spectator Sports:
Rugby, Ice Hockey,
Motorsports, NFL
Football

Available for Travel & Relocation

References provided upon request



Professional Experience (continued)

[Therakos Inc. – West Chester, PA](#)

VP Operations, 18 Months

Executive Leader of Operations and member of the Executive Leadership Team of a rapidly growing PMA combination medical therapy company. Led a dynamic operations team overseeing a virtual supply chain with strategic partners producing capital equipment, disposables and pharmaceuticals. Results:

- \$1.425B sale to Mallinckrodt Pharmaceuticals in September 2015
- 300% increase in disposable capacity
- 500% increase in instrument production capacity
- Intimate, interactive and collaborative partnership with all supply chain partners

[PA Consulting Group, Inc. — NYC, London, Boston](#)

Consultant-Partner, 20 years

Rapidly rose through the consulting ranks due to deep industry experience in the Life Sciences Industry. Promoted to partner in 2001 to lead Medtech.

- Responsible for \$2-5MM/year individual revenue
- Led PA's North American Technology Center in Princeton (1998-2007) – a product and process development laboratory dedicated to client defined products and processes
- Led PA's Medtech Industry team
- Member of the PA Management Group (Partners)
- Member Product and Process Engineering Practice Leadership 1998-2008