

TERRY N. LAYTON, Ph.D.

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Career Summary

Technical executive with strong background in building medical manufacturing companies. Diverse experience includes industry and consulting experience in product development, regulatory/QA, operations, IP, failure investigation and technology assessment.

Instructor and lecturer for Bioentrepreneur classes and seminars on medical device design and regulations, product development, emerging medical technologies, medical device commercialization and medical device industry skill sets.

Qualification Summary

Experienced innovative leader and manager proficient in product design, regulatory approval, and clinical evaluation for new health care markets and business ventures.

- Managed engineers, scientists, regulatory professionals & plant personnel
- Due diligence on 10 companies – 6 purchased; Licensed 4 technologies
- Developed and taught 4 Bioentrepreneur classes at University of Illinois, Chicago
- National Institutes of Health (NIH) consultant for Small Business Innovation Research Grants 1992-present
- FDA Medical Devices Advisory Committee - industry representative 2001-2005, 2008-2013.
- Network of Centres of Excellence-Canada; Regenerative Medicine Network & Stem Cell Network 2003-2005; BioMedlight 2011; Institute of Circulatory and Respiratory Health (ICRH) Emerging Networks 2012-13
- Kentucky Science & Technology Corporation - Expert Panel 2007, 2009-2014
- Defense Medical Research and Development Program 2009-2010
- Design of Medical Devices Conference 2011-Urology Products; CoChair
- 18 US Medical Device Patents issued and over 45 new products released to market
- Regulatory submissions-US and International; Fifteen (15) 510(k)s & CE Mark for 138 product codes
- Short term consulting assignments on, technology assessment, QSR, QM, regulatory documentation, product failure investigation, failure mode analysis, and audits.
- 35 Publications and presentations on medical devices and medical device skill sets for engineers in industry
- Provide technical assistance and guidance to medical device start-up companies

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Medical Device Experiences

(product development, regulatory and/or commercialization)

Anesthesiology	Assistive Technology	Cardiovascular
Catheters	Critical Care	Endoscopy
Implants	Instruments	IV Systems
Home Health Care	Monitoring Electrodes	Neurosurgery
Orthopaedic	Rehabilitation	Respiratory Therapy
Transducers	Urology	Vascular Compression

Experience

University of Illinois, Chicago

Nov 2000—Present

- Visiting Professor Bioengineering—University of Illinois, Chicago
- Lecturer: Technology Assessment & Medical Device Start-Up Companies, Emerging Medical Technologies, Medical Product Development, & GMP and Regulatory Requirements for Medical Products

Laytech Inc

Long Grove, IL

Nov 1999—Present

Consulting & Contract Services

- Technology Assessment Of Products and Processes
- Regulatory & Quality—QSR, QM, submissions, audits, failure modes, & documentation
- Start-up and Business Plans and Intellectual Property for new medical device companies
- Legal-IP (Infringement & Invalidity), Failure Mode Investigations & Expert Reports

Integra NeuroCare/NeuroCare Group

July 1994 – October 1999

Pleasant Prairie, Wisconsin

(Worldwide leader in neurosurgical implants and monitoring devices)

Vice President, Group Technical Officer

- On the original due diligence team for the purchase of the first platform company (Heyer-Schulte, a neurosurgical implant company) for the NeuroCare Group.
- Built technical organization, established US customer service & distribution departments & technically managed Puerto Rican manufacturing facility.
- Member of due diligence team for the purchase of 3 additional companies.
- Searched for, assessed, and licensed 2 major technologies used in present products.
- Obtained 11 510(k)s
- ISO Certification of 2 facilities and CE Mark for 138 product codes.
- Developed and released to market 20 new products in 5 years.

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Experience

Packer Engineering, Inc.
Naperville, Illinois

December 1991-July 1994

Director, Biomedical Engineering

- Start-up of a new Biomedical Division
- Technology transfer of an electro-mechanical rehabilitation device with a market potential of \$5 million in 3 years.
- Technology assessment of new concepts for both small and large medical device companies.
- In first year received grants and contracts for over \$500,000.
- Failure Investigations

Laytech, Incorporated
Arlington Heights, Illinois

March 1990 – December 1991

Technical Officer

- Coordinate manufacturing of disposable medical products
- Consulting assignments on technology assessment, product and process improvements, materials, and quality issues
- Product development, project management, failure mode analysis and FDA submissions

Baxter Healthcare Corporation
Round Lake, Illinois

May 1988 – March 1990

Manager, Advanced Device Technology

- Managed the engineering and product service activities for Vein Access product line.
- Managed the final design and implementation phases of a new technology that prevents accidental needle sticks---needle less access.
- Searched for and assessed new technologies that added value to products and processes.

The Kendall Company
Barrington, Illinois

June 1975 – May 1988

Manager, Medical & Sports Medicine Divisions

Section Head, Medical Specialties

Senior Research Scientist/Engineer

Research Scientist/Engineer

- Presented new product concepts and business opportunities to upper management. Products brought incremental sales volume of over \$5 million to the sales base of \$35 million.
- Urodynamic products--designed, clinically tested, and published results
- Technical responsibility of latex catheter plant in Malaysia.
- Managed Colgate/Bike Plastics Product Development

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Professional Societies (past and present)

ISPE-International Society of Pharmaceutical Engineers
Society of Plastic Engineers
BMES – Biomedical Engineering Society
IEEE - Institute of Electrical Electronics Engineers
IV Nurses Society
Urodynamics Society
Medical Device Guidance and Standards Committees

Education

Ph.D., Biomedical Engineering, University of Virginia, Charlottesville, VA
M.S., Bioengineering, University of Illinois @ Chicago
Electrical Engineering, University of Illinois, Champaign, IL
B.S., University of Wyoming, Laramie, WY

High School, Moline Senior High, Moline, IL

Continuing Education

FDA/ASQ Quality System Inspection Technique
ISO 9000 Auditor Training
Medical Device Pre-Marketing/GMP Requirements Workshop
OSHA Guidelines
FDA Design Control
Liability Prevention for the New Millennium
Project Management

Research Disclosures

Ten publications
Twenty-four presentations

Patents

Eighteen issued

Military Service

U.S. Army
Honor Graduate, Officer Candidate School
Instructor, Artillery School
Battalion Staff, South Korea

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