

CV for Richard P. Meyst

Selected Expertise

- Medical Product Design / Development
 - FDA-GMP Practices
 - Market / Patent Research
 - Rapid Prototyping
 - Tooling / Process Development
 - Manufacturing / Industrial Engineering
 - Project Planning / Management
 - Risk Analysis / Risk Management
 - Failure Analysis
 - Verification, Validation & Qualification
 - Regenerative Medicine Devices
 - Blood Filters, IV Filters
 - Laparoscopic Surgical Instruments
 - Umbilical Cord Blood Collection
 - Cell Therapy, Stem cells & bioreactors
 - Catheter Based Diagnostics
 - Therapeutic Catheters, angioplasty
 - Drug Delivery/ Infusion Devices
 - High Volume Sterile Disposables
 - Medical Device Regulatory Submissions
 - Grant Writing
 - Expert Witness
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Biography

Mr. Meyst is an accomplished engineer/program manager/entrepreneur and has been facilitating the advanced design and development of a wide range of successful medical technology products for the health care industry over the last 40+ years. He has extensive knowledge in product design and development, product prototyping, production startup, manufacturing engineering, risk analysis, strategic planning, grant preparation and market research. He has also provided expert witness assistance in IP cases, product failure analysis, and other medical products cases. He has held various engineering, development, operations and management positions at CR Bard, Fenwal Division of Baxter, IMED and other healthcare and consumer product companies. For the last 25+ years he has been an owner of Fallbrook Engineering. Since 2003 he has been the President and CEO. Selected product experience includes implantable vascular prosthesis, DNA amplifiers, vital signs monitoring, drug infusion pumps and systems, medical lasers, surgical instruments, catheters of all kinds, microprocessor based diagnostic and therapeutic instruments, blood cell collection and processing, filtration devices for blood and IV solutions, as well as stem-cell harvesting and cell expansion systems.

Mr. Meyst was a Principal Investigator on an NIH SBIR grant from the National Heart, Lung and Blood Institute developing a device for the improved collection of Umbilical Cord Blood Stem Cells. He served on the Board of Directors for the Society of Plastics Engineers/Medical Plastics Division and is a long time member. He is a member of the American Association of Blood Banks, the Association for the Advancement of Medical Instrumentation and the American Filtration Society. He is also a member of the Medical Device Steering Committee of BIOCOM. Mr. Meyst has recently been a juror in the UBM/Cannon Medical Design Excellence Awards competition. His Bachelors and Masters degrees in Mechanical Engineering are from the University of Wisconsin, Madison. He has been awarded sixteen US Patents, has over four applications pending and has been an invited speaker, presenting talks at numerous scientific and medical industry meetings.

Employment History

From: 1989 **Fallbrook Engineering, Inc.**
To: Present Escondido, CA

Position: ***2003-Present: President/CEO***

Fallbrook provides consulting engineering services to client companies in the medical, pharmaceutical, biotech, electronic and consumer product industries. Services include project management, product conception, design and development, product prototyping, design and process validation, manufacturing engineering, production startup, cost reduction, as well as regulatory affairs compliance and submissions. He was also a Principal Investigator on a Phase II NIH SBIR Grant for the development of an improved method for the collection of umbilical cord blood, a source rich in stem cells.

1989-2003: Vice President

Provided consulting engineering services to client companies in the medical, pharmaceutical, cosmetic, electronic and consumer product industries.

From: 1988 **Diatek Corp.**
To: 1989 San Diego, CA

Position: ***Manager, Manufacturing Engineering***

Designed/developed disposable for "next generation" tympanic electronic hospital thermometer. Designed and implemented high speed automated production equipment to produce 1 MM+ units per day. Supported existing vital signs and operating room product lines. Managed facility and plant maintenance departments.

From: 1983 **Imed Corp.**
To: 1988 San Diego, CA

Position: ***Manager, Pilot Engineering***

Ran pilot production facility for new product builds of complex medical electromechanical/electronics and sterile disposables. Managed "Specials" program to offer custom I.V. sets and I.V. pumps per hospital order. Managed team of technicians/engineers to move new products from R&D into Manufacturing.

Technical Product Manager

Managed I.V. disposables product line projects that resulted in \$4 MM annual savings. Developed organized plan, gained corporate support and supervised implementation. Achieved project objectives through design standardization, process simplification, quality/performance enhancements, plus multi-national manufacturing operations.

Manager, Disposable Design

Managed/directed design & implementation of 6 new I.V. disposable product codes, an enteral product line and numerous new components. Supported research of 3rd generation volumetric pump disposable. Supervised department's growth in handling design/drafting, engineering and technician support.

From: 1979 **Oak Industries**
To: 1983 San Diego, CA

Position: ***Manager of Telecommunications***

Consulted to headquarters and domestic operating companies. Managed \$500K annual acquisition and installation of telecom equipment/services. Utilized cost control programs, network optimization and the use of value-added services to save \$350K annually.

Manager, Training & System Development

Planned and directed implementation of facilities projects for nationwide Pay TV network offices/warehouses in Phoenix, Chicago and Dallas. Designed and supervised training programs for installers, service technicians, phone sales and billing agents. Improved overall efficiency by 40% and saved 20% labor cost. Planned/directed the buying and installation of telecom equipment/services serving 600+ users handling 20,000 calls per day.

From: 1974 **Baxter Travenol Labs, Fenwal Division**
To: 1979 Round Lake, IL

Position: ***Program Manager***

Supervised and directed experts in design/development of collection, fractionation, storage and administration of human blood component products. Product scope: sterile medical disposables and electronic, electro-mechanical biomedical hardware. Specific products: Membrane Plasmapheresis, Autologous Blood Collection and General Blood Collection & Administration Sets.

Section Manager

Directed 6 engineers, physiologists and technicians in R&D for entire blood filtration product line. Simplified several blood set codes with 30% increase in manufacturing yield. Pioneered blood set materials evaluation for conversion from ETO to Gamma Sterilization. Designed nonwoven composite filter cartridge for Cadiotomy Bypass Filter. First of code production achievements: Polyester Mesh Blood Administration Sets, Pediatric Microfilter and a Filtration Leukapheresis Disposable Circuit.

Senior Biomedical Engineer

Designed/tested and produced a Microaggregate Transfusion Filter product line for worldwide distribution. (Product performance remained tops through 20+ years of product life. Product is now discontinued.) Served on AAMI Microfilter Standards Committee. Redesignated Platelet Administration Set to improve yield 20%. Managed design of an Autologous Blood Collection Set. Developed filter for collecting cryoprecipitate to produce Factor VIII.

Senior Development Engineer

Reduced Blood Sets' field complaints by 50% through product redesign and manufacturing process modifications. Redesignated existing microfilter to double volume capacity with no cost increase. Introduced ultrasonic assembly techniques for several products to reduce costs and improve reliability.

From: 1972 **USCI, Division of C.R. Bard, Inc.**
To: 1974 Glens Falls, NY

Position: ***Product Engineer, Prosthetic Development***

Supported Vascular Graft and Cardiovascular Catheter product lines. Instituted program to quantify and control variables affecting product quality. Designed/implemented/evaluated specialty test equipment and testing procedures. Developed/wrote product specifications.

Expert Witness, Litigation Experience

Date	2018	Client: Akin Gump
	Case:	Aptar v. 3M & Meck
	Project:	Patent Infringement
Date	2017	Client: The Crites Law Firm
	Case:	Christina Morris
	Project:	Personal Injury
Date	2017	Client: Better Life Technologies
	Case:	BLT v. Kaiser Permanente
	Project:	Nondisclosure & Trade Secrets
Date	2017	Client: Klinck Law
	Case:	Blendermann v. LifeWave Inc.
	Project:	Patent Infringement
Date	2017	Client: Finnegan, Henderson, Farabow, Garrett & Dunner, LLP
	Case:	Zimmer Surgical v. Stryker Corp.
	Project:	Patent Infringement
Date:	2016	Client: Perkins Coie, LLP
	Case:	Fontem Ventures B.V. et al. v. R.J. Reynolds Vapor Co.
	Project:	Litigation and related IPRs
Date	2016	Client: Greenberg Traurig, LLP
	Case	B. Braun v. BD
	Project:	Patent infringement & IPRs
Date:	2016	Client: Perkins Coie, LLP
	Case:	Fontem Ventures B.V. et al. v. Nu Mark LLC
	Project:	Litigation and related IPRs

Date:	2016	Client: Gallagher Krich, APC
Case:		Cyth Systems v. CareFusion
Project:		Contract dispute
Date:	2016	Client: Davis, Grass, Goldstein & Finlay
Case:		Beatriz Picon v. San Antonio Regional Hospital
Project:		Failure analysis
Date:	2016	Client: Cooley LLP
Case:		Medline Industries, Inc. v. C.R. Bard, Inc.
Project:		Patent dispute
Date:	2016	Client: Hodgson Russ LLP
Case:		Curlin Medical, Inc. v. ACTA Medical, Inc.
Project:		Patent infringement
Date:	2016	Client: PJ West and Associates, Inc.
Case:		Undisclosed
Project:		Medical product failure
Date:	2016	Client: Girardi and Keese
Case:		Deirdree Lagewaard v. Medtronic Minimed, Inc.
Project:		Medical product failure analysis
Date:	2015	Client: Perkins Coie LLP
Case:		Fontem Ventures B.V. et al. v. NJOY Inc. et al.
Project:		Electronic Cigarette IP case: Infringement, Validity and IPRs
Date:	2014	Client: Novak Druce Connolly Bove & Quigg LLP
Case:		Larry G. Junker, Plaintiff v. Medical Components, Inc. and Martech Medical Products, Inc., Defendants
Project:		Catheter design patent
Date:	2014	Client: Lipeles Law Group
Case:		Robinson v Rheingold
Project:		Analysis of failed knee brace

Date: 2014 **Client: Law Offices of George B. Piggott**
 Case: Armand Maaskamp v. Theodore Wortrich
 Project: Technology Ownership and Contracts Dispute

Date: 2014 **Client: Knobbe Martens Olson & Bear LLP**
 Case: Masimo Corporation & Masimo International Sarl v. Shenzhen Mindray
 Bio-Medical Electronics., Ltd.
 Project: I.P. – Patent Infringement and Validity

Date: 2014 **Client: Johnson Moore**
 Case: Rosenwein v. UCLA Hospital, Bard Access Systems, Inc.
 Project: Patient Injury, Root Cause Investigation of Medical Device

Date: 2014 **Client: Orrick, Herrington & Sutcliffe LLP**
 Case: Flextronics v. ICU Medical
 Project: Development Project Arbitration Matter

Date: 2014 **Client: Leavitt, Yamane & Soldner**
 Case: Pre-case Evaluation
 Project: Patient Injury, Root Cause Investigation of Medical Device

Date: 2012 **Client: Weiss & Moy PC**
 Case: Pacific Bioscience Labs Inc. v. Nutra Luxe MD, LLC
 Contact: Jeff Weiss, Atty.
 Project: I.P. – Patent Infringement
 Tested and analyzed product, wrote expert reports, gave Deposition and
 Testimony

Date: 2012 **Client: Thomas Whitelaw**
 Case: Pabban Development, Inc. vs. Kyphon Sarl and Medtronic, Inc.
 Contact: James Whitelaw, Atty.
 Project: Contract Dispute
 Wrote expert reports, gave Deposition and Testimony in court.

Date: 2012 **Client: Gwilliam Ivary Chiosso Cavalli & Brewer**
 Case: Diane Ely vs. Barrx Medical, Inc. et al
 Contact: Steve Brewer, Atty.
 Project: Patient Injury, Root Cause Investigation of Medical Device

Date: 2011 **Client: DLA Piper**
 Case: Carefusion 303, Inc., Plaintiff-Counterclaim Defendant, v. Sigma International, Defendant-Counterclaimant.
 Contact: John Kinton, Atty.
 Project: I.P. – Patent Infringement – Medical Fluid Delivery Device
 Analyzed defendants product, conducted engineering analysis, reviewed patent claims

Date: 2011 **Client: Peach & Weathers**
 Case: Judy Franklin, Michael Franklin v. Ladies Workout, Omron
 Contact: Tim Peach, Atty.
 Project: Personal Injury – Product Liability – Body Fat Analyzer
 Performed research and conducted testing on a body fat analyzer, prepared declaration

Date: 2011 **Client: Beeler, Walsh and Walsh**
 Case: Walker v. Southwest Imaging
 Contact: Micky Walsh, Atty.
 Project: Personal Injury – Product Liability
 Performed research, conducted testing on insulin pump, prepared report

Date: 2011 **Client: Perkins Coie**
 Case: Currently Confidential
 Contact: Joseph Hamilton, Atty.
 Project: I. P. Patent Infringement - unnamed device
 Performed testing/evaluation/analysis of competitive devices, prepared report

Date: 2010 **Client: Thon Beck Vanni Callahan & Powell**
 Case: Jackson v. Ossur
 Contact: Daniel P. Powell, Atty.
 Project: Personal Injury - Product Liability - Cold Therapy System
 Performed research of: FDA requirements for labeling, misbranding, Maude database for similar products and did evaluation of product labeling and directions for use, gave Deposition

Date: 2010 **Client: Schuering Zimmerman & Doyle, LLP**
 Case: Fonti v. Wilmarth
 Contact: J. Hawken Flanagan, Atty.
 Project: Personal Injury – Product Liability – Electrosurgical Device
 Performed background research provided expert review and did product testing and evaluation

Date: 2009 **Client: San Diego IP Law Group**
 Case: I-Flow, Inc. v. Apex Medical Technologies
 Contact: Trevor Coddington, Ph.D., Atty.
 Project: I.P. – Patent Infringement – Medical Fluid Delivery Device
 Prepared Declaration, gave Deposition and Testimony

Date: 2008 **Client: Weston Herzog LLP Attorneys**
 Case: Staley v. Ukiah Valley Medical Center, Adventist Health, Allen Medical Systems, Inc., et. al.
 Contact: William Weston, Atty.
 Project: Personal Injury - Product Liability - Operating room table accessory
 Performed test and evaluation of product function and failure modes, prepared Expert Report, Declaration, gave Deposition and Testimony

Date: 2008 **Client: McKool Smith**
 Case: Medtronic Vascular, Inc., Medtronic USA, Inc., v. Boston Scientific Corp. Scimed Life Systems Inc., and Boston Scientific Scimed, Inc.
 Contact: Joshua Budwin, Atty.
 Project: I.P. – Patent Infringement - Angioplasty balloon/stent catheter
 Developed test methods, tested product, analyzed data and prepared reports

Date: 2007 **Client: The Law Offices of Morris & Player**
 Case: Pre-case evaluation
 Contact: Lea A. Player, Atty.
 Project: Personal Injury - Implantable drug infusion port
 Product research, background information gathering

Date: 2007 **Client: Holman Law**
 Case: Joseph Falagan v. Valley Medical Center, also known as Public Hospital District No. 1 of King County, a municipal corporation; Valley Medical Center Clinic; Kim B. Wright M.D. and Jane Doe Wright, M.D., his wife; Seattle Systems, Inc.; Camp, Inc.; United States Manufacturing Co.; Trulife Healthcare, a.k.a. Trulife Group

Contact:	James Holman, Atty.
Project:	Personal Injury - Neck brace Provided expert review, analysis, Risk Analysis, prepared Declaration
Date:	2007
	Client: Giovanniello & Michels LLP
Case:	Russ Whitmeyer v. Invacare Corporation, Apria Healthcare, Inc.
Contact:	Helen S. Peltekci, Atty.
Project:	Personal Injury - Oxygen concentrator Provided expert testing overview for Apria Healthcare
Date:	2006
	Client: Perkins Coie LLP
Case:	Venetec International, Inc. v. Medical Device Group
Contact:	Joseph Hamilton, Atty.
Project:	I. P. Patent Infringement - Foley catheter securement device Performed patent analysis, claim construction, prepared Expert Declaration & Rebuttal Report, gave Deposition
Date:	2006
	Client: Sanders Simpson Fletcher & Smith L.C.
Case:	Ayers v. Lafayette Regional Health Center
Contact:	Walter Simpson, Atty.
Project:	Personal injury - central venous catheter Performed consulting research, Product Failure Analysis, Expert Report preparation and gave Deposition
Date:	2006
	Client: Spencer Fane Britt & Browne LLP
Case:	NOXID Limited Company, et al. v. Mallinckrodt Inc., et al.
Contact:	Eric Solverud, Atty.
Project:	Contract compliance for best efforts in product development - Solution Warmer Did product research, prepared Expert Report, gave Deposition
Date:	2006
	Client: Mead & Mead
Case:	Rohde v. Smiths Medical, et. al.
Contact:	Katherine Mead, Atty.
Project:	Personal Injury - Central line port Performed consulting research on product failure
Date:	2005
	Client: Knobbe Martens Olson & Bear LLP
Case:	Applied Medical v. Synthion
Contact:	Joe Jennings, Atty.
Project:	I.P. – Patent Issues- Ligating clip applicator

Expert Report preparation, gave Deposition

Date: 2005 **Client: Luvera Law Firm**
Case: Singh v. Providence Health & Edwards Lifesciences
Contact: Joel Cunningham, Atty.
Project: Personal Injury- Thermal dilution catheter for cardiac output
Performed research & review of documentation, participated in Failure Analysis, prepared Declaration

Date: 2003 **Client: Tuverson & Hillyard**
Case: Luzmilla v. Richard Allen Medical, Imagyn Medical Technology & Conmed Corp.
Contact: Mario Iorillo, Atty.
Project: Personal Injury- Laparoscopic dissector/clip applier
Performed consulting research, gave Deposition and Testimony

Date: 2002 **Client: Payne & Fears**
Case: Pelagalli v. Premier Laser & Collette Cozan
Contact: Mark Butler, Atty.
Project: I.P. Ownership issues – Laser for dental applications
Provided research, prepared Expert Report & Rebuttal Report

Date: 2001 **Client: Leydig Voit & Mayer, Ltd.**
Case: Pall Corporation v. Hemasure
Contact: Mark Phelps, Atty.
Project: I.P. – Patent Issues – Leukodepletion blood filter
Research, claim construction, prepared Expert Report, gave Declaration

Date: 1999 **Client: Sanford Ehrmann, Esq.**
Case: Cohen v. Abbott
Contact: Sanford Ehrmann, Atty.
Project: “Personal” Injury - Over-the-needle IV catheter
Failure Analysis, Expert Report, catheter in race horse

Date: 1997 **Client: Jaman, Kahn & Associates**
Case: Auzenne v. Park Davis
Contact: Cori Steinberg, Atty.
Project: Personal Injury - Glass drug ampule
Product research, performed Risk Analysis, gave Deposition

Patents

Patent Number	Date Issued	Title
8,522,839	2013	Adapters for use with an anesthetic vaporizer
8,033,306	2011	Adapters for use with an anesthetic vaporizer
7,784,504	2010	Adapters for use with an anesthetic vaporizer
6,669,092	2003	Display apparatus
6,440,110	2002	Apparatus and method for collecting blood from an umbilical cord
6,190,368	2001	Apparatus and method for collecting blood from an umbilical cord
5,993,429	2001	Apparatus and method for collecting blood from an umbilical cord
5,919,176	2001	Apparatus and method for collecting blood from an umbilical cord
RE34,599	1994	Disposable probe cover assembly for medical thermometer
D336,862	1993	Probe cover holder for medical thermometer
5,056,682	1991	Container for fan-folded sheets
4,911,559	1990	Disposable probe cover assembly for medical thermometer.
4,736,736	1988	Cervical traction assembly having head cradle w/ occipital shelf
4,283,289	1981	Blood filter for leukocytes
4,170,056	1979	Blood filter
4,157,967	1979	Blood filter

Education

<u>Year</u>	<u>College/University</u>	<u>Degree</u>
1972	University of Wisconsin, Madison, WI	MS, Mechanical Engineering
1971	University of Wisconsin, Madison, WI	BS, Mechanical Engineering

Publications / Presentations

1. "Effective Strategic Alliances", Tech Coast Life Science Innovation Conference, September 28, 1999
2. "Effective Strategic Alliance Tactics", Tech Coast Life Science Innovation Conference, September 28, 2000, Irvine, CA.
3. "Strategies for Optimal Outsourcing Alliances", MD&M West 2001, January 9, 2001, Anaheim, CA.
4. "Winning Strategies for Commercialization", Tech Coast Life Science Innovation Conference, November 13, 2001, Irvine, CA.
5. "Seeing Green: Finding Money for Product Development" A Presentation for the 2002 Medical Design & Manufacturing Conference, Jan., 2002, Anaheim, CA.
6. "Running the Hurdles with NIH SBIR's" A Presentation for the 4th Annual NIH SBIR/STTR Conference, June 21, 2002, Bethesda, MD
7. "Running the Hurdles with NIH SBIR's", A Presentation for the 5th Annual Winter Conference, Association of University Research Parks, January 17, 2003, Newport Beach, CA
8. "NIH Grant \$ for Your Med Device/Biotechnology Project", Medcon, Conference for the Design and Manufacturing of Medical and Biotech Devices, April 28, 2004, Del Mar, CA
9. "NIH Grant \$ for your Nano-Biotechnology Project", A Presentation for the nanoSIG™ Forum, Commercial Applications in Nano-Bio Technology, February 26, 2004, San Diego, CA
10. "It's a risky world out there. Using Risk Management as a tool to ensure success in medical product design and development." A Presentation to the 2005 AOAC Two-Day cGMP Conference on Pharmaceuticals and Medical Devices, March 10 & 11, 2005, FDA Offices, Irvine, CA
11. "It's a risky world out there. Using Risk Management as a tool to ensure success in medical product design and development." A presentation for Medcon Expo April 28, 2005, Del Mar Fairgrounds, San Diego, CA
12. "Development of a new medical device for the efficient, safe and easy collection of umbilical cord blood." A presentation at the BIOCOM Medical Device Quarterly Event, August 11, 2005, San Diego, CA
13. "Risk Assessment: It's a Risky World out There" A presentation to the San Diego Regulatory Affairs Network, March 16, 2006, San Diego, CA

14. "Device & Diagnostic Development: Concept to Bedside" Panel member at the BIOCOM Medical Device Quarterly Event, October 22, 2008, San Diego, CA
15. "Risk Assessment: It's a Risky World out There" A presentation to a Masters Class at San Diego State University, April 2011, San Diego, CA
16. "Risk Assessment: It's a Risky World out There" A presentation to a Masters Class at the University of California, San Diego, August 2011, San Diego, CA
17. "Bioresorbable Polymers with Medical Devices – A (Still) Emerging Field" A presentation to the Medical Device and Design West Conference, February 13, 2012, Anaheim, CA
18. "Collect 250™, The Safest, Fastest and Most Effective Umbilical Cord Blood Collection System" A presentation to National Heart, Lung, and Blood Institute Innovation Conference, June 11, 2013, San Diego, CA
19. "Secrets to a Successful Startup" a panel member at 30th anniversary MD&M West Conferences, February 11, 2015 in Anaheim, CA

Professional Associations and Additional Activities

- Sr. Member, Society of Plastics Engineers (SPE), Medical Plastic Division
 - Member, AAMI, Association for the Advancement of Medical Instrumentation
 - Member, AABB, American Association of Blood Banks
 - Member, AACC, American Association for Clinical Chemistry
 - Member, American Filtration and Separations Society
 - Member, BIOCOM, San Diego
 - Member, The Designers Accord
 - Member, SDRAN, San Diego Regulatory Affairs Network

 - Served as a juror in the UBM/Cannon Medical Design Excellence Awards competition
 - Served as a judge in a San Diego CONNECT Capital Competition for start-ups
 - Advisor to Valley Center High School Computer Aided Design (CAD) program
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