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

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 30+ 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 been a juror in the UBM/Cannon Medical Design Excellence Awards competition. His Bachelor's and Master's degrees in Mechanical Engineering are from the University of Wisconsin, Madison. He has been awarded sixteen US Patents, has 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 Cardiotomy 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. Redesigned 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. Redesigned 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
To: 1974

USCI, Division of C.R. Bard, Inc.
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	2019	**Client: Brown Christy and Green**
	Case:	Mary Wheatly v. Altus Lufkin, LP et al
	Project:	Product Failure Analysis, over infusion
	Technology:	IV Pumps, Infusion Pumps and Disposables
Date	2019	**Client: K&L Gates**
	Case:	Baxter v. Becton Dickinson
	Project:	I.P. Patent Dispute; Prepared Declarations for IPRs
	Technology:	Sterile Disposable Patient Fluid Lines, Anti-microbials, Catheters, Patient Fluid Line Access Valve, Disinfecting Caps
Date	2019	**Client: Wilke, Fleury, Hoffelt, Gould & Birney**
	Case:	Mary Munson v. Robert McCary, M.D., et al.
	Project:	Product Failure Analysis
	Technology:	IV Pumps, Infusion Pumps and Disposables
Date	2019	**Client: DLA Piper**
	Case:	Facet Technologies v. Cilag GMBH International and Lifescan, Inc.
	Project:	Contract Dispute, Arbitration Hearing
	Technology:	Lancing Device, Lancets for Blood Glucose Monitoring, Diagnostic
Date	2019	**Client: Robins Kaplan**
	Case:	Vascular Solutions et al v. Medtronic
	Project:	Product Analysis and Research
	Technology:	Guide Extension Catheter, Interventional Cardiology
Date	2018	**Client: Buchanan Ingersoll & Rooney**
	Case:	Larry G. Junker v. Medical Components, Inc. and Martech Medical Products, Inc**.**
	Project:	I.P. Design Patent Infringement, Expert Opinion and Affidavit
	Technology:	Split Sheath Introducer, Tearaway Sheath Dilators

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