

CURRICULUM VITAE

JAMES DENNIS BRUNER, Ph.D., P.E.

MEDICAL DEVICES

Litigation – Quality Systems – Regulatory Compliance

Updated 1 January 2006

Personal Information:

Address: 6054 S. Krameria Street, Centennial, Colorado 80111-4274

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Education:

1953 – 1955 Loveland High School, Loveland, Colorado

1955 – 1957 Canon City High School, Canon City, Colorado

1957 – 1961 Colorado State University, Fort Collins, Colorado

- B.S. Degree, Mechanical Engineering

1962 – 1966 University of Houston, Houston, Texas

- M.S. Degree, Mechanical Engineering

- Part time (night) student

- Thesis Title: Filtering Characteristics of a Long Steel Bar with Discontinuities in Cross Sectional Area.

- Thesis Advisor, Douglas Muster, Ph.D., Department Chairman

1966 – 1969 University of Houston, Houston, Texas

- Ph.D. Degree, Mechanical Engineering

- Dissertation Title: A Blood Pump for Closed Chest Left Ventricular Bypass.

- Dissertation Advisors: Charles Dalton, Ph.D., Univ. Houston

Leslie A. Geddes, Ph.D., Baylor Medical*

- A large portion of course work and all research were done in the Physiology Department of Baylor College of Medicine, Houston, Texas.

1973 – 1974 Harvard Medical School at The Peter Bent Brigham Hospital

- Post Doctoral Studies in Biomedical Engineering, Pulmonary and Intensive Care Medicine, Department of Surgery.

- Advisor: Philip A. Drinker, Ph.D.

Academic Honors:

Pi Tau Sigma, Mechanical Engineering Honorary, C.S.U.

Omicron Delta Kappa, Scholastic and Service Honorary, C.S.U.

Sigma Xi, Research Oriented Honorary, Univ. Houston

Fellowships and Teaching Experience:

Texaco Fellow in Mechanical Engineering, Univ. Houston, 1966 – 1969.
Student Asst., “Classical Physiology and Modern Instrumentation”, Baylor, 1967.
Laboratory Assistant, Physiology Laboratory, Baylor, 1966 – 1969.

Professional Affiliations:

National Society of Professional Engineers (NSPE)
American Society of Mechanical Engineers (ASME)
American Society for Quality (ASQ), Senior Member
Regulatory Affairs Professional Society (RAPS)
Association for the Advancement of Medical Instrumentation (AAMI)
American Society of Extracorporeal Technology (AmSECT)
National Academy of Forensic Engineers (NAFE) Senior Member and Board
Certified Diplomate in Forensic Engineering by NAFE, a CESB Member Board
Registered Professional Engineer in Colorado (Reg. No. 10025)

Past Affiliations:

Certified Clinical Engineer by AAMI
American Academy of Cardiovascular Perfusion (AACVP)
AdvaMed (Formerly Health Industry Manufacturers Association, HIMA)

Professional Experience:

- 1961 – 1966 Texaco, Inc., Research and Technical Division, Bellaire, Texas
- Position: Mechanical Engineer
- Job Description: Mechanical design of miniature mechanisms, acoustic wave propagation, oil well drilling research, electromechanical and nuclear well logging research, hydraulic power design.
- 1966 – 1969 Texaco, Inc., On educational leave.
- 1969 – 1973 Monaghan Company, Littleton, Colorado
- Positions: Product Development Engineer; Manager, Product Development
- Job Description: Design and development of products used in diagnosis and treatment of lung disease; respirators, humidifiers, pulmonary function analyzers, and intensive care ventilators.
- 1973 – 1974 Harvard Medical School (see above for details)

- 1974 – 1977 Monaghan Company (Became Hospal Medical Corporation)
 - Positions: Staff Scientist; Product Manager
 - Job Description: Acted as consultant to engineering and marketing departments in several phases of product planning and development. Participated in advanced product research projects.
- 1977 – 1986 COBE Laboratories, Inc., Lakewood, Colorado
 - Positions: Clinical Monitor (Cardiovascular Division); Manager, Clinical Affairs (Cardiovascular Division); Manager, Advanced Projects (Hemodialysis Division)
 - Job Description: Responsible for clinical evaluation of new cardiovascular surgery products. In charge of quality engineering and clinical evaluation for cardiovascular products. Manager of a group responsible for technological outreach in dialysis research and development.
- 1986 – 1990 COBE Laboratories, Inc., Lakewood, Colorado
 - Position: Director, Quality Assurance, Cardiovascular Division
 - Job Description: Responsible for all quality assurance and regulatory activities for one of two corporate divisions dealing with extracorporeal life support, physiologic pressure monitoring, and surgical blood salvage. Included quality control, quality engineering, corporate biological and chemistry laboratories, product liability, and regulatory activities. Also responsible for environmental health and safety issues for the corporation.
- 1990 – 1999 COBE Cardiovascular, Inc. Arvada, Colorado (New Corporation)
 - Position: Director, Quality and Regulatory Affairs
 - Job Description: Responsible for all quality and regulatory activities in the fields of extracorporeal life support, physiologic pressure monitoring, surgical blood salvage and related products. Responsibilities included domestic and international regulatory and standards compliance and submissions activities (FDA, ISO 9001 and CE Marking), quality assurance, quality engineering, clinical monitoring, receiving quality, product release, corporate blood testing laboratory, material toxicity testing, microbiology, OSHA, EPA, and product liability.
- 1999 – 2001 Gambro Renal Products, Inc. Lakewood, Colorado
 - Position: Director, Quality and Regulatory Compliance
 - Job Description: Responsible for quality and regulatory compliance for a manufacturer of hemodialysis equipment. Responsibilities included regulatory and standards compliance for FDA, ISO 9001 and CE Marking, quality engineering, receiving quality, and complaint management.

2001 – Present J. Dennis Bruner, Ph.D., P.E., Inc.

- Position: Owner and Principal Consultant

- Job Description: Consultant in quality systems, regulatory compliance and litigation involving medical devices. Expert witness in issues involving medical devices, specializing in cardiothoracic surgery, dialysis, respiratory care, and labels/labeling. Work includes research, investigation, report writing, counseling, and expert testimony in a wide variety of medical device malfunctions and related cases.

Patents:

Holder of the following U.S. patents in the fields of oil well drilling and medical devices:

3,719,239

3,467,582

3,451,263

3,266,550

Publications; Major:

Schuhmann, RE, Bruner, JD, Geddes, LA, Hoff, HE, Moore, AG, and Peters, JD, **Active Push-Pull Pump for Total Left Ventricular Bypass in the Closed Chest Animal**, Proc. 20th Annual SWIEECO Conference, 9B1-9B2, 1968.

Bruner, JD, and Muster, D, **Filtering Characteristics of a Long Cylindrical Steel Bar with Discontinuities in Cross Sectional Area**, American Society of Mechanical Engineers, Paper No. 66-PET-22, 1969.

Bruner, JD, Schuhmann, RE, Geddes, LA, and Hoff, HE, **Design and Performance of a Vacuum Reservoir Blood Pump**, Journal of the Association for the Advancement of Medical Instrumentation, C4(5), 182-188, 1970.

Gemer, M, Dunegan, LJ, Lehr, JL, Bruner, JD, Stetz, CW, Don, HF, Hayes, JA, and Drinker, PA, **Pulmonary Insufficiency Induced by Oleic Acid in the Sheep**, The Journal of Thoracic and Cardiovascular Surgery, 69, 793 – 799, 1975.

Bruner, JD, and Drinker, PA, **The Physician, the Manufacturer, and Medical Devices**, Archives of Surgery, 110, 1511 – 1515, December 1975, and Medical Trial Technique Quarterly, 307 – 319, Winter 1977.

Gemer, M, Drinker, PA, Lehr, JL, Bruner, JD, Don, HF, Hammer, HO, Whitin, EW, and Melnick, JH, **Acute Respiratory Insufficiency, Mechanisms of Improving Oxygenation by Partial Cardiopulmonary Bypass**, Surgical Forum, 27, 200 – 202, 1976.

Fisk, RL, Bates, P, Austin, J, and Bruner, JD, **Evaluation of a Topical Myocardial Cooling Device and Comparison of Modalities for Maintaining Myocardial Hypothermia**, The Journal of Extracorporeal Technology, 13(2), 194 – 197, 1976.

Publications; Posters and Abstracts:

Gemer, M, Dunegan, LJ, Lehr, JL, Bruner, JD, Stetz, CW, and Drinker, PA, **Experimental Model of Acute Pulmonary Insufficiency and its Use in Investigating Extracorporeal Support**, Federation Proceedings, 33, 353, 1974.

Gemer, M, Dunegan, LJ, Lehr, JL, Bruner, JD, Don, HF, Hammer, RO, Whitin, EW, and Melnick, JH, **Mechanisms of Improving Systemic Oxygenation in Partial Cardiopulmonary Bypass**, The American Society of Artificial Internal Organs, Abstracts, 3,25,1974.

Gemer, M, Lehr, JL, Bruner, JD, Don, HF, Hammer, RO, Whitin, EW, Melnick, JH, and Drinker, PA, **Effect of Pulmonary Artery PO₂ on Q_s/Q_t During Partial Cardiopulmonary Bypass for Acute Respiratory Insufficiency**, Federation Proceedings, 34(3), March 1, 1975.

J. Dennis Bruner, Ph.D., P.E., Inc.

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**MEDICAL DEVICES
Litigation – Quality Systems – Regulatory Compliance**

**Fee Schedule
Medical Device Litigation
Effective 1 January 2006**

**Inspection, investigation, record review,
research, report writing and presentation,
counseling, conferencing, etc.\$275.00 per hour**

Testifying under oath (e.g. deposition, trial)\$350.00 per hour

**Travel time to and from destinations outside
Denver metro area.....\$150.00 per hour**

NOTES:

- **Personal car travel is billed at the current IRS business reimbursement rate per mile.**
- **Minimum out of town billing is 4 hours.**
- **All fees are plus normal traveling expenses of airline, train, taxi, personal car, parking , food, lodging, long distance phone calls, copying, etc.. Air travel within the continental U.S. and Canada will be coach. Travel outside the continental U.S. and Canada will be business class. All travel costs will be billed at actual costs.**
- **Invoices will be sent monthly or as approximately 20 billable hours are accrued. Invoices are payable net 30 days from date of invoice.**
- **Accounts over 30 days past due will accrue interest at the rate of 2% per month beginning two months from the invoice date.**
- **Advance payment, including estimated travel costs, is required for testimony appearances requested by parties other than the primary client. Amount billed will be based on estimated appearance time plus estimated travel time and expenses. Over payments will be refunded and underpayments will be billed as soon as possible following appearance.**
- **Advance payment (retainer) of \$1000 is required for new clients. This amount will count toward last billing.**