

JAMES HARVEY KNAUSS

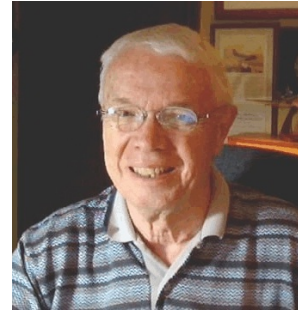
Delphi Consulting Group

832-285-9423

832-615-3550 Fax

harvey@delphiconsulting.com

www.delphiconsulting.com



CAREER HIGHLIGHTS

Director/Owner 1987

DELPHI CONSULTING GROUP, Houston, Texas

Formed new company to provide medical device regulatory, engineering services, compliance programs and medical device FDA release to market for client companies

Director of Regulatory Affairs

PREEMICARE CORPORATION, Houston, Texas

Responsible for regulatory, quality control functions, interface with FDA, medical device product release to market.

Director of Regulatory Affairs

NARCO BIO-SYSTEMS, Houston, Texas

Responsible for regulatory, quality control functions, interface with FDA, medical device product release to market and product service department

Vice-President & COO

GRAPHIC ARTS MFG., CO., INC., Houston, Texas

Responsible for all manufacturing, purchasing, regulatory and marketing of custom industrial controls

Branch Manager

VOLT TECHNICAL CORP., Houston, Texas

Responsible for marketing of engineering services and personnel to the Houston petrochemical and general industrial market

Supervisor

PHILCO-FORD CORP., Webster, Texas

Responsible for technical and engineering services to NASA manned space flight control center during the "put a man on the moon" era. Received a "Recognition of Service" award for notable contributions to the success of the Apollo 11 manned lunar landing.

MILITARY SERVICE

United States Air Force, one and half years detached service with the National Security Agency.

EDUCATION

BS Engineering, U. of Illinois

LICENSES

FCC Amateur Radio -- K5OZO

PUBLICATIONS

Medical Device Commercialization in the United States of America, Introduction to FDA and UL Regulatory Issues. Houston, Texas: LSR, 1994.
A number of presentations in the areas of FDA Release to Market and GMPs.

SOCIETIES AND COMMITTEES

Regulatory Affairs Professionals Society
Reader Board Member MD&DI magazine
Reader Board Member Smithsonian magazine.

CONSULTING ACTIVITIES, [abbreviated list]

FDA "Release to Market" via 510(k), IDE and PMA
CGMP Quality System Development
CGLP Quality System Development
Process Validation Development and Implementation
Design Review Facilitation
Sterilization Validation Development and Implementation
Regulatory Project Management
Procedure Development
Investment Regulatory Review and Analysis
Audits, FDA CGMP, GGLP, ISO, product and/or company.
US and International Safety Standards Review and Listing, i.e., UL, CSA, and IEC 601
Medical Device Release to Market and/or Listing in Japan, and Europe
Third Party FOI and Data Base Searches
Assistance with FDA & State FDA Inspection, and replies to FDA Form 483 Notices
Regulatory Retainer Programs for Audits, Inspections and Listing
Clean Room Implementation and Validation

PRODUCT EXPERIENCE, [abbreviated list]

Blood oxygenates
Endotracheal and Tracheal Tubes

PRODUCT EXPERIENCE, [abbreviated list] Cond.

Perfusion Tubing Sets
Heart and Blood Pumps
Orthopedic Devices
Oncology Devices
Vision Systems
Catheters: Angioplasty, Vascular, Embolectomy, Monitoring
Lasers: YAG, Argon, CO2
Stents
Syringes: Standard and Pre-Filled
Instrumentation: Monitors, Diagnostics, Life Support
Defibrillator/Monitor
Respiratory Products: Ventilators, O2 Concentrators, Anesthesia Equipment
Ultra Sound
Doppler Devices with Probes
Nuclear Devices
High Dose Rate Brachytherapy
Vascular Products: Angioplasty, Surgery Kits
Electrodes
Cancer Detection Instrumentation
Monitoring Equipment: EEG, EKG, Anesthesia, Blood Gases, ICU Systems.
Infant Incubators and Warmers
Gynecological Devices and Instruments
Powered and Non-powered Surgical Instruments
X-Ray and MRI
Osteosynthesis Systems
Contract Manufacturers
Contract Sterilize
Contract Testing Laboratories

Over 250 FDA 510(k) release to market have been obtained for clients since 1987.

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