C.V.

JAMES HARVEY KNAUSS
Delphi Consulting Group (DCG)
832-675-9281 Direct
832-692-5364 Mobile
harvey.knauss@gmail.com
www.delphiconsulting.com

CAREER HIGHLIGHTS

Director/Owner since *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 (Contract)
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

Engineer Manager
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.
A number of presentations in the areas of FDA Release to Market and GMPs.

SOCIETIES AND COMMITTEES

Reader Board Member MD&DI magazine
Reader Board Member Smithsonian magazine.
Charter Member GCMDA

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
US and International Safety Standards Review and Listing, i.e., UL, and IEC 60601
Third Party FOI and Data Base Searches
Assistance with FDA & State FDA Inspection, and replies to FDA Form 483 Notices
Regulatory Retainer Programs for Listing.

PRODUCT EXPERIENCE, [abbreviated list]

Blood oxygenates
Endotracheal and Tracheal Tubes
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 Devices
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
PET Scanners
X-Ray and MRI
Osteosynthesis Systems
Contract Manufacturers
Contract Testing Laboratories, monitoring of client testing