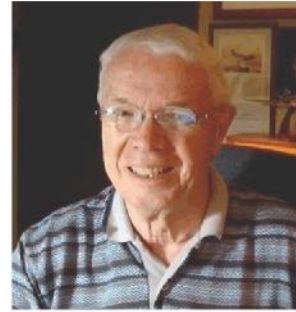


c.v.

**JAMES HARVEY KNAUSS**

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**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*

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. 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.  
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 Sterilize  
Contract Testing Laboratories

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