

Medical Device Industry Veteran Kevin Morningstar joins ValveXchange as Senior Director, Regulatory Affairs and Quality Assurance.

February 14, 2011. Denver - ValveXchange Inc. is pleased to announce that Mr. Kevin Morningstar has joined the VXi team to direct the regulatory compliance program. With ValveXchange now moving toward a "First-in-Man" study during 2011, Mr. Morningstar has joined the Executive Team of ValveXchange on a full-time basis to take on the role of Senior Director, Regulatory Affairs and Quality Assurance.

Mr. Morningstar has over 25 years experience in regulatory affairs and quality assurance in the medical device manufacturing industry. He began his medical device career in 1983, and has held positions in Operations, Engineering, Regulatory Affairs, Quality Assurance, and Executive Management. He has extensive on-the-job experience with medical devices used in cardiology, neurosurgery, anesthesiology, and nephrology. His cardiac device experience includes cardiopulmonary bypass equipment, implantable cardiac pacemaker leads and programmers, digital stress echo systems, 3-D and 4-D digital cardiac imaging, aortic balloon pumps and catheters, and endocardial laser catheters. Prior to creating his own regulatory consulting practice in 1997, Mr. Morningstar held engineering, regulatory, and management positions with TomTec Imaging Systems, Ohmeda, Telectronics Pacing Systems, and COBE Laboratories. He also co-founded Silverglide Surgical Technologies, Inc., a surgical instrument business successfully sold to Stryker Corporation in 2006 in a planned exit strategy. He is a seasoned engineer, manager, entrepreneur and investor.



Mr. Morningstar has a broad depth of experience with FDA regulatory requirements for medical devices, for both product marketing approvals and quality systems compliance. He is also very knowledgeable with respect to corresponding European and Canadian medical device requirements. Over the years he has worked on many Section 510(k) Premarket Notifications, Premarket Approval Applications, and European CE Mark Applications. He has broad experience in quality system architecture, process development, design assurance, quality system audit, FDA inspections, international standards conformance, promotional material, labeling, risk management, medical device recalls, adverse event reporting, process validation, employee training, and production and process control.

Mr. Morningstar received his undergraduate degree in Electrical Engineering from Michigan State University in 1980. In 1984 he became a Registered Professional Engineer in the State of Colorado. He earned a Regulatory Affairs Certification from the Regulatory Affairs Professionals Society in 1992 and became a Certified Quality System Auditor in 1993. In 2005 he earned a Certificate in Production and Inventory Management (CPIM) from APICS. Mr. Morningstar is named co-inventor on two patents in the electrosurgery field. He is a seasoned speaker and instructor, and continues to be involved in regulatory consulting to medical device companies in the U.S. and Europe.