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 Christian Brothers University
GRADUATE ENGINEERING
650 EAST PARKWAY SOUTH
MEMPHIS, TENNESSEE 38104

• A S E M I N A R •
**INTRODUCTION TO REGULATORY AFFAIRS:
MEDICAL DEVICE INDUSTRY**

 **Christian Brothers University**
GRADUATE ENGINEERING

October 16, 2009 • 7:30 a.m.-noon
Montesi Executive Center, Buckman Hall

P R E S E N T E R S

KIM ARMSTRONG, M.S.E.

Prior to consulting, Kim spent 3 years at Medtronic Spinal and Biologics working on design control activities, annual reports, PMA supplements, change control, and labeling related to cervical and lumbar arthroplasty devices. She also spent two years at Cook Med Institute developing clinical protocols and managing studies for peripheral bare metal and drug-eluting stents. Engineering principles were used to develop regulatory strategy and pre-clinical testing to obtain clearances and approvals.

Kim received a Bachelor of Science in Mechanical Engineering from The University of Memphis and a Master of Science in Engineering from the department of Aeronautics and Astronautics at Purdue University. She has completed other graduate engineering courses at The University of Memphis with an emphasis in materials.

CHRISTINE SCIFERT, M.S., M.E.M.

Prior to consulting, Christine spent 9 years at Medtronic Spinal and Biologics directing the regulatory department of 22 people. As Senior Director of the group, she set regulatory strategy, oversaw global submissions, developed a design control process, interfaced with FDA and notified bodies, oversaw modification and implementation of procedures to maintain regulatory compliance and performed due diligence activities for potential acquisitions. Prior to Medtronic, she performed evaluations of injury mechanisms associated with automobile collisions, slip and falls, and sport/recreation accidents.

Christine received a Bachelor of Science in Physics from Hamline University and a Master of Science in Biomedical Engineering from University of Iowa. She also completed a Master of Engineering Management from Christian Brothers University.

Regulatory is a necessary step on the way to bringing a product to market, whether you like it or not.

The regulatory affairs role in the medical device industry provides a conduit to FDA oversight ensuring that product on the market is safe and effective. This seminar will cover basic concepts of regulatory affairs with a concentration towards the U.S. It is intended for those currently in the medical device industry to learn more about the regulatory function and how regulatory interacts with other departments. It is also intended for those desiring to become part of the medical device industry to learn the basics of regulatory affairs.

SEMINAR SCHEDULE:

7:30 - 8:00 a.m..... Continental breakfast
8:00 - 9:45 a.m..... Seminar
9:45 - 10:15 a.m Break
10:15 a.m. - noon Seminar

Please RSVP to memp@cbu.edu by Monday, October 12, 2009.

For more information about the seminar, please contact the Graduate Engineering Office at (901) 321-3282 or memp@cbu.edu