Quality of Medical Devices Graduate Certificate

The Graduate Certificate in Quality of Medical Devices was created to meet the needs of the Medical Device industry. It expands knowledge to improve job performance and increase the opportunities for advancement in the medical device industry.

Required Courses:

- **ENGM 605. Quality Assurance**: Statistical quality control methods for products and services; design of quality control systems; control of quality control inputs. Lecture and problem solving. Three credits (*Instructor: Susan Bell*).


- **ENGM 650. Regulatory Affairs and Quality Systems**: Develop a basic understanding of regulatory affairs and quality systems related to medical devices to provide a better cross-functional working relationship and process efficiency. Three credits (*Instructors: Christine Scifert and Kimberly Strohkirch*).

- **ENGM 652. Quality Systems for the Medical Device Industry**: Develop a basic understanding of quality system requirements for medical device manufacturers based on both FDA and ISO standards. Three credits (*Instructor: Susan Bell*).

Instructors:

- **Susan Bell** is Assistant Professor in the Mechanical Engineering Technology department at Southwest Tennessee Community College. She has an ASET from Southwest, a BSET from the University of Memphis, as well as a MEM from CBU. Susan retired from Smith & Nephew in 2013 after 24 years as a Quality professional. She is a member of the American Society for Quality & holds several certifications including Certified Quality Engineer, Certified Quality Auditor, Certified Biomedical Auditor, and Certified Manager of Quality/Operational Excellence.

- **Dr. Asit Ray** is a professor of chemical engineering at CBU. He earned his Ph.D. from Lehigh University and has over 20 years of teaching/research experience at Auburn and CBU. Dr. Ray spent seven years in the polymer industry, and was four times a NASA/ASEE Summer Faculty Fellow engaging in polymer research at NASA Kennedy Space Center and Langley Research Center. He is actively engaged in laboratory research in polymeric and biomaterials and has published over fifteen refereed papers. He is a member of Institute of Packaging Professionals.

- **Christine Scifert** has been a managing partner with Memphis Regulatory Consulting, LLC for over 5 years and supports large and small medical device companies related to regulatory, quality and clinical activities. 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 Masters in Engineering Management from Christian Brothers University.
• **Kimberly Strohkirch**: Kim has been a managing partner with Memphis Regulatory Consulting, LLC for over 5 years and supports large and small medical device companies related to regulatory, quality and clinical activities. 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 Masters of Science in Engineering from the department of Aeronautics and Astronautics from Purdue University. She has completed other graduate engineering courses at The University of Memphis with an emphasis in materials.

• **Yongquan Zhou** is a project engineer in Packaging Design and Development at FedEx Corp. He received his B.E. in packaging engineering and M.E. in mechanical engineering from the Wuxi Institute of Light Industry in China, and his M.S. in packaging science from the Rochester Institute of Technology. Mr. Zhou is a Certified Packaging Professional (CPP) with more than 30 years of experience in the packaging industry, academic classrooms, and research and testing laboratories. Mr. Zhou serves on various IoPP, ASTM, and ISTA technical committees, and was an IoPP AmeriStar Packaging Competition judge from 1997 to 2001. He has published articles in *Packaging Technology and Engineering* and other magazines.

**Admission Requirements:**

• A complete application form (online at [http://cbu.edu/future/apply.html](http://cbu.edu/future/apply.html)) with application fee.

• One official transcript of previous academic credits from each of the colleges or universities previously attended.

• Two letters of recommendation from former teachers or immediate supervisors qualified to attest to the applicant’s preparation and ability to perform graduate study.

• Current resume.

• Personal statement describing the fit between career objectives and a master’s certificate.

• For International Students Only:
  o If English is not the native language or was not the language of instruction for a foreign applicant’s baccalaureate degree, a minimum proficiency in English equivalent to a TOEFL score of 550 (paper-based test), 231 (CBT/computer-based test), or 79 (iBT/internet-based test) must be demonstrated.
  o World Education Services (WES) Comprehensive Course-by-Course Report. This evaluation is required for those whose highest degree is from a foreign University.

**FOR MORE INFORMATION, CONTACT THE GRADUATE ENGINEERING OFFICE AT 901-321-3410 OR MEMP@CBU.EDU.**

11/10/2014