

# Clinical Engineering: Curriculum Development at Miami University

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## Abstract

In order to address the needs of hospitals with respect to recruiting clinical engineers, and that of medical device manufacturing companies that employ engineers and professionals who are well versed in regulatory affairs and medical device design, new curriculum at Miami University has been designed. Beginning this calendar year, the coursework related to new minors in clinical engineering and regulatory affair is being offered to the students. In addition, graduate level coursework has been developed for students who want to pursue higher studies. The overall eight broad areas of learning are explored: (i) introduction to profession, (ii) instrumentation related to hospitals and biomed profession, (iii) design of medical devices, (iv) hospital rotation, (v) regulatory affairs, (vi) clinical trials, and (viii) project management. The program combines technical skills with soft skills that are needed to be successful in the profession. Another unique feature of the program is that for most part courses are being offered online.

## Keywords

Clinical Engineering, Medical Device, Engineering Design, Regulatory Affairs

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## Biographies

**Dr. Lei Kerr**, PhD is the founding member of the clinical engineering program at Miami University where she serves as a professor in the Chemical, Paper and Biomedical Engineering department since 2004. She received her PhD in Chemical Engineering from the University of Florida.

**Dr. Shashi Lalvani**, PhD, is the founding chair of the chemical engineering and bioengineering majors at Miami University where he serves as a professor in the Chemical, Paper and Biomedical Engineering department since 2003. He is a co-founder of the clinical engineering program led by Lei Kerr.