Drug and Device Development

Course Director: J. Matthew Luther, MD, MSCI
Summer [3 hours credit] Luther

This seminar styled course is designed to provide an overview of the drug and device development process and will include issues of drug discovery, pre-clinical drug development, Phase I through IV human testing, device development and the role of the FDA in regulatory affairs. Learning objectives will include:

1. To provide an overview of the drug development process from initial compound discovery, through clinical trials, to post-marketing issues;

2. To provide an overview of device development, and to contrast this to the process of drug development.

3. To provide some insight into the function of the Food & Drug Administration (FDA).

4. To discuss topical issues related to drugs, devices, and the FDA by using current events in the news.