COURSE DESCRIPTION  This course teaches you to write methods and procedures complying with the FDA’s Good Manufacturing Practices regulations. Instruction provides interpretations of GMP’s through case studies, guest lectures, reference materials and handouts. Topics include:

- The Food, Drug and Cosmetics Act.
- The Regulatory Structure.
- The Device and Drug GMP.
- State and Federal Requirements.

PRE-REQUISITES  None.

TEXT  Code of Federal Regulations, Section 21 Part 210 & 211.
- Part 210 – Current Good Manufacturing Practice in Manufacturing, Processing, Packing or Holding of Drugs, General.
- Part 211 – Current Good Manufacturing Practice (cGMP) for Finished Pharmaceuticals.

OBJECTIVES  • Learn how to inspect your facility and procedures by using FDA guidelines and by designing your own internal audit forms.