Regulatory agencies around the world use inspections/audits to ensure that companies that are manufacturing health care products (GMP), conducting analytical and animal studies (GLP) and/or human clinical trials (GCP) that comply with the regulatory requirements defined by their country’s legislation and align with industry best practices as outlined by the International Council on Harmonization (ICH). This course will introduce the students to all aspects of auditing as it relates to development and manufacturing for all types of healthcare products (drugs, devices, dietary supplements and biologics).

Each student will be required to attend Day 1 of the course where an overview of auditing principles, documentation and best practices will be introduced. A second class day of your choice that is specific to the auditing of either Good Laboratory, Good Manufacturing or Good Clinical Practices will also be required. The deliverable for this course will be an Audit Plan, including Process Flow and Checklist for the applicable best practice.

For more information or to register, contact Alexander Alschuler (alschule@usc.edu). NOTE: The last day to register is Friday, September 29.