The goal of this course is to give graduate students exposure to the statistical issues and methodology facing statisticians who design and analyze biopharmaceutical clinical trials with a focus on those pertinent to International Regulatory bodies such as the Food and Drug Administration, Europe's EMEA, or Japan's MHW. Since the early 1990's there are various published documents providing both guidance for statistical practice and background documents concerning aspects of statistical methodology. Examples include the International Conference on Harmonization (ICH) guidances, EMEA's "Points to Consider", and FDA guidelines. Virtually all of these are web-based publications. In this course, we will examine many of these documents focusing on the statistical details and relate these to statistical theory, thereby obtaining a better understanding of the guidances' intents. This understanding will foster our ability to develop new statistical methods in the spirit of these guidances. In order to do so, we will read current statistical research papers to connect select topics in the literature to the guidances. In addition to providing students with an appreciation of global statistical practice, a secondary goal is to suggest areas of further statistical research.

This is a seminar course and no more than 15-20 students are expected. There will be no exams and students will be asked to work individually and in groups for two major presentations during the semester.

This is a second-level applied statistics course suitable for graduate students in statistics or biostatistics. Required background is a sequence in applied statistics (e.g., STAT2131/2132 or BIOSTAT2049, and familiarity with linear models), a math/stat sequence (e.g., STAT1631/1632 or BIOSTAT2043/2044) and some additional exposure in applications of statistics/biostatistics either through course work, consulting, or employment experience. Some exposure to clinical trials issues (e.g., BIOSTAT2062 or EPI2181) would be beneficial, but is certainly not necessary.

The course instructor has published extensively on clinical trials methodology and has had many years of experience in the design and analysis of biopharmaceutical trials, as well as serving on Food and Drug Administration Advisory Committees. In addition he has offered mini-workshops on the ICH Efficacy Guidelines. For further information contact Allan Sampson at 412-624-8372 or asampson@stat.pitt.edu.

This course is offered on an infrequent schedule, and was last taught in Fall 2007.