

Clinical Trials Program at UCSD Extension Celebrates 10th Anniversary; Announces Response to New FDA Regulations

May 18, 2007

Henry DeVries

The Clinical Trials and Research Program at the University of California, San Diego will celebrate a 10th anniversary with a reception from 5 to 7 pm Wednesday, May 23 in the central patio courtyard of the UCSD Extension Complex at Muir College Drive and North Torrey Pines Road in La Jolla.

Designed in partnership with leaders in the pharmaceutical and biomedical research industry, the UCSD Extension clinical trials certificate programs continue to provide leading-edge practical education, preparing a highly trained and globally competitive workforce for the local, national, and international biotech communities. New courses, created in response to new FDA regulations and industry standards, will be revealed at the reception.

The first educational program of its kind, more than 2,300 students have participated in the program from such local and national companies as Amilyn, Pfizer, Novartis, Gen-Probe, Biogen Idec, Neurocrine, and Quintiles. In addition to having a tremendous local impact, the program continues to increase its national reputation and global reach by attracting about 7 percent of its students from New York, Massachusetts, Florida and more than a dozen other states plus international students from England, Japan, Australia, New Zealand, Singapore, Denmark, Canada, Jordan and other foreign countries.

Pharmaceutical and medical device development has become one of the premier industries of the 21st century, with San Diego taking an international role in biomedical research and biotechnical development. Critical to the industry are clinical trials, the experiments to evaluate new drugs, medical devices or other interventions on patients in strictly scientifically controlled settings that are required for regulatory authority approval of new therapies.

Today's clinical trials require careful planning and cooperation among a variety of professionals within the pharmaceutical/biotechnical industry, clinical practice, and governmental or industrial agencies who need both specialized expertise and general familiarity with a variety of procedures.

However, before the UCSD Extension certificate program was developed, exposure to this knowledge was difficult to acquire and was frequently obtained only through on-the-job experience over a number of years. During the past decade nearly a thousand professionals have received either the Professional or Specialized certificates.

The Professional Certificate in Clinical Trials Design and Management is 200+ hours in length with about half of the classes offered online, and the rest offered on weeknights and Saturdays. The program may be completed in as little as six months, although most students prefer to take one to two years to complete. The typical cost is usually about \$3,100-\$3,700, depending on the student's choice of electives.

The Specialized Certificate in Clinical Trials Administration is 100 hours in length and costs \$1895 complete. A condensation of the required courses from the design and management certificate and a number of the most relevant elective courses, the administration program starts with a five-day workshop (upcoming session: August

6-10, 2007 in San Diego), followed by three online classes, and concludes with a two day workshop on February 28-29, 2008.

Clinical trials have come a long way since James Lind's 1747 demonstration that citrus fruits cure scurvy. Lind, a Royal Navy doctor who said scurvy caused more deaths in the British fleets than French and Spanish arms, tested various foods to discover that groups of sailors given oranges and lemons recovered from scurvy in only 6 days.

In 2007 global pharmaceutical research and development spending is projected to top \$100 billion. One of the most significant challenges facing pharmaceutical and biomedical companies in the coming decade is clinical trial recruitment. To manage these challenges, companies are looking to conduct clinical trials outside the U.S., particularly in Asia, Central and South America, and Russia.

Media Contact: Henry DeVries, (858) 534-9955 or 619-540-3031