13 January 2014

Amarex's Dr Mukesh Kumar to conduct workshops in Argentina on preparation of non-U.S. generated clinical and manufacturing data to support US FDA approval of medical products

Amarex Clinical Research's Regulatory Affairs Director Dr. Mukesh Kumar, along with Ms. Paula Pirson of Argentina's ANMAT, will present two 2-day workshops in Argentina in February and March. The workshops will provide thorough instructions on the best preparation of clinical and manufacturing data to achieve U.S. FDA marketing approval for the sale of medical products in the U.S.

Intended for management level professionals in the biotech industry, the workshops will help Latin American companies prepare the most critical element of successful product introduction into the U.S. - the validity, accuracy and format of product data. Dr Kumar stated, "Amarex is pleased to have this opportunity to help Latin American biotech innovation become a reality in the US marketplace."

The first workshop will occur February 27-28, 2014 in Buenos Aires, and the second March 3-4, 2014, in Mar del Plata. For more information, please visit FDA Map or contact info@amarexcro.com to request a workshop brochure.

Amarex is a global Contract Research Organization (CRO) that provides complete clinical product development services to bioscience companies to achieve FDA approval for their new medical products. General service categories include: 1) product development plan creation, 2) product safety and efficacy testing, and 3) applications to the FDA for marketing approval of new or improved medical products.

Contact:
Mirtha Lopez
mirthal@amarexcro.com
20201 Century Blvd, 4th Floor
Germantown, MD 20874
USA
+1-301-528-7000