

## ISO certification for Semler Research Center

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Semler Research Center (SRC), a leading Indo-US based clinical research organization (CRO), has been awarded International Standards Organization's (ISO) 9001:2008 and ISO 27001:2005 certification in recognition of its standardized best practices and effective IT infrastructure deployment for data security across the organization.

The move comes as SRC looks to leverage on domestic and international expertise to embrace global standards of service provision in compliance with applicable regulatory requirements to further its business objectives and scientific goals, and provide superior quality to its sponsors. The scope of the registration includes bio-availability and bio-equivalence, clinical development, scientific and medical writing, and pharmaceutical development services.

Speaking on the occasion, Dr Krathish Bopanna, president and executive director, said, "The ISO 9001 certification is a guarantee of our excellence in service and will certainly reinforce our credentials as a leading CRO. This achievement of certification confirms our commitment to quality and meeting the requirements of customers resulting in customer satisfaction without compromising the regulatory requirements."

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### Quintiles invests in cancer company

Quintiles invested in a new company, Oxford Cancer Biomarkers, that provides oncology consulting services and new cancer biomarkers, the key to scientific selection of the right drug for the right patient. Oxford Cancer Biomarkers will develop biomarkers using CancerNav, a proprietary DNA and protein-based assay technology platform, invented by Mr Nick La Thangue, chair of Cancer Biology at Oxford University.

Mr David Kerr, professor of cancer medicine at the University of Oxford and a world-renowned expert in cancer clinical

research and policy development, will serve as the new company's chief medical officer. Quintiles is the largest shareholder in Oxford Cancer Biomarkers. The other major shareholders are the University of Oxford and professors La Thangue and Kerr.

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## **ICON in partnership with Shire Pharma**

ICON, a global provider of outsourced development services to the pharmaceutical, biotechnology and medical device industries, signed a strategic partnership with Shire Specialty Pharmaceuticals to serve as the sole global provider of central laboratory services and one of the two strategic partners for clinical development services.

As a partner for clinical development, ICON will provide Shire with a full range of services, including site and country feasibility, ethics and regulatory submissions, clinical trial monitoring, project management, site and study team support, medical management and medical data review. Shire will also utilize ICON Central Laboratories' extensive test menu from its global network of laboratories.

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## **Clinical trial to begin for Sumagen's HIV vaccine**

Omnia Biologics' customer Sumagen will begin clinical trials of their revolutionary HIV vaccine design. The Food and Drug Administration-approved phase I clinical trial will begin in early 2012.

The design and testing of the vaccine was spearheaded by Dr Chil-Yong Kang, a professor at the University of Western Ontario's medical school. Dr Dale Vander Putten of Omnia Biologics, said, "To date, experimental HIV vaccines have been largely either subunit vaccines or used non-HIV vaccine vectors and have universally failed in the clinic."

Dr Kang and his team took a page from the successes of polio, flu, rabies and other highly effective vaccines focusing instead on a viral vaccine that is genetically attenuated, irradiated and chemically inactivated," he said.

Omnia, a drug development and manufacturing services provider, participated in the international effort to propel this important advance into the clinic by providing process and assay development services, and manufacturing the vaccine under GMP for South Korean biotech company Sumagen and their academic partner Dr Kang and UWO. Preclinical testing has shown the vaccine to be safe and produce strong immune responses.

Mr Steve Hubert, vice president of operations at Omnia, said, "It is especially heartening for our team at Omnia to be able to translate this important technology into the clinic as other well established contract manufacturers failed in their attempts to produce the vaccine at clinical scale."