

Loma Linda University and Siemens' PETNET Solutions, Inc. announce operational state-of-the-art PET production and research facility to advance molecular imaging



LOMA LINDA UNIVERSITY
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LOMA LINDA, CA, June 2, 2016 – Loma Linda University and Siemens' PETNET Solutions, Inc. completed and brought operational a state-of-the-art PET production and research facility to advance molecular imaging.

Molecular imaging is *“the visualization, characterization and measurement of biological processes at the molecular and cellular levels in humans and other living systems.”*

The facility is located on the Loma Linda University Health campus and includes a dedicated, fully-equipped research radiochemistry lab operated by Loma Linda University, as well as a radiopharmacy and commercial production facility operated by Siemens' PETNET Solutions. The center has two cyclotrons, one dedicated to research production and the other to the commercial operation, each capable to support the other endeavor for backup to ensure the highest reliability.

“With this investment, in addition to the existing pre-clinical imaging lab, Loma Linda University Center for Imaging Research has exponentially advanced its research capabilities and potential to advance molecular imaging,” H. Roger Hadley, dean of Loma Linda University School of Medicine, said. “In April, we completed the build-out of our radiochemistry lab with cutting edge technology and equipment. This offers significant testament to the commitment that Loma Linda University Health has for advanced cancer research.”

“We will be ready for human subject research soon,” Hadley continued.

The opening of this center lays the groundwork for the expansion of new biomedical and molecular imaging research, enabling further exploration in personalized medicine.

Radiochemistry, the [chemistry](#) of [radioactive](#) materials, incorporates radioactive [isotopes](#) into molecules. The addition of radioactivity provides the mechanism to image the molecules for pre-clinical development work and in the human body, and for the properties and chemical reactions of the molecules to be studied.

Due to the short half-life of the isotopes, it is critical that the radiopharmacy and radiochemistry labs are located next to the cyclotron which produces the isotopes that are then chemically bound to molecules in the labs.

The new Loma Linda University Center for Imaging Research radiochemistry lab offers state-of-the-art equipment for this purpose, including a synthesis lab with hot cells to protect operators while working with the isotopes, a quality control unit to ensure the products are of suitable quality and pure, a clean room hot cell for sterile manufacturing, and various automated synthesis platforms to manufacture a range of products. These platforms include a dedicated C-11 acetate module, a C-11 multiproduct module, a Fluorine-18 module and an O-15 water module.

The LLU Radiochemistry lab capability includes pre-clinical use and clinical trials. This month, equipment for purification of the agents manufactured in the radiochemistry lab will be installed, the last element required for human subject clinical trials to begin.

Barbara Holshouser, PhD, medical physicist and Director of the Center for Imaging Research said, "The Center will act as a core facility to provide radiochemistry and imaging expertise to researchers and clinicians at LLU and their collaborators who want to conduct basic science research and clinical trials using molecular imaging and therapy agents."

Holshouser continues, "Molecular medicine is the future of medicine that personalizes clinical care by characterizing specific disease processes at the cellular level in individual patients. For example, there are molecular imaging agents designed to target specific cancers such as prostate or breast cancer for enhanced detection of metastatic lesions. Once the lesions are visualized, we can use molecular therapies designed to target and deliver localized radiation to the metastatic lesions. This one day may diminish the need for more toxic treatments such as chemotherapies or large area radiation."

The first LLU project will be to finish the current study underway on neuropathic pain in patients with spinal cord injury, a Department of Defense (DoD) funded study. Several DoD grants amounting to millions of dollars provided the funds for Loma Linda to purchase a cyclotron and other equipment. Additional studies will involve Alzheimer research, and the Loma Linda University Center for Imaging Research will continue to apply for research grants and participate in clinical trials.

"Loma Linda University Center for Imaging Research is registered with the Clinical Trials Network of the Society of Nuclear Medicine and Molecular Imaging. LLU is one of a select number of sites on the west coast with the capability for production of PET radiopharmaceuticals as well as imaging capabilities that will provide numerous research opportunities in all disciplines", said Holshouser.

Another component of the new facility is the radiopharmacy and commercial manufacturing operation run by Siemens' PETNET Solutions. Through this facility, PETNET Solutions supplies clinical doses of radiopharmaceuticals to aid in the diagnosis of cancer and other diseases. Biomarkers produced by Siemens' PETNET Solutions are also supplied to researchers interested in investigating new applications or to use as screening tools in support of the clinical trials of therapeutics.

Clinical doses are generated daily on customer demand due to the short life of the products. They are shipped in the early morning throughout Southern California, arriving in hospitals and imaging centers on time to enable patient scanning.

Barry Scott, head of Siemens' PETNET Solutions commented, "We are very proud of this high-capacity, versatile facility which will enable us to produce a wide range of biomarkers to serve patient needs. The collaboration with Loma Linda University Health is a perfect synergy, where we are able to supply clinical products today and LLU is able to conduct research to answer health care challenges through imaging. Siemens' PETNET Solutions' expertise in cyclotron operations and GMP production are of benefit to both efforts, which makes for an efficient use of resources. This site is an important part of our network to ensure we can meet the radiopharmaceutical demand in Southern California".

Siemens' PETNET Solutions provides the maintenance and operation of both cyclotrons and supplies Loma Linda University researchers with clinical doses of specific agents on an as-needed basis. These products are frequently very short-lived to where they must be made on-site and just-in-time to support LLU research, while others can be distributed regionally.

Groundbreaking for the facility took place in January 2014. Construction was completed in February 2015, followed by a rigorous process of validation, qualification, inspection and licensing to ensure the highest quality and compliance with the U.S. Food and Drug Agency (FDA) and State requirements. Siemens' PETNET Solutions shipped the first clinical dose from the center on September 17, 2015.

Siemens' PETNET Solutions Inc. is a wholly owned subsidiary of Siemens Medical Solutions USA, Inc., and operates 46 production locations worldwide. The facility at Loma Linda University is the fifth Siemens' PETNET Solutions site in California.

¹ Society of Nuclear Medicine, *mi gateway newsletter*, Vol 1, Issue 1, January 2007: 3.

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Loma Linda University Health includes Loma Linda University's eight professional schools, Loma Linda University Medical Center's six hospitals and over 800 faculty physicians located in the Inland Empire of Southern California. Established in 1905, Loma Linda University Health is a global leader in education, research and clinical care. It offers over 100 academic programs and provides quality health care to

40,000 inpatients and 1.5 million outpatients each year. A Seventh-day Adventist organization, Loma Linda University Health is a faith-based health system with a mission "to continue the teaching and healing ministry of Jesus Christ."

Siemens AG (Berlin and Munich) is a global technology powerhouse that has stood for engineering excellence, innovation, quality, reliability and internationality for more than 165 years. The company is active in more than 200 countries, focusing on the areas of electrification, automation and digitalization. One of the world's largest producers of energy-efficient, resource-saving technologies, Siemens is No. 1 in offshore wind turbine construction, a leading supplier of combined cycle turbines for power generation, a major provider of power transmission solutions and a pioneer in infrastructure solutions as well as automation, drive and software solutions for industry. The company is also a leading provider of medical imaging equipment – such as computed tomography and magnetic resonance imaging systems – and a leader in laboratory diagnostics as well as clinical IT. In fiscal 2014, which ended on September 30, 2014, Siemens generated revenue from continuing operations of €71.9 billion and net income of €5.5 billion. At the end of September 2014, the company had around 357,000 employees worldwide. Further information is available on the Internet at <http://www.siemens.com>