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These medical isotope-fueled compounds are being used for the diagnosis and treatment of cancer, neurological disorders, and cardiovascular disease. Jay Ripton | Aug 24, 2023

The Supply and Availability of Radiopharmaceuticals: The Importance of the Last Mile

As the field of biotechnology advances, the ability to treat previously incurable diseases is becoming more of a reality. And one of the champions that's gaining a lot of attention in the space is radiopharmaceuticals. These medical isotope-fueled compounds are now being used for the diagnosis and treatment of health conditions including cancer, neurological disorders, and cardiovascular disease. And because of this, their availability and reliable supply have become a top priority for healthcare professionals and patients alike.



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What are Radiopharmaceuticals?

Radiopharmaceuticals are biological compounds that contain radioactive isotopes. These isotopes emit radiation that can be delivered and detected using specialized equipment, allowing doctors to see and pinpoint the internal structures and functions of organs and tissues in the body. Radiopharmaceuticals can be administered orally, intravenously, or by inhalation.

"One of the most common uses of radiopharmaceuticals is in cancer diagnosis and treatment," said RLS CEO Stephen Belcher. "Cancer cells grow and divide rapidly and can be identified by the high rate of metabolism. Radiopharmaceuticals are designed to bind to specific molecules on cancer cells, allowing physicians to identify and locate the tumor. They can also be used to directly target cancer cells, killing them and reducing the growth of tumors without harming healthy tissues."

RLS is the nation's only accredited nuclear pharmacy group, and it owns and operates 31 radiopharmacies across 18 states. The company offers an extensive portfolio of diagnostic products and has become one of the fastest-growing distributors of radiopharmaceutical therapeutics. According to sources, the company dispenses 100% of injectable unit dose products in clean rooms built to ISO 1644-1 specifications. RLS currently has more than 1,500 customers.

Supply Chain Challenges

The radiopharmaceutical supply chain process represents a complex system involving several crucial steps starting from production, synthesis, quality control, and dispensation to patients. A robust supply chain process ensures these life-saving compounds are readily available at the right time and place. This process begins with radioisotope production, which involves using higherenergy elements like uranium and thorium to produce isotopes such as actinium-225 (Ac-225), Lead-212 (Pb-212), molybdenum-99 (Mo-99), iodine-131 (I-131). These isotopes are then transported to different laboratories worldwide, where they undergo purification to produce radiopharmaceuticals.

"Once radiopharmaceuticals are produced, they undergo rigorous quality control tests to ensure they meet regulatory standards," said Belcher. "These strict quality assurance parameters guarantee safety and efficacy. After passing all tests, these radiopharmaceuticals are transported to hospitals and clinics for the benefit of patients."

However, like all good things, getting radiopharmaceuticals to patients is an intricate process that involves multiple stages and stakeholders. The most critical of which is the last mile, as it determines the success of the entire process.

The Last Mile

The importance of the last mile in the radiopharmaceutical supply chain lies in its impact on patient outcomes. Without quality and reliable radiopharmaceuticals delivered safely and timely, the full potential of these molecular imaging probes and therapies will not be realized. Patients who need timely diagnosis and treatment may suffer delays, increased costs, or even risk of further complications and progression of their conditions. Therefore, the last mile is crucial in ensuring that radiopharmaceuticals reach their intended patients timely, safely, and with their full quality intact.

"No matter how much work goes into developing a radiopharmaceutical, they are useless unless the right dose arrives at the right hospital, the right department, and to the right patient, at the right time," said Belcher. "Medical isotopes have an extremely short half-life, so it is essential that the compounds reach patients quickly. Inconsistencies in the last mile could lead to delays that affect a drug's stability, reducing its efficiency and ultimately patient care."



Importance of the Last Mile

The last mile of radiopharmaceutical delivery is especially important because these drugs have a limited shelf-life and are sensitive to external factors that can affect their potency and safety. For example, some radiopharmaceuticals require refrigeration to maintain their quality while others need to be prepared or activated shortly before use. Any delay or mishandling during the last mile can compromise the drug's effectiveness, leading to inaccurate diagnoses or ineffective treatments. And that's where radio pharmacies come in.

"The last mile is the final step in the radiopharmaceutical supply chain," said Belcher. "It's where the radiopharmaceuticals are checked, transported, and traced to ensure patient safety, regulatory compliance, and timely delivery."

Radiopharmacies are an essential component of the modern healthcare system, providing crucial support for physicians, researchers, and patients. Their services are vital to the diagnosis and treatment of complex and challenging medical conditions, providing precise and targeted therapy while maintaining the highest standards of safety and quality. The field of radiopharmaceuticals continues to advance, and radiopharmacies are at the forefront of these developments, providing cutting-edge technology, research, and clinical trials. The future of radiopharmacies is bright, and their role in improving human health is set to continue to grow.

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The RefleXion X1 PET-CT machine with Scintix therapy is a hybrid platform that uses both biologic technology for tumors in motion and anatomic capabilities through X1's fan-beam kVCT.

Katie Hobbins | Aug 25, 2023

RefleXion Medical, a therapeutic oncology company, has treated its first patient with <u>Scintix</u> biology-guided radiotherapy on the RefleXion X1 PET-CT machine. Scintix therapy is a radiopharmaceutical-directed treatment for early and late-stage cancers. The modality uses a single radiotracer injection to transform cancer cells into real-time biological beacons, which uses the individual biology of each tumor to drive its own treatment by controlling external-beam radiotherapy delivery to multiple tumors. The RefleXion X1 PET-CT machine with Scintix therapy is

a hybrid platform that uses both biologic technology for tumors in motion and anatomic capabilities through X1's fan-beam kVCT.

In February, the biology-guided radiotherapy was <u>FDA cleared</u> to treat patients with lung and bone tumors — these "tumors may arise from primary cancers or from metastatic lesions spread from other cancers in the body," according to RefleXion. Prior to the February clearance, Scintix was also designated as a Breakthrough Device for lung tumor treatment due to its potential to "precisely manage tumor motion."

The first patient was treated at Stanford Medicine Cancer Center and, over the coming weeks, other cancer centers in the United States will also begin offering the therapy, including City of Hope Comprehensive Cancer Center in Southern California, and sites in Pennsylvania and Texas. Additionally, Scintix therapy will be available in New Jersey, Connecticut, and Oregon by the end of 2023, according to the company.

For more information on Radiopharmaceuticals, click: <u>The Supply and Availability of</u> <u>Radiopharmaceuticals</u>

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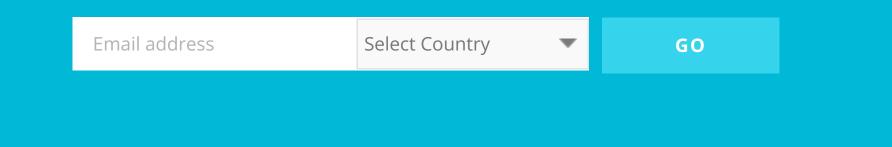


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