

Translational Imaging Center

# Cyclotron Core and Nuclear Pharmacy Core

## Cyclotron Core

The Cyclotron Core was started to address the unmet needs of bringing investigational radiopharmaceuticals within patient reach. Few academic institutions have a cGMP-compliant cyclotron facility committed to manufacturing research radiopharmaceuticals, which attracts many investigators and industry sponsors aiming to provide clinical translation of promising radiopharmaceuticals, particularly in preclinical to early phase clinical trials. The Cyclotron Core collaborates with both the Nuclear Pharmacy and PET Imaging Core to provide unmatched translation of novel radiotracers into clinical practice. Additionally, this Core supports the Preclinical Imaging Core with radioisotopes and radiotracers.

### Services

- Contract manufacturing for both in-house and industry sponsored research radiopharmaceuticals
- Radiopharmaceutical manufacturing process validation
- Perform radiodistribution and radiometabolite testing to determine the degree metabolites will interfere with a diagnostic scan.
- Provide preclinical evaluation of radiopharmaceutical toxicity studies
- File regulatory applications for submission to the FDA such as Investigational New Drug (INDs) and Abbreviated New Drug (ANDAs) applications
- Internal quality control testing for radiopharmaceuticals (i.e. radiochemical and radionuclidic tests, pyrogen and sterility tests)

### Equipment

- General Electric (GE) PETtrace 16.5 MeV negative ion isochronous cyclotron
- Nine ventilated hot cells for housing radiosynthesis modules
- Six radiosynthesis modules for production of C11, F18, Ga68, and NH3
- Fully equipped quality control laboratory with four Agilent HPLC's, two Scion GC's, two TLC scanners, and an MCA
- Two ISO 5 dispensing hot cells with telemanipulators for radiopharmaceutical patient specific dose dispensing.
- ISO 5 clean room for aseptic assembly of sterile components in manufacturing



## Nuclear Pharmacy Core

As one of the nation's few academic research nuclear pharmacies with access to an onsite cyclotron, the Nuclear Pharmacy Core collaborates with physicians and researchers from various specialties such as oncology, cardiology, urology, and neurology to safely compound, prepare and dispense sterile radiopharmaceuticals for patient-specific diagnostic imaging scan or therapeutic treatment. This Core coordinates with the cyclotron for radiopharmaceutical manufacturing and the Positron Emission Tomography (PET) Imaging Core for in-house diagnostic imaging providing translation of novel radiotracers into clinical practice.

### Services

- Authorize Nuclear Pharmacists and Technicians will compound, prepare, and dispense FDA approved clinical and investigational radiopharmaceuticals
- Review clinical trial drug study protocols for site initiation
- Assess drug safety (pharmacovigilance) profile
- Advise on facility design for implementation of radiotherapeutic drugs
- Provide expertise on United States Pharmacopeia (USP) 825 compliance of radiopharmaceuticals
- Establish environmental monitoring program for maintaining sterile processes
- Perform acceptable quality control set forth by USP Monographs or Manufacturer's specifications
- Distribute internal and external radiopharmaceuticals

### Equipment

- USP 825 and State Board of Pharmacy compliant nuclear pharmacy facility with aseptic ISO 5 dispensing hot cell and telemanipulators for radiopharmaceutical dispensing
- USP 797 compliant dedicated ISO 5 clean room for nonradioactive aseptic preparations and manufacturing processes

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