Associate Director, Regulatory & Safety, PET Center

Position Title	Associate Director, Regulatory & Safety
Working Title	Associate Director, Regulatory & Safety, PET Center
Profession	Pharmacist (PharmD)
Department	Radiology, Division of Molecular Imaging and Therapeutics Research
Center	Columbia University PET Center
Reports To	Director, PET Center
Location	Columbia University Irving Medical Center
Position Type	Full-time
Appointment	Posted at all faculty ranks (Assistant to Associate Professor), commensurate with experience
Salary Range	$190,000-$215,000

Position Summary

The Associate Director, Regulatory & Safety, PET Center is a pharmacist (PharmD) who provides leadership and operational oversight for radiopharmaceutical production, quality control, dispensing, and clinical PET imaging, and serves as a key institutional resource for patient safety, quality assurance, GMP manufacturing, regulatory affairs, and FDA compliance.

The position operates at the intersection of clinical nuclear medicine, radiochemistry, radiopharmaceutical manufacturing, radiation safety, and regulatory affairs. The successful candidate will have experience with radiopharmaceutical production and clinical PET operations and will possess a strong understanding of FDA and other federal and state regulatory requirements governing radioactive materials, radiopharmaceuticals, and investigational drug products, including documentation of manufacturing processes, quality-control testing, batch records, deviations, corrective and preventive actions, and preparation for regulatory inspections. The role carries primary responsibility for maintaining regulatory and quality systems for the PET Center and serves as a principal point of contact for FDA inspections, radioactive-material licensing, radiopharmaceutical regulatory requirements, and institutional quality and safety programs.

The Associate Director will work closely with radiochemists, nuclear medicine physicians, PET Center leadership, medical physicists, radiation safety personnel, research investigators, quality personnel, and institutional regulatory offices to ensure that radiopharmaceuticals are produced and administered safely, consistently, and in compliance with applicable regulatory and institutional requirements.

This position represents an opportunity to help build and establish a state-of-the-art academic PET and radiopharmaceutical program supporting clinical care, translational research, and development of novel radiopharmaceuticals.

Key Responsibilities

Clinical PET and Radiopharmaceutical Operations

- Provide pharmacy expertise and operational oversight for clinical PET radiopharmaceutical procurement, receipt, storage, preparation, dispensing, and administration.
- Collaborate with nuclear medicine physicians, technologists, and other clinical personnel to ensure timely and appropriate availability and use of radiopharmaceuticals for clinical and research imaging.
- Develop and implement SOPs and quality processes for clinical radiopharmaceutical operations.
- Provide leadership for patient-safety and quality-assurance processes related to radiopharmaceutical preparation, dispensing, administration, and clinical PET operations.
- Support integration of new radiopharmaceuticals and imaging agents into clinical practice.

Radiopharmaceutical Manufacturing and Radiochemistry

- Provide pharmacy and manufacturing expertise for production of PET radiopharmaceuticals in accordance with applicable FDA, USP, institutional, and radiation-safety requirements.
- Work closely with radiochemists and production personnel on development, validation, optimization, and implementation of radiopharmaceutical manufacturing processes.
- Maintain technical familiarity with automated radiochemistry synthesis equipment, including GE FX, FASTlab, and comparable automated synthesis systems, as well as associated modules, consumables, and production workflows.
- Review and approve production documentation, including master production records, batch production records, equipment logs, and related quality documentation.
- Provide pharmacy oversight at the interface between radiochemistry production and clinical PET operations, ensuring that radiopharmaceuticals released for patient use meet established specifications and requirements.
- Support translation of experimental radiopharmaceutical production methods into reproducible, documented, and clinically appropriate manufacturing processes.

FDA Regulatory Compliance, Quality Systems, and Inspection Readiness

- Serve as a principal resource for FDA compliance, regulatory inspections, and federal and state requirements governing radiopharmaceuticals and radioactive materials.
- Maintain inspection readiness and coordinate preparation for FDA inspections, regulatory audits, and institutional reviews.
- Participate directly in inspections and serve as a subject-matter expert regarding radiopharmaceutical production, quality control, documentation, and clinical operations.
- Support preparation, maintenance, and amendment of radioactive-material licenses and related federal, state, and institutional regulatory documentation.
- Provide regulatory expertise for investigational radiopharmaceutical programs, including IND-related documentation and clinical research activities.
- Develop and maintain quality systems encompassing document control, SOPs, batch records, deviations, investigations, CAPA, change control, out-of-specification results, equipment qualification, process validation, and inspection readiness.
- Ensure that production, testing, and experimental activities are documented accurately, contemporaneously, completely, and in a manner suitable for regulatory review and clinical translation.
- Review quality-control results and ensure compliance with established specifications, including applicable testing for radiochemical purity, radionuclidic identity and purity, chemical purity, residual solvents, pH, sterility and endotoxin, and other release criteria.
- Coordinate responses to regulatory findings and oversee implementation and documentation of corrective actions.

Radiation Safety

- Work closely with the institutional Radiation Safety Office and medical physics personnel to ensure safe handling, production, dispensing, and administration of radioactive materials.
- Maintain working knowledge of radiation protection principles, radioactive-material regulations, contamination control, shielding, radioactive waste management, radiation detection equipment, and personnel monitoring applicable to PET operations.
- Develop and implement radiation-safety procedures for radiopharmaceutical production and clinical use, and participate in radiation-safety investigations, inspections, and corrective actions as appropriate.
- Provide radiation-safety expertise for new radiopharmaceuticals, production processes, equipment, and facility modifications.

Research and Translational Medicine

- Support investigators developing and translating novel radiopharmaceuticals from preclinical research through first-in-human and subsequent clinical studies.

- Provide pharmacy and regulatory expertise for investigational radiopharmaceutical manufacturing, clinical trial protocols, and IND-related activities.
- Collaborate with investigators, radiochemists, physicians, and regulatory teams to establish manufacturing and quality strategies appropriate for early-phase clinical trials.
- Review research radiopharmaceutical protocols from the perspectives of patient safety, pharmaceutical quality, regulatory compliance, and clinical feasibility.
- Contribute to an integrated translational infrastructure linking radiochemistry, manufacturing, PET imaging, dosimetry, regulatory compliance, and clinical research.

Required Qualifications

- Doctor of Pharmacy (PharmD) or equivalent professional pharmacy degree.
- Current New York State pharmacist license or eligibility for licensure.
- Significant experience in hospital pharmacy, nuclear pharmacy, radiopharmacy, radiopharmaceutical production, or a closely related environment.
- Demonstrated understanding of radiopharmaceutical preparation, quality control, and clinical PET operations, including familiarity with PET radiotracers such as FDG, F-18 labeled compounds, Ga-68 labeled compounds, and other investigational radiopharmaceuticals.
- Experience with FDA-regulated pharmaceutical or radiopharmaceutical manufacturing environments.
- Knowledge of GMP and cGMP principles and applicable USP requirements.
- Demonstrated experience with regulatory documentation, quality systems, and inspection preparation.
- Experience supporting FDA inspections or regulatory submissions involving radiopharmaceuticals, and experience developing SOPs, batch records, specifications, and quality-management systems.
- Familiarity with radiation safety principles and radioactive-material handling.
- Experience with automated radiochemistry synthesis equipment and radiopharmaceutical production systems.
- Strong written and verbal communication skills and the ability to work effectively across clinical, scientific, technical, and regulatory teams.
- Demonstrated ability to interpret and implement federal and state regulations governing radioactive materials and radiopharmaceuticals.

Preferred Qualifications

- Residency or fellowship training in nuclear pharmacy, radiopharmacy, or a related discipline.
- Board certification in Nuclear Pharmacy (BCNP).
- Experience with IND-directed radiopharmaceutical manufacturing.
- Experience with aseptic processing and sterile drug manufacturing, process validation, analytical method validation, equipment qualification, and computerized systems validation.
- Experience with GE FX, FASTlab, or comparable automated radiochemistry systems.

Key Attributes

The successful candidate will be detail-oriented, collaborative, an excellent communicator, and solutions-oriented. The role contributes to the expertise and discipline of a team ensuring that Columbia's expanding PET and radiopharmaceutical activities meet the highest standards of patient safety, regulatory compliance, and scientific rigor.

Equal Employment Opportunity

Columbia University is an Equal Opportunity Employer. The University does not discriminate in employment on the basis of any protected characteristic, and encourages applications from candidates of all backgrounds.