

# Putting Patient Safety First



## Patient safety and the quality of radiopharmaceuticals compounded and dispensed by our pharmacies are top-line priorities for Jubilant Radiopharma.

Our highly trained nuclear pharmacists and technicians prepare these specialized products based on a prescription order from the prescribing physician and with strict adherence to quality standards and aseptic technique. Supporting their efforts is our company's industry-leading quality management and internal safety audit program, which helps guarantee compliance with applicable regulations and standards.

We have made significant capital investments in our nationwide network of pharmacies to ensure that they meet the guidelines for the preparation, compounding, dispensing, and repackaging of radiopharmaceuticals as defined by the United States Pharmacopeia (USP <825>) and Board of Pharmacy regulations.

Our customers, and the patients they serve, can feel secure that every step is taken to assure the quality and integrity of radiopharmaceuticals dispensed by Jubilant Radiopharma.

### **Our Quality and Safety Pledge.**

As a customer of Jubilant Radiopharma, you can rely on us to put the safety of your patients and the quality of your radiopharmaceuticals above all else. We pledge to take every step necessary to earn the confidence placed in us as your nuclear pharmacy provider and trusted advisor. We are customer driven and quality focused..

### **Following USP <825>**

The United States Pharmacopeia (USP) Chapter <825> entitled "Radiopharmaceuticals-Preparation, Compounding, Dispensing, and Repackaging" required industry to change. The purpose of <825> is to provide uniform minimum standards for the preparation, compounding, dispensing, and repackaging of sterile and non-sterile radiopharmaceuticals for humans and animals that occur as part of state-licensed activities (e.g., the practices of pharmacy and medicine). USP <825> describes facilities and engineering controls, personnel training and qualifications, and procedural standards for processing radiopharmaceuticals in nuclear pharmacies, nuclear medicine areas in hospitals and clinics, and other healthcare settings that utilize radiopharmaceuticals. For sterile radiopharmaceuticals, these standards balance aseptic handling practices with radiation protection practices to describe appropriate strategies that provide assurance of maintaining patient safety while also ensuring the safety of individuals performing these activities.

### **Compliant in Quality**

- All Jubilant Radiopharma pharmacies are licensed by the applicable State Boards of Pharmacy and either the Nuclear Regulatory Commission (NRC) or the appropriate Agreement State RAM Agency, and have been approved for all required permits as required by state and federal law.
- Pharmacies are designed to ensure compliance with USP <825> required ISO specifications for ante-room, buffer room, and segregated radiopharmaceutical processing areas (SRPA) within the pharmacy.
- Cleanrooms or SRPA's are certified every six months at ISO 7 or ISO 8, according to USP <825>.
- All biological safety cabinets and laminar flow hoods are certified every six months at ISO 5.
- Certification is performed by a qualified vendor following Controlled Environment Testing Association's (CETA) current guide for sterile compounding facilities.
- Adherence to rigorous daily, weekly, and monthly cleaning and disinfection procedures is required, according to USP <825> and Jubilant Radiopharma policies and procedures. Specific validated procedures have been established for unit dose shield (pig) disinfection prior to reuse.
- Each pharmacy is subject to inspection by internal audit and external agencies at any time. The Agency Inspection success rate and internal audit scores are key metrics for evaluation of our pharmacy teams.



## Safe Environments

- All Jubilant Radiopharma pharmacists and technicians are licensed, registered and certified as specified by the local State Board of Pharmacy.
- Our dose drawing technicians are trained through an accredited Nuclear Pharmacist Technician instruction program, which is designed to assess competence in nuclear pharmacy practice. All are Certified Pharmacy Technicians (CPhT) or otherwise licensed or registered, as required by the local state Boards of Pharmacy.
- All compounding personnel undergo an initial Competency Assessment, which is repeated annually. The assessment includes media fill and gloved fingertip sampling, as well as other required training topics to demonstrate aseptic process competency.
- All pharmacy personnel receive specific training on aseptic technique, garbing, hand hygiene, and cleaning on an annual or more frequent basis. They also receive specific training on Radiation Safety/ALARA, Pharmacy Quality and General Safety (OSHA) topics.
- Delivery employees undergo a rigorous background check upon hire and are trained according to DOT requirements; HazMat and RAM Security are emphasized.
- Our pharmacies work closely with individual nuclear medicine departments to establish specific RAM delivery and security procedures that match our customers' institutional policy.



## Trained Personnel

- In accordance with Board of Pharmacy regulations, prescription orders are required for all radiopharmaceutical preparations dispensed by Jubilant Radiopharma.
- Prior to delivery, a specially-trained team member performs radiopharmaceutical quality control testing (QC) on each lot of compounded radiopharmaceutical.
- We procure and supply FDA-approved radiopharmaceutical products exclusively from FDA-approved compliant manufacturers. Our company does not procure products from other compounding pharmacies or any gray market sources.
- Our company fully supports FDA guidelines outlined in the Food Drug and Cosmetic Act, including the 2013 FDA Drug Quality & Security Act, including Title I – Compounding Quality Act and Title II – Drug Supply Chain Security Act, as well as other industry guidelines as provided by USP, SNMMI, ASHP, APhA, and others.

## Quality Products

- An industry leader in nuclear pharmacy, we have established comprehensive internal quality and safety audit programs with structured corrective action plans for identified gaps.
- Our pharmacies report quality related events and incidents using an online tool that allows the tracking of any corrective actions to closure. Following incident investigation, a corrective action plan is developed for significant incidents.
- To ensure USP <825> compliance, a comprehensive set of Policy and Procedures have been developed by our corporate Quality & Safety Department.

To learn more about our quality Initiatives, contact  
your local Jubilant Radiopharma Representative

2020-US-PHARM-00092

