Quality Systems Personnel Training Program for Radiopharmaceutical Manufacturing

Sally W. Schwarz, MS, RPh, BCNP, SNMMI President

The manufacture of radiopharmaceuticals is dependent on skilled personnel who are cross-trained in several disciplines, and currently too few people have the necessary training. To fill this educational gap, SNMMI is spearheading the development of a Quality Systems Personnel Training Program to cross-train chemists and pharmacists—providing the theoretical knowledge and practical experience needed to assume responsibility for the small-scale manufacture, quality control, and release of radiopharmaceuticals.

Specific needs include cross-training in the principles and practice of radiopharmaceutical science; manufacturing and quality assurance of radiopharmaceuticals—both in the academic and commercial settings; synthesis and pharmaceutical formulation of radiopharmaceuticals, especially from cyclotron-produced radionuclides; application of radiopharmaceuticals in biomedical research and clinical nuclear medicine; and compliance, including all regulatory requirements associated with radiopharmaceutical manufacture and release.

The target learners would have either a PharmD, BS, or MS in pharmacy or an MS or PhD in chemistry or radiochemistry. The goal is to prepare individuals to:

- Manufacture radiopharmaceuticals;
- Comply with regulations associated with production and development;
- Understand how to handle FDA manufacturing audits;
- Assume responsibility for small-scale radiopharmaceutical manufacturing; and
- Collaborate, advocate, and promote standards of practice in radiopharmaceutical production and development.

Sally W. Schwarz, MS, RPh, BCNP

Industry experts will be invited to participate in content development. Because the program is designed for working professionals, it will require self-directed learning and minimal time away from work and home. There will be a combination of directed self study, supervised by subject-matter experts, and practical experience at appropriate sites. The program will allow learners to test out of subjects based on prior knowledge. A certificate will be developed to issue after completion of the program and passing of an exam administered by the American Board of Nuclear Medicine.

Demonstrated competence will be required in the areas of quality systems, procedures, and instrumentation; laws and administration; good manufacturing practice (GMP) operations; radiochemistry; radiopharmaceutical formulation and quality control; nuclear physics and instrumentation; radiopharmacology and clinical applications; dosimetry; and experiential GMP education.

The first phase of this project is development of the training program. A certification exam would be developed later, and continuing education could also be added for those updating their initial certification.

I am excited to get this important training program underway and look forward to providing updates on its development. The manufacture of radiopharmaceuticals is a key step in providing patients with appropriate diagnostic and therapeutic care.