Overview of the SNMMI Quality Systems Personal Training Program (QSPTP)

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PURPOSE & SCOPE

The Society of Nuclear Medicine & Molecular Imaging (SNMMI) Qualified Systems Personnel Training Program (QSPTP) has been developed to define the competencies of a Qualified Person in the release of manufactured radiopharmaceuticals, providing experts in the field of radiopharmaceutical science guidance in program development.
DEFINITION OF NEED

• The manufacture of radiopharmaceuticals and the ongoing production of radiopharmaceuticals is dependent on skilled personnel cross-trained in several disciplines. There is a need to educate, train and develop individuals with a pharmacy or chemistry background in production and release of radiopharmaceuticals.

• At the current time there are insufficient individuals with this type of training, and it would benefit both academic and commercial entities by providing these trained individuals.
OVERVIEW

• Provide theoretical knowledge and practical experience needed to assume responsibility for small scale manufacture, quality control and release of radiopharmaceuticals.
• Cross-training chemists and radiopharmacists
• Provide training in manufacturing and quality assurance of radiopharmaceuticals for both the academic and commercial settings
• Training in synthesis and pharmaceutical formulation of radiopharmaceuticals—PET, SPECT and radiotherapeutics, especially from cyclotron produced radionuclides
• Understand compliance with regulatory requirements associated with radiopharmaceutical manufacturing
• Application of radiopharmaceuticals in biomedical research and clinical nuclear medicine
• Research applications including IND and RDRC processes

TARGET LEARNERS

• Prior training: PharmD, B.S. or M.S. Pharmacists or M.S. in Chemistry prior to beginning QSPTP Program
• Lectures can be taken independently for the training
COURSE FEES

The SNMMI QSPTP course fee includes all Part One/Two learning modules. No CE credit is available for this program.

- SNMMI Members: $1,495 | Nonmembers: $2,195
- Institutions (up to 5 personnel): $2,495

Part Three Hands-on/Experiential Learning program fee will be determined by the participating site.

PROGRAM OVERVIEW

PART ONE - REGULATORY

- Quality Systems (Procedures and Operations: Basic concept, QA Management and Structure)
- Pet Drugs - Current Good Manufacturing Practice (CGMP)
- Overview of 21 CFR Part 211
- Overview of 21 CFR Part 212 and USP Chapter 823
- Historical Overview USP
- USP Chapters 797 and 825
- NDA and ANDA Submission
- Reporting Requirements
- IND submission
- Contract Manufacturing
- 21 CFR 212 Subpart C: Quality Assurance (212.20)
- 21 CFR part 212 Subpart D: Facilities and Equipment (212.30)
- 21 CFR Part 212, Subpart E: Control of Components, Containers and Closures (212.40)
PROGRAM OVERVIEW
PART ONE - CONTINUED

- 21 CFR Part 212 Subpart F: Production and Process Controls (212.50) and Subpart G: Laboratory Controls (212.60) PART 1
- 21 CFR Part 212 Subpart F: Production and Process Controls (212.50) and Subpart G: Laboratory Controls (212.60) PART 2
- 21 CFR Part 212 Subpart H: Finished Drug Product Controls and Acceptance
- 21 CFR Part 212 Subpart I: Packaging and Labeling (212.80) & Subpart J: Distribution (212.90) Subpart K: Complaints (212.100) & Subpart L: Records (212.110)
- Quality Assurance
- Cyclotron and PET Chemistry Synthesis Modules; Maintenance and Calibration
- Microbiology

PROGRAM OVERVIEW
PART TWO –SCIENCE

- Nuclear Physics and Instrumentation: Atomic Structure and Radioactive Decay
- Nuclear Physics and Instrumentation: Interaction of Radiation with Matter and Radiation Detection
- Nuclear Physics and Instrumentation: Nuclear Counting Statistics
- Nuclear Physics and Instrumentation: Nuclear Counting Systems
- Radiation Dosimetry for Radiopharmaceuticals
- Radionuclide Production Devices
  1. Radionuclide Production - Reactors
  2. Radionuclide Production - Cyclotrons
  3. Radionuclide Production Radionuclide - Generators
- Substrate Specific radiopharmaceutical Localization
- Substrate Non-Specific radiopharmaceutical Localization
- Pharmacology of radiopharmaceuticals "Radiopharmacology" PART 1
- Pharmacology of radiopharmaceuticals "Radiopharmacology" PART 2
- Pharmacology of radiopharmaceuticals "Radiopharmacology" PART 3
PROGRAM OVERVIEW
PART TWO - CONTINUED

• Introduction to Radiopharmaceuticals
• Basic Nuclear and Radiochemistry
• Radiochemical Syntheses - Automated
• Non Metal Radionuclides General Concepts and $^{18}\text{F}$
• Non Metal Radionuclides $^{11}\text{C}$, $^{13}\text{N}$, $^{15}\text{O}$, $^{124}\text{I}$
• Non Metal SPECT Radionuclides, Imaging & Therapy
• Radiometals - General concepts
• Radiometals - Single Photon Radiometals $^{99m}\text{Tc}$, $^{111}\text{In}$, other
• Radiometals - Positron-Emitting radiometals
• Radiometals - Therapeutic Radiometals
• Quality Control Techniques - Visual, pH, Methods, TLC
• Quality Control Techniques - HPLC
• Quality Control Techniques - GC
• Quality Control Techniques - Dose Calibrator and MCA
• Quality Control Techniques - PET Quality Control & Analytic Methods Transfer
• Quality Control of Radiopharmaceuticals

PROGRAM OVERVIEW PART THREE
EXPERIENTIAL LEARNING--FDA MANUFACTURING SITES

Applicants will take part in an experiential learning program at a participating institution for ~4-6 weeks. A separate fee (determined by the participating site) will apply for this component.

Institutions:
1. University of California San Francisco
2. Massachusetts General
3. Washington University School Medicine in St. Louis
4. Sloan Kettering
5. University of Michigan
6. MD Anderson Cancer Center
7. University of Alabama
8. University of Iowa
9. University of Michigan
10. University of Pennsylvania
1. Aseptic Training
2. Media Fill Testing
3. Laminar Flow Cleaning
4. Assembly of Final Product Vial
5. Environmental Monitoring
6. Facility Cleaning
7. Production procedures
8. Quality Control Instrumentation and Procedures
   a. HPLC (standard curves, development and maintenance)
   b. GC (standard curves, development and maintenance)
   c. TLC Scanner
   d. Filter Integrity testing
9. Dose Calibrator
   a. Gamma
   b. Beta
10. System Suitability
11. Standard Operating Procedures (SOPs)

QUALIFIED PERSON (QP) CERTIFICATE

• Based on prior training, candidates can test out of course areas
• Certificate of Training will be issued on completion of the Didactic Program
• Certificate of Program Completion will be issued on completion of the Hands on Program
Conclusion

• There are insufficient individuals with this type of training, and it would benefit both academic and commercial entities by providing this training opportunity.

• It could also offer training for potential investigators who will be inspecting in the field of radiopharmaceuticals.
Thank You!

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