University "Goce Delchev" Stip
Faculty of Medical Sciences

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TRAINING COURSE OF RADIOPHARMACY
Certified program
16 JANUARY – 10 MARCH 2017

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Stip

University recognized certificate:

Certificate for training in Radiopharmacy

1. General description of the training course

The two monts Radiopharmacy training course provides comprehensive training and the opportunity to acquire the scientific knowledge, technical skills and professional judgment required to promote patient care through assurance of the safe and efficacious use of radiopharmaceuticals and ancillary medications for diagnosis and therapy.

The Radiopharmacy training course offers theoretical knowledge and practical experience to assume responsibility for the small-scale production and quality control of radiopharmaceuticals, both SPECT and PET and therapeutical radiopharmaceuticals for clinical application including current regulation in Radiopharmacy, base of GMP, GRPM, QA and distribution of radiopharmaceuticals.

2. Purpose and justification for the training course

The training program in Radiopharmacy aims profiling staff able to produce, label, control and menage radiopharmaceuticals and:

- to extent clinical activities for which support is required from the radiopharmacy
- to follow current legislative requirements, standards, professional guidance and related scientific and technical data. This will include receipt, storage, handling and disposal of radioactive materials, manufacture of sterile radioactive medicinal products, administration of radioactive materials to humans, and transport of radioactive materials
- requirements for manufacturing of investigational medicinal products for clinical trials
- principles, use, capabilities and limitations of existing and planned radiopharmacy facilities and equipment
- risks associated with the provision of a radiopharmacy service and associated control measures
- principles of quality assurance, clinical and research governance and quality management systems
- principles of operation and limitations of equipment
- identify and consult with relevant stakeholders to identify local or regional clinical requirements for radiopharmacy services
- identify professional, scientific and technical support required to meet the identified clinical need consistent with legislative requirements and professional guidance
- confirm with relevant experts the current relevant legislative requirements for existing and planned radiopharmacy facilities and their use

These skills include knowledge and basic and specific skills of:

- Pharmaceutical, chemistry and physics basic knowledge
- Production and sysntesis of radionuclide and radiopharmaceuticals
- Quality control of radiopharmaceuticals;
- Quality assurance program, Regulatory aspects, Qualification and validation in radiopharmaceutical manufacturing
- Pharmacopoeial and Authority Expectations, Inspection and Audits

A radiopharmacy is a branch of pharmacy dealing with radioactive drugs. It is also the name of a registered facility which prepares and dispenses radioactive medications. A radiopharmacy also stores and disposes of radioactive materials.
Radiopharmacy is a branch of nuclear medicine which deals with all aspects of radioactive pharmaceuticals including compounding and quality control. Compounding is combining key ingredients to form a drug. Typically a radiopharmacy has a specialized lab to manufacture, label and store each different radioactive drug.
A radiopharmacist can be graduated person who is specialized and adequaly trained for handling radiopharmaceuticals and radioisotopes. Radioisotopes can be used to help diagnose, explore and investigate, and treat certain disease processes. They are also utilized for medications employed for things like radioisotope scanning, a diagnostic procedure, or radiotherapy, a cancer treatment option.
Radiopharmaceuticals are drug substances containing radioactive atoms that can be safely used on humans. It's primarily use is for diagnostic purposes, or to help identify certain problems or conditions inside the body. However, radiopharmaceuticals are sometimes used as a form of therapy or treatment for specific ailments.
After completion of two months training course students will be able to work in all spheres of the modern Radiopharmacy facilities and also in the conventional hospital Radiopharmacy or small departments. They will have competencees in production, labeling and quality control of radiopharmaceuticals (SPECT and PAT), including capability of QA and to cover all the regulatory aspects related to radiopharmaceuticals.

The study program contains items that can be grouped in five categories:

- Knowledge of pharmacy, chemistry, physcs,
- Knowledge of of pharmaceutical chemistry, production of radioisotope and radiopharmaceuticals, quality control, clinical application in SPECT, PET and therapy
- Knowledge of current regulation in Radiopharmacy, base of GMP, GRPM, QA and design
- Practical exsercices dedicated to be able to work in practice concerning in all field of Radiopharmacy

3. Specific qualifications descriptors that determine learning outcomes for the program of the training course

Knowedge and understanding

- breadth of clinical activities for which support is required from the radiopharmacy service
- current legislative requirements, standards, professional guidance and related scientific and technical data. this will include receipt, storage, handling and disposal of radioactive materials, manufacture of sterile radioactive medicinal products, administration of radioactive materials to humans, and transport of radioactive materials
- requirements for manufacturing of investigational medicinal products for clinical trials
- principles, use, capabilities and limitations of existing and planned radiopharmacy facilities and equipment
- risks associated with the provision of a radiopharmacy service and associated control measures

- principles of quality assurance, clinical and research governance and quality management systems
- principles of operation and limitations of equipment
- extent clinical activities for which support is required from the radiopharmacy – production, labeling, quality control

Applying knowledge and understanding

- identify and consult with relevant stakeholders to identify local or regional clinical requirements for radiopharmacy services
- identify professional, scientific and technical support required to meet the identified clinical need consistent with legislative requirements and professional guidance
- confirm with relevant experts the current relevant legislative requirements for existing and planned radiopharmacy facilities and their use

Ability for evaluation

- identify risk factors associated with radiopharmacy services and their corresponding control measures
- specify the training needs to comply with legislative requirements
- specify resources and capacity required to deliver professional, scientific and technical and legislative services for radiopharmacy
- specify methods and measures for quality assurance, clinical and research governance and audit for radiopharmacy services
- identify, interpret, and implement national and international legislation and guidelines into local clinical practice and standard operating procedures
- identify high risk procedures and obtain organisational approval in accordance with current legislation and organisational protocols

Communication skills

- Demonstrate ability to communicate effectively linking concepts, problems and solutions in the field of computer science.
- Demonstrate the ability to effectively work independently or as a productive member of the team who may be multidisciplinary.
- Argue the position and results of operations.
- Demonstrate skills in taking personal responsibility for communication in the area they operate.

Learning skills

- Easy to adapt to learning for radiopharmaceuticas or a new radiopharmaceuticals and method of synthesis, production and control
- Demonstrate awareness of new technologies and the ability to evaluate and use of modern development radiopharmaceuticals.
- use information technology for distance and e-learning. understand the need and have the capability of continuing professional development through the use of technical and scientific literature, professional training, continuing formal education, membership in professional organizations, etc

4. Conditions for enrollment

The conditions and criteria for admission of new participants is regulated by the open call for enrollment of new students, which is issued few times during the year. Enrollment participants are done on the basis of open application or direct contact.

5. Data provided space for the realization of the training program

For successful implementation training course Goce Delcev University has sufficient condition for the realization of lectures, laboratory and auditory exercises together with the independent University Institute for Positron Emission Tomography.
Some of topics will be realized in collaboration with the National Agency of Drug and Medical Devices and another institutions in the country.

The University will provide teaching material in electronic form (CD), booklet for practical fork and additional material.

SYLABBUS OF THE RADIOPHARMACY TRAINING PROGRAM

WEEK	TOPICS AND ACTIVITIES
1	**Introduction of the course** **Theoretical part** Introduction to Radiopharmacy Basic principle of pharmacy and pharmaceuticals Nuclear medicine physics, Radiation protection, safety and Regulation **Practice** (group of 4-6 persons) Instrumentation, measurement, calculation, dosimetry
2	**SPECT Radiopharmacy and radiopharmaceutical chemistry** **Theoretical part** SPECT radioisotope production and radiopharmaceutical preparation - generators, cyclotron, reactors - small scale production for clinical use, labelling, dispensing - operational level 1a, 1b, 3a Quaity control of SPECT radiopharmaceuticals **Practice** (group of 4-6 persons) SPECT Radiopharmaceutical Preparations and quality control Clinical application of SPECT radiopharmaceuticals
3	**Therapeutical Radiopharmacy and radiopharmaceutical chemistry** **Theoretical part** Radioisotope for therapy and radiopharmaceutical preparation, Theranostic - small scale production for clinical use, labelling, dispensing - operational level 1b, 3a Quaity control of therapeutical radiopharmaceuticals **Practice** (group of 4-6 persons) Therapeutical Radiopharmaceutical Preparations and quality control Clinical application of therapeutical radiopharmaceuticals
4	**Blood Cell labeling** **Theoretical part** Laboratory practices and environmental conditions necessary for safe manipulation and radiolabelling of autologous blood cells and components for re-injection into the original donor/patient. Labeling of RBCs, WBCs, platelets - operation level 2b

	Practice (group of 2 persons) Isolation and radiolabeling of RBCs and WBCs with 99mTechnetium and quality control of labeling
5	**PET Radiopharmacy and radiopharmaceutical chemistry – general** **Theoretical part** PET radioisotope production and radiopharmaceutical preparation - cyclotron produced radioisotopes - generator produced radioisotopes - Operation in PET facility – production and equipment - Syntesis, production, dispensing, distribution - operational level 3b Quaity control of PET radiopharmaceuticals **Practice** (group of 4-6 persons) PET Radiopharmaceutical Preparations and quality control Clinical application of PET radiopharmaceuticals
6	**PET Radiopharmacy and radiopharmaceutical chemistry – Fluorine-18** **Theoretical part** F18 radiopharmaceuticals - syntesis, production, dispensing, distribution Quaity control of Fluorine-18 radiopharmaceuticals radiopharmaceuticals **Practice** (group of 2 persons) Preparations of 18F-FDG and quality control Clinical application of 18F-FDG
7	**PET Radiopharmacy and radiopharmaceutical chemistry – Carbon-11, Nitrogen-13, Galium-68** **Theoretical part** Other PET radiopharmaceuticals - syntesis, production, dispensing, distribution Quaity control of other PET radiopharmaceuticals **Practice** (group of 2 persons) Preparations of 11C-Choline and quality control Preparations of 68Ga-DOTA peptide and quality control Clinical application of other PET radiopharmaceuticals
8	**Regulatory aspects of radiopharmaceuticals** **Theoretical part** Qualification and validation in radiopharmaceutical manufacturing Quality, Safety and GMP in radiopharmaceutical practice Sterile Radiopharmaceuticals and Endotoxins Pharmacopoeial and Authority Expectations

	Inspection and Audits **Practice** (group of 4-6 persons) Cleanrooms for Radiopharmaceuticals - Inspections, experiences Industrial Manufacturing including FDG production **Self-study,** **Test, assessment,** **Certification and closing**

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