CTE Session 4
Technologists Committee
Monday, October 17, 09:45-11:15

Session Title
Research in Radiopharmacy

Chairpersons
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Programme

09:45 - 10:15	**Ana Sofia Capacho** (Lisbon, Portugal): Good Manufacturing Practice in Radiochemistry Principles - Standard Operating Procedures and Documentation
10:15 - 10:45	**Neil Hartman** (Swansea, United Kingdom): GMP Elements - Quality Control & Quality Management
10:45 - 11:15	**Gert Luurtsema** (Groningen, Netherlands): Radiopharmaceutical Metabolism Activity - How to Trace What's Left?

Educational Objectives
1. Present the basics of Good Manufacturing Practice in radiopharmacy.
2. Inform about the principles of a quality management system and the quality risk management.
3. Characterize the basics of radiopharmaceuticals quality control.
4. Describe good quality control (QC) laboratory practice.
5. Explain the principles and novelties in radiopharmaceuticals synthesis and the procedure of radiolabelling (substitution, chelation, indirect radiolabelling of the vector molecule).
6. Summarize the background information of drug/tracer metabolism in the body.
7. Discuss the methods of detecting metabolites in radiopharmaceuticals biokinetics.
8. Present the process of blood sampling, sample preparation and blood analysis.
9. Explain the impact of radio-metabolites in tracer development.

Summary
Radiochemistry is one of the most rapidly evolving area of nuclear medicine fields, especially considering radionuclide therapy. The possibility of use the radiochemical compounds is strictly regulated and followed with standards and Good Manufacturing Practice (GMP).
The GMP elements and principles include quality control (QC) and quality assurance (QA) of radiopharmaceuticals, standard operating procedures (SOPs), waste management and many more. All above-mentioned areas of GMP interests have been developed to prepare the manufacturers for both production and distribution of radiopharmaceutical. They also help personnel involved into radiopharmacy to prepare, dispense, and release radiopharmaceuticals properly.
One of particularly important elements of the radiopharmaceuticals' use is to track and define metabolites following radiotracer's biodistribution in human body. The methods of detecting metabolites in radiopharmaceutical biokinetics demands specific knowledge and proper qualifications.

Key Words
Quality Control; Radioisotopes; Radionuclides; Radiochemistry