Mini Course 3
Technologists Committee
Wednesday, October 23, 10:15 - 11:15

Session Title
Quality Management System

Chairpersons
Agata Pietrzak (Poznan, Poland)
Harry Hendrikse (Amsterdam, Netherlands)

Programme

10:15 - 10:35 **Jane Vredenbregt** (Rotterdam, Netherlands): Quality Management System – why we need it?

10:35 - 10:55 **Zéna Wimana** (Brussels, Belgium): Good Manufacturing Practice – step by step

10:55 - 11:15 **Jean-Paul Thys** (Bonheiden, Belgium): From being "basic" to becoming "advanced" – procedures, documentation, Standard Operating Procedures

Educational Objectives

1. Present the leading objectives and pillars of the Quality Management System (QMS).
2. Outline the importance of introducing QMS in the daily practice.
3. Discuss the principles of Good Manufacturing Practice (GMP).
4. Characterize the particular elements of maintaining GMP.
5. Explain the procedures and documentation following GMP maintenance.
6. Overview the principles of QMS and GMP in local vs commercial laboratories along with the documentation.
7. Highlight the regulatory requirements to be followed considering QMS and GMP in Europe.
8. Present the importance and structure of the Standard Operating Procedures (SOPs).

Summary
Following drugs used for Nuclear Medicine procedures' development, the Quality Management System (QMS) as a synergic set of processes and procedures ensuring the highest quality of the products and services, became an inevitable element of the radiochemical compounds' synthesis. Following QMS, the Good Manufacturing Practice (GMP), describes the minimal standards which shall be met by the pharmaceuticals' manufactures to ensure the drugs' safety and efficacy.

Although, equally relevant for local and commercial laboratories daily practice, both QMS and GMP present slightly different demands, resulting in the necessity to preserve the appropriate procedures and legislation. A variety of aspects is going to be presented during the session, among which legislation, documentation and practical views on the QMS as a whole are going to be discussed.

Key Words
Good manufacturing practice; GMP; nuclear medicine; quality management system; QMS; radiochemistry; standard operating procedures; SOP