Pre-Congress Symposium 5 (Radiopharmacy)
Saturday, October 21, 09:00-12:00

Session Title
Validation & Risk Assessment

Chairs
Sergio Todde (Monza)
Petra Kolenc Peitl (Ljubljana)

Programme

09:00 - 09:20 Rainer Suchi (Braunschweig): Economic Impact of Qualification/Validation from Full GMP Perspective

09:20 - 09:40 Nicholas Mathew Gillings (Copenhagen): Validation of Analytical Methods

09:40 - 10:00 Valentina Ferrari (Buckinghamshire): Risk Assessment - How Much Validation is Needed?

10:00 - 10:15 Discussion

10:15 - 10:45 Coffee Break

10:45 - 11:15 Lars Perk (Nijmegen): Design, Qualification and Validation of a Cyclotron Facility: It's Fun! – Practical Example

11:15 - 11:45 Paolo Colombo (Monza): Risk Assessment – Practical Example

11:45 - 12:00 Discussion

Educational Objectives
Upon completion of this symposium the attendee will:

1. Be updatedon the economic impact of full GMP qualification/validation and be able to estimate the impact for small small-scale "in house" preparation of radiopharmaceuticals
2. Get an overview of the complexity of validation/qualification activities and understand how to use the risk assessment tools to determine the required amount of validation
3. Understand how the principles of validation and risk assessment can be applied into daily routine practice

Summary
It is a requirement of GMP that manufacturers identify what validation work is needed to prove control of the critical aspects of their particular operations. A quality risk management approach should be applied throughout the lifecycle of a medicinal product. As part of a quality risk management system,

decisions on the scope and extent of qualification and validation should be based on a justified and documented risk assessment of the facilities, equipment, utilities and processes.

Radiopharmaceuticals are very special group of drugs,especially due to their short half-life and radiation emissions. Due to logistics and patient tailored medicine they are regularly prepared in hospital settings.This is recognizedin different documents like PIC/S Guide to good practices for the preparation of medicinal products in healthcare establishments Annex 3: Good practices for preparation of radiopharmaceuticals in healthcare establishments. Small-scale preparation of radiopharmaceuticals iseven more specifically addressed in various guidelines issued by Radiopharmacy committee of EANM. Next to "Guidelines on Good Radiopharmacy Practice (GRPP)" "Guidance on Validation and Qualification of Processes and Operations Involving Radiopharmaceuticals" and "Risk Management guidelines applied to radiopharmaceuticals" will be issued to append the GRPP.

Since validation may ultimately be considered as a useful way to increase reliability and prevent deviations and out of specification in the day by day operation in the radiopharmaceutical preparation process, the aim of this course is to strengthen the understanding of rationality, feasibility and usefulness of various tools and procedures in qualification/validation processes.