GMP and Quality Requirements for Radiopharmaceuticals

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Speakers

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Highlights

- Regulatory Developments and Authorities Expectations
- Rooms and Personnel Issues
- QRM – Challenge Quality Risk Management
- Microbiological Safety
- Equipment Qualification and Method Validation
- Data Integrity
- GDP – Good Distribution Practice for Radiopharmaceuticals

Experiences of Authority, Industry and Academic
Objective

During this course, representatives of regulatory authorities will present the current development of radiopharmaceutical regulations and their experiences during the inspection of manufacturing establishments including the possible impacts of the new Annex 1. Furthermore, speakers from nuclear medicine departments from universities and hospitals as well as from industry will share their experiences with GMP implementation. You will become acquainted with possible solutions for the special challenges and practical approaches on room qualification for GMP-compliant manufacturing. They will cover the really “hot topics” in the world of pharmaceutical QA and QC like Qualification, Validation, Monitoring and Good Distribution Practice and more with a special focus on Radiopharmaceuticals.

The speaker team is set up to provide you with the unique possibility to discuss the current status and the future expectations with representatives of national authorities as well as professionals from universities, hospitals and engineering.

Background

The manufacturing of radiopharmaceutical products confronts the producing establishment with a collection of challenges. On the one hand, there is the challenge by the contradictory requirements of quality and safety guidelines of pharmaceutical products and the standards of staff safety and radiation protection. On the other hand, there are issues of small batch sizes and short shelf life. The short shelf life necessitates fast transportation and application to the patient. These circumstances mean that classical requirements like sterility testing before release and application cannot be fulfilled and GDP is a real challenge.

Target Audience

This course is aimed at the personnel of hospitals, pharmaceutical companies, their suppliers and authorities who are involved in

- Quality Control
- Quality Assurance
- Inspection and Audits
- Qualification and validation
- Radiopharmaceutical manufacturing.

Moderator

Axel Schroeder, Concept Heidelberg

Programme

Regulatory Requirements for Radiopharmaceuticals

- Directive 2001/83/EC
- Regulation EU No 536/2014
- EU GMP Guidelines and their annexes 1, 3 and 13
- Guidance Documents

Rooms and Personnel – GMP Requirements for Product Safety

- Design and qualification of facilities
- Containment vs. contamination control
- Training, qualification and monitoring program

QRM Principles – the modern way for QA

- Pharmaceutical Quality System, QRM, and risk assessment(s)
- Quality Risk Management (QRM) in manufacturing of sterile medicinal products
- Major changes of Annex 1 (draft) regarding QRM principles

From Equipment Qualification to Process Validation

- Annex 15 and its key elements
- How to consider User Requirements
- Equipment and Hot Cell Qualification
- Process Validation Requirements

Radiation Protection and Personnel Safety Requirements

- Regulatory requirements
- General concepts and workflow
- Constructional realization in a cleanroom environment
- Waste handling

IMPD Issues

- Chemical pharmaceutical data
- Drug substance
- Medicinal product
- Non-clinical pharmacology, pharmacokinetics and toxicology
- Clinical data
- Benefits and risks assessment

Requirements on Data Integrity

- Regulatory Background
- Quality and Manufacturing sections to be adjusted for DI
- Critical steps in manufacturing
- DI assessment of computer systems

How to handle audits- a manufacturers experience

- Hot Cell issues
- Monitoring and Validation
- Process Validation
- Data Integrity
- Miscellaneous Audit Findings over the Years.
Microbiological Control – from Sterility to Endotoxins

- Regulatory Requirements vs. small batch size and short shelf life
- Challenges and Benefits of Modern Micro Methods
- Parametric Release
- Pharmacopeia methods for endotoxin testing (Ph. Eur. 2.6.14)
- LAL kinetic chromogenic methodology for rapid detection of endotoxins
- LAL used for Radiopharmaceuticals
- LAL method validation and data processing

Validation of Analytical Methods

- Regulatory Background
- Guidelines and Definitions
- Specific Application to Ph. Eur. methods
- Additional Aspects for Radiopharmaceuticals

Cleaning and Disinfection Requirements

- General GMP requirements on Cleaning and Disinfection
- Traditional disinfectants and new methods
- Validation of disinfection procedures

Sterility Testing of Radiopharmaceutical and Parametric Release

- Regulatory Requirements vs. small batch size and short shelf life
- Challenges and Benefits of Modern Micro Methods
- Parametric Release

Monitoring Requirements

- Regulatory requirements on monitoring
- Qualification and routine monitoring
- Alert and action levels
- Trending of data

GDP a special Challenge

- The revised EU Guidelines on Good Distribution Practice (GDP)
- Who is responsible for maintaining product quality in the supply chain
- Key challenges and risks to consider
- Cold chain and ambient storage and transportation
- Role of the Responsible Person (RP)?
- Special Challenges - Transportation under quarantine status – in bond shipment

Speakers

Arjan Langen, GE Healthcare, The Netherlands
Lead Sterility Assurance & QC Microbiology
Arjan Langen has over 20 years of experience within the field of pharmaceutical microbiology. He worked for several pharmaceutical and biotech companies (Nobilon, DSM, MSD) and had various local and global roles within QC, QA, manufacturing and auditing. Currently he is a Sterility Assurance & QC Microbiology lead at GE Healthcare in Eindhoven – The Netherlands. Besides he is a member of the ECA Annex 1 task force that works on the detailed review of the draft revision text of Annex 1. He is a microbiologist by training and is Green Belt certified.

Dr Franz Schönfeld, Government of Upper Franconia
GMP Inspector
Franz Schönfeld is a pharmacist by profession. After his graduation, he worked at a hospital in Nuremberg and at a retailer in Bayreuth. In 2003 he joined the local GMP inspectorate in Ansbach before he was transferred to Munich and Bayreuth. He was formerly deputy head of the national experts group for radiopharmaceuticals and is now head of the national expert group for APIs and excipients.

Dr István Boros, University of Cambridge, Wolfson Brain Imaging Centre, UK
Head of Quality Control/Quality Assurance
István Boros studied at the Universities of Cluj-Napoca and Debrecen. Furthermore, he graduated further education as Quality Systems Manager and the Q3P Qualified Person Personalised Programme. He worked at the Hungarian Paten Office and Astra Zeneca before he joined the University of Cambridge, Wolfson Brain Imaging Centre.

Dr Hendrikus Boersma, University Medical Center Groningen
Hospital Pharmacist/ Clinical Pharmacologist (PharmD, PhD) and Qualified Person
After studying Pharmacy in Groningen, Hendrikus worked 9 years at Maastricht University Hospital as pharmacist. In the meantime, he obtained his PhD on a radiopharmaceutical subject. He joined the UMCG in 2007 and is currently staff hospital pharmacist and QP.

Dr Gerald Reischl, University Tübingen, Preclinical Imaging and Radiopharmacy
Radiochemist, Qualified Person, Head of Quality Control
Dr Gerald Reischl is Assistant Professor in Radiopharmacy at the Department of Preclinical Imaging and Radiopharmacy, University Hospital of Tübingen, Germany. He has worked in the field since 1996 and became head of radiopharmaceutical production in 2008.
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