Speakers

Nic Gillings
Copenhagen University Hospital, Rigshospitalet, Denmark

Thijs Kroon
GE Healthcare Biosciences, The Netherlands

Arjan Langen
GE Healthcare, The Netherlands

Prof Dr Gerald Reischl
University Tübingen, Germany

Dr Dirk Freitag-Stechl
CUP Laboratorien

Dr Franz Schönfeld
Government of Upper Franconia, Germany

Marlous van der Hooft
Scitech, Germany

GMP and Quality Requirements for Radiopharmaceuticals

18/19 June 2024 | Heidelberg, Germany

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

Programme

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 preparation and/or manufacturing.

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

Overview of Radiopharmaceuticals in Ph. Eur.

- General monographs and chapters in relation to radiopharmaceuticals
- Chemical precursors and radionuclides for radiolabelling
- New developments on therapeutic and PET radiopharmaceuticals

Annex 1 – Impact on Radiopharmaceuticals

- Important changes of the revised Annex 1 – from CCS to QRM
- Relevant requirements for radiopharmaceuticals
- Approaches for implementation
- Annex 1 vs. Annex 3

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

Equipment Qualification & Process Validation in Radiopharmaceutical Production

- Phases of Equipment Qualification
- Principles of Process Validation
- Case Studies and Industry Best Practices

Radiation Protection and Personnel Safety Requirements

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

How to handle Audits- a Manufacturer's Experience

- Hot cell issues
- Monitoring and validation
- Process validation
- Data integrity
- Miscellaneous audit findings over the years

Cleaning and Disinfection Requirements

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

Supplier Qualification

- Legal framework
- Active pharmaceutical ingredients
- Supplier selection
- Supplier evaluation
- Approved suppliers
- Quality agreement
- Data integrity

Monitoring Requirements

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

Types and Implementation of Chemical and Microbiological Analyses

- Analysis of precursors, radionuclides and excipients
- Tests of the finished products: Purity, sterility and extractables & leachables

Evaluation of Rapid Microbiological Methods

- Benefits
- Overview of methods
  - Growth dependent
  - Growth independent
- Validation and implementation
- Future challenges

Validation of Analytical Methods

- Regulatory Background
- Guidelines and Definitions
- Specific Application to Ph. Eur. methods
- Additional aspects for radiopharmaceuticals

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

Moderator

Clemens Mundo, Concept Heidelberg

Speakers

Nic Gillings, Copenhagen University Hospital, Rigshospitalet

Nic Gillings has over 30 years experience in the field of radiopharmaceuticals, the last 22 in Copenhagen, where he is QA Manager and QP. He was a member of the Radiopharmacy Committee of the European Association of Nuclear Medicine for 6 years and has co-authored a number of guidelines on radiopharmacecutical-related GMP issues. He is also a member of the Editorial Board of the European Journal of Nuclear Medicine and Molecular Imaging, Radiopharmacy and Chemistry.

Thijs Kroon, GE Healthcare

Thijs Kroon is trained as a pharmacist and has more than 30 years of experience in the radiopharmeceutical industry in QA , QC, RA and Operations. His experience covers both conventional as well as PET radiopharmaceuticals. He is member of the European Pharmacopoeia expert group on radiopharmaceuticals which he also chaired for a number of years.

Arjan Langen, GE Healthcare Biosciences

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 Director Sterility Assurance at GE Healthcare, responsible for the global Sterility Assurance program. 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 microbiologist by training, qualified IRCA/QCI auditor and Green Belt certified.

Prof Dr Gerald Reischl, University Hospital Tübingen

Dr Gerald Reischl is Associate 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 radiopharmacy in 2008.

Dr Franz Schönfeld, Government of Upper Franconia

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 expert group for radiopharmaceuticals and is now head of the national expert group for APIs and excipients.

Dr Dirk Freitag-Stechl, CUP Laboratorien

Dr Dirk Freitag-Stechl studied chemistry at the Technical University of Dresden and business management at the Dresden International University. After his dissertation in the field of organic chemistry, a research stay at the Polo Scientifico "Ugo Schiff" in Florence and a position as laboratory manager in the central research department of Henkel AG & CO. KGAA in Düsseldorf, he took over the management of CUP Laboratorien in 2008. Since March 2021, he has also been a partner and CFO of TRIMT GmbH.

Marlous van der Hooft, Scitech

Managing Director and General Manager with more than 20 years' experience working in a wide range of senior operational management and project roles in the radiopharmaceutical, pharmaceutical and devices business.

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Reservation Form (Please complete in full)

GMP and Quality Requirements for Radiopharmaceuticals, 18/19 June 2024, Heidelberg, Germany

Title, first name, surname

Department | Company

Important: Please indicate your company's VAT ID Number | Purchase Order Number, if applicable

City | ZIP Code | Country

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If you cannot attend the conference you have two options:
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Date
Tuesday, 18 June 2024, 09.00 – 18.00 h
(Registration and Coffee 08.30 – 09.00 h)
Wednesday, 19 June 2024, 09.00 – 17.00 h

Venue
Qube Hotel Bahnstadt
Grüne Meile 21
69115 Heidelberg, Germany
Phone: +49 6221 639000
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Fees (per delegate, plus VAT)
ECA Members € 1,690
APIC Members € 1,790
Non-ECA Members € 1,890
EU GMP Inspectorates € 945
The conference fee is payable in advance after receipt of invoice and includes lunch on both days and all refreshments. VAT is reclaimable.
(A limited number of places are available for students and doctoral students with reduced participation fees. Please enquire.)

Accommodation
CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form/POG when you have registered for the course. Reservation should be made directly with the hotel. Early reservation is recommended.

Registration
Via the attached reservation form, by e-mail or by fax message.
Or you register online at www.gmp-compliance.org.

Presentations/Certificate
The presentations for this event will be available for you to download and print before and after the event. Please note that no printed materials will be handed out on site and that there will not be any opportunity to print the presentations on site. After the event, you will automatically receive your certificate of participation.

Conference language
The official conference language will be English.

Organisation and Contact
ECA has entrusted Concept Heidelberg with the organisation of this event.
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