ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Quality Assurance Manager

Speakers

Dr Dirk Freitag-Stechl
CUP Laboratorien

Marlous van der Hooft
Scitech

Thijs Kroon
GE Healthcare, The Netherlands

Arjan Langen
GE Healthcare, The Netherlands

Dr Franz Schönfeld
Government of Upper Franconia

GMP and Quality Requirements for Radiopharmaceuticals

Live Online Training on 29/30 April 2025

Highlights

- Regulatory Developments and Authorities' Expectations
- Radiopharmaceuticals in Ph. Eur. and Annex 1
- QRM – Challenge Quality Risk Management
- Microbiological Safety
- Equipment Qualification and Method Validation
- GDP – Good Distribution Practice for Radiopharmaceuticals

Experiences of Authority and Industry

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 contract laboratory and manufacturing 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

Moderator

Clemens Mundo, Concept Heidelberg

Programme

Regulatory Requirements for Radiopharmaceuticals

- Directive 2001/83/EC
- Regulation EU No 536/2014
- EU GMP Guidelines and their annexures 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 and exhaust

How to Handle Audits- View of an Inspector

- 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

- 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
- The "UNTIE®" process
- 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

Speakers

Dr Dirk Freitag-Stechl
CUP Laboratorien, Managing Director

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

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.

Thijs Kroon
GE Healthcare, the Netherlands
Senior QA Manager

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, 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 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.

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.

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Reservation Form (Please complete in full)

GMP and Quality Requirements for Radiopharmaceuticals, Live Online Training on 29/30 April 2025

Title, first name, surname

Department | Company

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

City | ZIP Code | Country

Phone / Fax

E-Mail (Please fill in)

General terms and conditions
If you cannot attend the conference you have two options:
1. We are happy to welcome a substitute colleague at any time.
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- Cancellation until 3 weeks prior to the conference 25 %,
- Cancellation until 2 weeks prior to the conference 50 %
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In case you do not appear at the event without having informed us, you will have to pay the full registration fee, even if you have not made the payment yet. Only after we have received your payment, you are entitled to participate in the conference (receipt of payment will not be confirmed)! (As of January 2012).
German law shall apply. Court of jurisdiction is Heidelberg.

Privacy Policy: By registering for this event, I accept the processing of my Personal Data. Concept Heidelberg will use my data for the processing of this order, for which I hereby declare to agree that my personal data is stored and processed. Concept Heidelberg will only send me information in relation with this order or similar ones. My personal data will not be disclosed to third parties (see also the privacy policy at http://www.gmp-compliance.org/eca_privacy.html). I note that I can ask for the modification, correction or deletion of my data at any time via the contact form on this website.

Date of the Live Online Training

Tuesday, 29 April 2025, 08.30 h – 18.00 h
Wednesday, 30 April 2025, 08.30 h – 17.00 h
All times mentioned are CEST

Technical Requirements

We use WebEx for our live online training courses and webinars. At https://www.gmp-compliance.org/training/online-training-technical-information you will find all the information you need to participate in our trainings and you can check if your system meets the necessary requirements to participate. If the installation of browser extensions is not possible due to your rights in the IT system, please contact your IT department. WebEx is a standard nowadays and the necessary installation is fast and easy.

Fees (per delegate, plus VAT)

ECA Members € 1,690
APIC Members € 1,790
Non-ECA Members € 1,890
EU GMP Inspectorates € 945
The fee is payable in advance after receipt of invoice.

Registration

Via the attached reservation form, by e-mail or by fax – or search and register directly at www.gmp-compliance.org under the number 21864.

Presentations/Certificate

The presentations will be made available to you prior to the Live Online Training as PDF files. After the event, you will automatically receive your certificate of participation.

Internationally Acknowledged Certificate from ECA Academy

The EU GMP Guide requires: „... All personnel should be aware of the principles of Good Manufacturing Practice that affect them and receive initial and continuing training.... " This is why you receive an acknowledged participant certificate, which lists the contents of the seminar in detail and with which you document your training.

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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