ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Quality Assurance Manager

Speakers

Dr István Boros
University of Cambridge, Wolfson Brain Imaging Centre, UK

Dr Clemens Decristoforo
University Hospital Innsbruck, Austria

Nic Gillings
Copenhagen University Hospital, Rigshospitalet

Dr Jacek Michał Koziorowski
RadCad

Arjan Langen
GE Healthcare, The Netherlands

Dr Gerald Reischl
University Tübingen

Dr Franz Schönfeld
Government of Upper Franconia

GMP and Quality Requirements for Radiopharmaceuticals

Live Online Training on 23/24 March 2021

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 Live Online Training, 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 Manufacturer's 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

Supplier Qualification

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

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

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

Dr István Boros, University of Cambridge, Wolfson Brain Imaging Centre, UK

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 Clemens Decristoforo, University Hospital Innsbruck, Austria

Clemens Decristoforo worked as a radiopharmacist at the Institute of Nuclear Medicine Innsbruck from 1991 -1997. After his PhD he was a post doc at the Nuclear Medicine Research Laboratory, St Bartholomew's Hospital, London. In 1998 he came back to Innsbruck to the Institute of Nuclear Medicine Innsbruck. Between 2009 and 2010 he was a research associate at the Industrial Applications and Chemistry Section, Division of Physical and Chemical Sciences, IAEA. He is also a member of the Editorial Board of the European Journal of Nuclear Medicine and Molecular Imaging, was Chairman of the Radiopharmacy Committee of the European Association of Nuclear Medicine and a member of the Expert Group 14 European Pharmacopeia.

Nic Gillings, Copenhagen University Hospital, Rigshospitalet

Chief Radiochemist, Qualified Person, PET & Cyclotron Unit (3982)

Dr Jacek Michał Koziorowski, RadCad

Jacek Koziorowski obtained his PhD in organic chemistry in 1998. He has worked as a radiochemist and radiopharmacist in the field of Positron Emission Tomography (PET) for the last 25 years. He has set up and started three PET centres,. He was active within the European Association of Nuclear Medicine for the training of new PET radiopharmacists and is also a consultant for the IAEA. 2019 he started his own business at RadCad.

Arjan Langen, Director Sterility Assurance, GE Healthcare, The Netherlands

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.

Dr Gerald Reischl, University Tübingen, Preclinical Imaging and Radiopharmacy

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.

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 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 23/24 March 2021

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

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General terms and conditions
If you cannot attend the conference you have two options:
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Date of the Live Online Training

Tuesday, 23 March 2021, 09.00 – 18.00 h CET
Wednesday, 24 March 2021, 09.00 – 17.00 h CET

Technical Requirements

For our Live Online Training Coures we use Cisco WebEx, one of the leading suppliers of online meetings.
At http://www.webex.com/test-meeting.html you can check if your system meets the necessary requirements for the participation at a WebEx meeting and at the same time install the necessary plug-in. Please just enter your name and email address for the test. If the installation is not possible because of your rights for the computer 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 € 1,590
APIC Members € 1,690
Non-ECA Members € 1,790
EU GMP Inspectorates € 895
The fee is payable in advance after receipt of invoice.

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 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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