20 YEARS | ECA Academy
Your GMP/GDP Information Source

Radiopharmaceuticals

Quality, Safety and GMP Requirements

Current Regulatory Developments and Practical Experiences

Speakers


Kathrine Ask Asmussen
Danish Medicines Agency


Dr Hendrikus Boersma
University Medical Center, Groningen


Dr István Boros
University of Cambridge Wolfson Brain Imaging Centre


Jan van den Bos
GE Healthcare


Robert Hebel
PPH


Stefan Kürpig
University Hospital Bonn


Dr Gerald Reischl
University Tübingen

Dr Antonia Richter
University Hospital of the Technical University Munich


Markus Roemer
comes compliance services


Dr Christian Schmidt
Life Molecular Imaging GmbH


Dr Franz Schönfeld
Government of Upper Frankonia


Dr Ingrid Walther
Pharma Consulting Walther

26/27 March 2019, Vienna, Austria

HIGHLIGHTS

- Regulatory Developments and Authorities' Expectations
- Annex 1 – Impact
- QRM – Challenge Quality Risk Management
- Data Integrity and Computer Validation – Requirements and State of the Art
- Bioburden Testing
- Analytical Methods Validation
- GDP – Good Distribution Practice for Radiopharmaceuticals

This conference is recognised for the ECA GMP Certification Programme „Certified Quality Control Manager".
Please find details at www.gmp-certification.eu

Radiopharmaceuticals

26/27 March 2019, Vienna, Austria

Objectives

During this conference, 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 Computer Validation, Data Integrity and Good Distribution Practice.

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 conference 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.

Programme

Current Regulatory Developments – Authorities' View

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

Franz Schönfeld, GMP Inspector, Germany

Radiopharmaceuticals and GMP – Practical Experiences

- Possibilities and Limitations
- Pitfalls

Dr Antonia Richter, University Hospital of the Technical University Munich

Quality Risk Management for Radiopharmaceutical Manufacturing

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

Dr Ingrid Walther, Walther Consulting

From Old to New - Case Study on the Revision of an Existing Building

- Important Questions – Pitfalls of the Project
- Basic Conditions – What is to be observed?
- Realisation - to make sure that nothing has been forgotten
- Use – How to go on?

Dr Robert Hebel, PPH | Dr Stefan Kürpig, University Hospital Bonn

Programme

Supplier Management
- Good Manufacturing Practice
- Legal Framework
- Active Pharmaceutical Ingredients
- Supplier Selection
- Supplier Evaluation
- Approved Suppliers
- Quality Agreement

Istvan Boros, University of Cambridge

GDP – The crucial role of Good Distribution Practice in the supply of Radiopharmaceuticals
- Delivery to Customers – Customer Qualification
- Route Qualification – Transport studies
- Transportation under quarantine status – in bond shipment
- Role of Responsible Person

Jan van den Bos, GE Healthcare

Inspection Experiences and possible Impacts of Annex 1 Revision
- The basis for radiopharmaceuticals (PET/TC Generator and Kit)
- Inspections
- Typical deficiencies

Kathrine Ask Asmussen, Danish Medicines Agency

Annex 1/Sterile Manufacturing – We are ready?
- Effective Root Cause Analysis
- Education, not training
- Use of Vapour Hydrogen Peroxide
- PUFIT
- Contamination Control Strategy document

Istvan Boros, University of Cambridge

Case Study: Audit Findings and their impact and the related GMP aspects
- Hotcell issues
- Monitoring and validation
- Process validation
- IMPD issues
- Data integrity
- Miscellaneous audit findings over the years

Hendrikus Boersma, University Medical Center Groningen

Computer System Validation and Data Integrity – a chance for improvements
- Lean Project & IT Management Approach - secure your investments
- Data Mapping and Data Mining – secure your knowledge
- GMP digitalisation – secure your future
- Modern Validation Approach – secure your compliance

Markus Roemer, comes compliance services

Bioburden Testing of Radiopharmaceuticals
- Sample Frequency
- Method of Sampling
- How to define Specification

Christian Schmidt, Life Molecular Imaging

Validation of Analytical Methods
- Regulatory Background
- Validation Strategies

Gerhard Reischl, University Tübingen

Speakers

Kathrine Ask Asmussen | Danish Medicines Agency | Medicines Inspector

Kathrine studied at the Danish Pharmaceutical University. Following she worked for the Statens Serum Institut and NNE Pharmaplan. Since 2015 she is employed as Inspector at the Danish Medicines Agency.

Dr Hendrikus Boersma | University Medical Center | Groningen

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 István Boros | University of Cambridge | Wolfson Brain Imaging Centre | Cambridge, 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 Patent Office and Astra Zeneca before he joined the University of Cambridge, Wolfson Brain Imaging Centre.

Jan van den Bos | GE Healthcare | Qualified Person and Responsible Person

Jan van den Bos is as QP responsible for the quality and release of SPECT and PET products manufactured in Eindhoven, the Netherlands. In addition, he is one of the Responsible Persons for GDP compliance of the Wholesale distribution activities.. Recently he was engaged in the setup of new destinations to deliver radiopharmaceuticals outside Europe.

Robert Hebel | PPH

Robert Hebel studied Physics and Biomedical Engineering at the University in Erlangen, Germany. During close to 30 years experiences at Siemens Medical and at a radiopharmaceutical company, gained experiences in Risk Analysis, Qualification, Validation in the setting of an aseptic radiopharmaceutical production. He is co-founder of the company pph GmbH, Erlangen, Germany which provides GMP Consulting together with Technology Sourcing.

Stefan Kürpig | University Hospital Bonn | Head of Department

After studying chemistry he worked as developer at ravtest isotope gauges and as project manager for the BMBF Projekt MoBiVir. Since 2010 he is deputy head of the radiopharmaceutical department at the hospital for nuclear medicine Bonn.

Dr Gerald Reischl | University Tübingen

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, became head of radiopharmaceutical production in 2008.

Dr Antonia Richter | University Hospital of the Technical University Munich

Antonia Richter studied Molecular Biotechnology at the TU Munich. And worked there as scientist until 2014. After getting her PhD, she joined the nuclear medicine department of the hospital of the Technical University Munich.

Markus Roemer | comes compliance services | General Manager

Markus Roemer started his professional career as a team member of the computer validation department at Vetter Pharma Fertigung in Ravensburg. Later he was (amongst others) Senior Validation Consultant at Invensys Validation Technologies in Montreal, Canada and Director Compliance at Systec & Services.

Christian Schmidt | Life Molecular Imaging GmbH Director Global Manufacturing

Christian Schmidt studied Pharmacy at the Universities of Hamburg and Kiel. He joined Eli Lilly in 2000 and changed to NOXXON Pharma in 2007. Since 2013 he is heading the CMC team of Life Molecular Imaging (fka. Piramal Imaging) where he is in charge of the global manufacturing of its first commercial PET tracer Neuraceq used for ß-Amyloid imaging (Alzheimer's Disease).

Franz Schönfeld | Government of Upper Frankonia 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 Ingrid Walther | Pharma Consulting Walther

Dr Walther joined Fresenius AG in 1986 and was employed in various positions and has many years of experience in research and development, quality assurance/quality control and the management of strategic projects. Since July 2009, she runs her own business as GMP compliance consultant.

Easy Registration

Reservation Form:
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69007 Heidelberg
Germany

Reservation Form:
+ 49 6221 84 44 34

e-mail:
info@concept-heidelberg.de

Internet:
www.gmp-compliance.org

Date
Tuesday, 26 March 2019, 09.30 – 18.00 h
(Registration and coffee 09.00-09.30 h)
Wednesday, 27 March 2019, 09.00 – 16.00 h

Venue
Radisson Blu Park Royal Palace Hotel, Vienna
Schlossallee 8
1140 Vienna, Austria
Phone +43/1/89110 9 200
info.parkroyalpalace.vienna@radissonblu.com

Conference fees (per delegate plus VAT)
ECA Members € 1,590
APIC Members € 1,690
Non-ECA Members € 1,790

There is a limited number of authority and academic rates available:
EU GMP Inspectorates € 895
Students and Postgraduates € 895

The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the first day, lunch on both days and all refreshments. VAT is reclaimable

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 conference. Reservation should be made directly with the hotel. Early reservation is recommended.

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

Conference language
The official conference language will be English.

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

CONCEPT HEIDELBERG
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For questions regarding content please contact:
Mr Axel Schroeder (Operations Director) at
+49-62 21/84 44 10 or per e-mail at
schroeder@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc. please contact:
Mr Niklaus Thiel (Organisation Manager) at
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Registration form (please complete in full)

Radiopharmaceuticals – Quality, Safety and GMP Requirements
26/27 March 2019, Vienna, Austria

☐ Mr ☐ Ms Title _____

First name, surname

Company

Department

Important: Please indicate your company's VAT ID Number

Purchase Order No. (if applicable)

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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.
2. If you have to cancel entirely we must charge the following processing fees: Cancellation
- until 2 weeks prior to the conference 10 %,
- until 1 weeks prior to the conference 50 %
- within 1 week prior to the conference 100 %.

CONCEPT HEIDELBERG reserves the right to change the materials, instructors, or speakers without notice or to cancel an event.
If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid. CONCEPT HEIDELBERG will not be responsible for discount airfare penalties or other costs incurred due to a cancellation.
Terms of payment: Payable without deductions within 10 days after receipt of invoice.
Important: This is a binding registration and above fees are due in case of cancellation or non-appearance. If you cannot take part, you have to inform us in writing. The cancellation fee will then be calculated according to the point of time at which we receive your message. 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.

Social Event

In the evening of the first conference day, you are cordially invited to a social event.

This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.

GMP/GDP Certification Programme

This conference is recognised within the GMP/GDP Certification Programme Module "Quality Control Manager". By attending selected seminars, the participant can acquire an additional certificate. We offer the following modules:

- ECA Certified Validation Manager
- ECA Certified QA Manager
- ECA Certified API Production Manager
- ECA Certified Quality Control Manager
- ECA Certified Technical Operations Manager
- ECA Certified Computer Validation Manager
- ECA Certified Regulatory Affairs Manager
- ECA Certified Microbiological Laboratory Manager
- ECA Certified Sterile Production Manager
- ECA Certified Biotech Manager
- ECA Certified Pharmaceutical Development Manager
- ECA Certified GMP Auditor
- ECA Certified GDP Compliance Manager
- ECA Certified Packaging Manager
- ECA Certified Data Integrity Manager

On the internet at www.gmp-compliance.org you will find a text explaining which seminars are recognised for which certificates. Or you send an e-mail to info@gmp-compliance.org or a fax to +49-6221- 84 44 64 with the request for information about the GMP Certification Programme. We will then send you our brochure on the topic.

What are The ECA Foundation and the ECA Academy?

The European Compliance Academy Foundation (ECA Foundation) is an independent professional organisation chaired by a Scientific Advisory Board with members from the pharmaceutical industry and regulatory authorities. The ECA Foundation's goal is to support to the Pharmaceutical Industry and Regulators to promote the move towards a harmonised set of GMP and regulatory guidelines by providing information and interpretation of new or updated guidances. The ECA Academy offers professional basic and advanced education (training) programmes. All services offered by the ECA Academy and with regard to ECA Academy Memberships are solely managed by Concept Heidelberg (a leading European training and information services provider). The ECA Foundation is conceptual sponsor of the ECA Academy.

How Do You Become Member of ECA?

By participating in one of the ECA Academy Conferences or Courses you will automatically become a ECA Academy Individual Member for two years - free of charge. More information about ECA Academy can be obtained on the Website http://www.gmp-compliance.org

What Are the Benefits of ECA?

During the membership, you enjoy a € 200,- discount on the regular participation fee of any European Conference or Course presented by the ECA Academy. In addition you will receive the GMP Guideline Manager Software with a large number of guidelines, e.g. EC Directives, FDA Guidelines, ICH Guidelines.

Special offer with Lufthansa

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As an ECA course or conference attendee, you will receive **up to 20% discounted travel fares** (according to availability). And as Lufthansa German Airlines offers a comprehensive global route network linking major cities around the world you will most likely be able to benefit from these special prices and conditions.

And this is how it works: Once you registered for a course or conference you will receive a link together with your registration confirmation. Opening that link will take you to the Mobility Partner Program website where you can enter a code in the "Access to Event Booking" area you will also receive. This will take you into an online booking platform that will automatically calculate the discount offered or provide you with an even better offer if another promotional fare is available.

We look forward to welcoming at one of our next events – and we already wish you a pleasant flight!