21-22 February 2017, Vienna, Austria

HIGHLIGHTS

- Regulatory Developments and Inspection Experiences
- IAEA Global Quality Initiatives
- Production considering GMP Aspects
- Qualification of
  - Rooms
  - Hot Cells and Equipment
- LIMS
- Radiation Protection
- Bacterial Endotoxin Testing
- Risk Assessment/Deviation Management
- Case Study: New Pharmaceutical Production Unit
During this conference representatives of regulatory authorities and pharmacopoeial experts will present the current development of radiopharmaceutical regulations and their experiences during the inspection of manufacturing establishments.

Furthermore, speakers from nuclear medicine departments from universities and hospitals 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.

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 and the International Atomic Energy Agency (IAEA), pharmacopoeial experts as well as professionals from universities, hospitals and engineering.

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.

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
in radiopharmaceutical manufacturing.

The conference programme includes:

**Current Regulatory Developments – Authorities’ View**
- Directive 2001/83/EC
- Regulation EU No 536/2014
- EU GMP Guidelines and their annexes 1 and 3

**Guidance Documents and further Guidelines – Aspects for Small Scale Preparation/ The Hospital Settings**
- Current good practice for the small-scale preparation of radiopharmaceuticals
- EANM guideline for the preparation of an Investigational Medicinal Product Dossier (IMPD)
- EANM Guidance on Validation and Qualification of Processes and Operations Involving Radiopharmaceuticals

**Quality Risk Management – a way to reduce Deviations**
- Deviations as a Routine?
- Risk Assessment to improve Quality
- Risk Management Process

**Case Study: New Pharmaceutical Production Unit**
- Role of Karaj for Pars Isotope in the past and in future
- Supplier Selection - National versus International Sourcing
- Implementation of a Quality System - The Role of VMP
- Following the V-Model - From Design to Implementation
Production of Ga-68 radiotracers under GMP and regulatory aspects – A German perspective
- Regulations
- Technical and practical requirements
- Setting up a multicenter clinical trial with a Ga-68 radioligand

Radiation Protection in Radiopharmaceutical Production
- Regulatory requirements
- General concepts and workflow
- Constructional realization in a cleanroom environment
- Waste handling

The Qualification of hot-cells and principal manufacturing equipment
- An examination of the key Annex 15 qualification elements and how they fit with the Validation Life Cycle
- The benefits of an integrated validation approach in support of the Project timelines
- Key considerations to achieve meaningful User Requirement Specifications
- A risk-based approach to the qualification of principal equipment within the hot cells including the issues arising from multi-qualifications of inter-connected equipment.

The IAEA role in the development of radioisotopes/radiopharmaceutical production and application in Member States
- The coordinated research program (CRP) mechanisms to initiate product-directed activities
- The technical cooperation (TC) programs for implementation of technical infrastructure
- The initiation of technical meetings to focus on the existing challenges in the field
- Support of the participation of fellows and students in related events
- Preparation of appropriate publications and TecDocs for global use

Inspections – Experiences
- The basis for radiopharmaceuticals (PET/TC Generator and Kit)
- Inspections
- Typical deficiencies

Bacterial Endotoxin Testing
- 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

LIMS in Radiopharmaceutical Manufacturing
- Why LIMS?
- Obtaining and purchasing a LIMS
- Escrow agreement
- IQ/OQ
- Training
- Data integrity and GMP compliance.

Cleanrooms for Radiopharmaceuticals: Initial and Periodical Qualifications
- Regulations: a European Overview at a glance
- Physical and Microbiological Qualifications
- An example of a Cleanroom Qualification
Dr Joel Aerts, University of Paris, France
Joel Aerts studied chemistry and pharmacy in Liege University Belgium and got his PhD in 2008 in the field of PET tracers development. He has worked from 1998 as industrial pharmacists and radiopharmacist at Cyclotron Research Center of Liege, implementing GMPs and producing PET tracers with marketing authorization or for clinical trials. He is Belgian expert at EDON. Since 2013, he has been Associate Professor at Paris-Diderot University/ IN- SERM U1148/ Bichat Hospital Paris, and Invited Professor at Liege University.

Dr Istvan Boros, University of Cambridge, Wolfson Brain Imaging Centre, Cambridge, UK
Istvan Boros studied at the Universities of Cluj-Napoca and Debrecen and finalized with a PhD in Chemistry. Furthermore, he graduated during his career 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 in 2008. His current position there is Head of Quality Control/Quality Assurance. Additionally he works as temporary GMP consultant for the IAEA.

Martin Bradney, Proceutical Ltd., United Kingdom
Martin is a professional engineer with over 35 years’ experience in the pharmaceutical industry, mostly gained working in a Global QA/Engineering role with GE Healthcare and its predecessors. He joined Proceutical Ltd as a consultant in 2014. He has an extensive knowledge and practical experience of: Design, build and operation of specialist aseptic and PET cleanroom facilities, specialist knowledge relating to bespoke HVAC systems, WFI, Pure Steam, Freeze Drying and other specialist pharmaceutical/PET plant, equipment and processes; Project Management and hands-on experience of “real world” pharmaceutical capital projects; Regulatory “risk based approach” to ensure consistent equipment performance in the manufacture of Pharmaceuticals and Medical Devices and Integrated Qualification and Validation to deliver a flexible and innovative approach in a GxP environment.

Robert Hebel, PPH GmbH, Germany
Robert Hebel studied Physics and Biomedical Engineering at the University in Erlangen, Germany and obtained his Diploma of Physics in 1984. He has conducted a General Management Training at London Business School. He spent 23 Years with Siemens Medical in Erlangen in different businesses (Ultrasound, Computed Tomography, Magnetic Resonance Tomography, PET and Software Development) mostly in the fields of requirements engineering, development and marketing. While leading a radiopharmaceutical company in Erlangen for seven years he planned and built a green field PET Production Center according to the latest GMP regulations. During this time, he became an expert for a Quality System, Risk Analysis, Requirement Definition, 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.

Prof Amir Jalilian, International Atomic Energy Agency, Austria
Prof Jalilian has a PhD degree in Radiopharmacy (2000) and a PharmD degree (1995), followed by two post doc fellowships in University of Alberta, Canada and Yale School of Medicine, USA. During last 15 years, he has been active in the development of new radiopharmaceuticals in developing countries leading to the completion of clinical trials and the marketing of 6 radiopharmaceuticals. He has published more than 250 papers in peer-reviewed journals and 3 books and supervised more than 30 MSc and PhD theses. At the moment he is the technical officer at Radioisotope Products and Radiation Technology Section, IAEA, Vienna.

Mohsen Kamalidehghan, Pars Isotope Co., Iran
He studied applied physic at The Islamic Azad University of Karaj. He also passed a training course on Production of Radioisotopes at the Karlsruhe Institute of Technology and several training courses on GMP and Quality Assurance. Mohsen was working in the field of radioisotopes/radiopharmaceuticals production since 1997 in a cyclotron facility as well as being involved in research programs and also cooperation in a few projects in the field of PET imaging and targeted therapy applications. He joined Pars Isotope Co. as Cyclotron Radiopharmaceuticals production manager in 2012 Besides he was a consultant for designing and implementing GMP compliance PET production facility in Kazavi Charity Hospital, Mashhad, Iran. Currently, he is project manager of the new EU-GMP compliance cyclotron based radiopharmaceuticals production facility in Karaj and also PET production facility in Tehran at Pars Isotope Company known as “Pars”.

Dr Petra Kolenc-Petil, University Medical Centre Ljubljana
Petra Kolenc Petil studied pharmacy at the Faculty of Pharmacy in Ljubljana. After a master degree and a pharmacist registration examination (2001), she joined the radiopharmacy group at the Department of Nuclear Medicine, University Medical Centre Ljubljana (UMCL), where they deal mostly with small-scale preparation of radiopharmaceuticals within the hospital setting. She got her Ph.D. degree in medicinal chemistry (2011). She is a tutor at the Faculty of Pharmacy and Faculty of Health Sciences. She is a member of the research council within the UMCL, member of extended expert committee for the field of nuclear medicine at national Ministry of Health and a member of Radiopharmacy committee at EANM (European Association of Nuclear Medicine).

Dr Jacke Koziorowski, Linkoping University Hospital, Sweden
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, two of which have LIMS. He is active within the European Association of Nuclear Medicine for the training of new PET radiochemists and is also a consultant for the IAEA.

Dr Oliver Neels, German Cancer Research Center (DKFZ), Heidelberg
Oliver Neels studied chemistry and business administration at the University of Oldenburg and earned his PhD at the University of Groningen, The Netherlands. From 2007 - 2011, he was radiochemist within the Cooperative Research Centre for Biomedical Imaging Development (CRCBID). After that he became Head of Radiochemistry and Radiopharmacy at the Department of Nuclear Medicine, University Medical Center Rostock, Germany. Since 2013 he has been Radiopharmaceutical Chemist, Head of Production, Qualified Person and Radiation Safety Officer at the Division of Radiopharmaceutical Chemistry, German Cancer Research Center (DKFZ) Heidelberg, Germany.

Dr Gerald Reischl, University Tübingen, Germany
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 and acts as Qualified Person, head of quality control and Radiation Safety Manager in his institution.

Dr Franz Schönfeld, German GMP Inspectorate Upper Franconia, Bayreuth
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.

Mona Vyheved, Linkoping University Hospital, Sweden
Mona studied Chemistry at Linkoping University. From 1998-2005 she worked as Radioisotope Production Manager and Quality Assurance Manager at Studsvik Nuclear AB. In 2007 she joined Herlev University Hospital, Denmark as Radiopharmaceuticals Production Manager. Currently, she is Quality Assurance Coordinator at Linkoping University Hospital, Dept. of Clinical Physiology, Nuclear Medicine.
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.

This conference is recognised within the GMP 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.

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.

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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.

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!
Date
Tuesday, 21 February 2017, 09.30 – 17.30 h
(Registration and coffee from 09.00 – 09.30 h)
Wednesday, 22 February 2017, 09.00 – 14.00 h

Venue
Austria Trend Hotel
Park Royal Palace Vienna
Schlossallee 8
1140 Vienna, Austria
Phone +43/1/891 109 200
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Conference fees (per delegate plus VAT)
ECA Members € 1,490
APIC Members € 1,590
EU GMP Inspectorates € 845
Students and Postgraduates € 845
Non-ECA Members € 1,690
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 when you have registered for the conference. Please use this form for your room reservation to receive the specially negotiated rate. 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
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Registration form (please complete in full)
Radiopharmaceuticals – Quality, Safety and GMP Requirements
21-22 February 2017, Vienna, Austria

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First name, surname

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General Terms of Business
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 % of the registration fee.
- until 1 week prior to the conference 50 % of the registration fee.
- within 1 week prior to the conference 100 % of the registration fee.
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. You are not entitled to participate in the conference until we have received your payment (receipt of payment will not be confirmed!! (As of January 2012)}