Leachables & Extractables Testing & Assessment

Addressing all relevant aspects ranging from regulatory requirements to routine leachables testing in QC

26-27 April 2016, Copenhagen, Denmark

SPEAKERS:
Dr Armin Hauk
Intertek Expert Services
Petra Motzkau
Sartorius Stedim Biotech
Dr Andreas Nixdorf
SGS Institut Fresenius
Dr Ralph Nussbaum
Analytical Services
Gaby Reckzügel
Boehringer Ingelheim Pharma
Dr Mike Schäfers
West Pharmaceutical Services
Karl-Heinz Schneider
schneiDeRS Consulting
Dr Jörg Zürcher
Bayer Pharma

PROGRAMME:
- Regulatory Requirements for Extractables / Leachables Testing
- Extractables and Leachables Testing in Packaging Material
- Practical Approaches for L&E Testing in QC
- GMP-compliant Approach to a Process Specific Extractable / Leachable Study
- Plastic-Derived Materials for Manufacturing of Biopharmaceuticals
- Extractables from Glass
- Potential Extractables from Elastomers
- Printing Inks as Potential Sources of Leachables and Extractables

This education course is recognised for the ECA GMP Certification Programme „Certified Packaging Manager“. Please find details at www.gmp-certification.eu
Learning Objectives

Over the last years, the requirements on the assessment of substances that could leach into the drug product in the course of its life cycle have increased considerably.

The kind of leachable you would have to look for can vary from organic oligomers and catalyst residues to heavy metals – to name a few. Due to the resulting complexity, it is very important to consider the potential risk already at a very early stage in process development.

Packaging materials have been in the focus of such investigations for a long time as the contact time between drug product and packaging material is rather long.

But in addition you have to consider other possible sources of contamination. Recently, particular attention was paid to devices and equipment used in the production process itself, e.g. filters, bags, tubes. The trend towards single-use equipment might relieve the pressure on cleaning validation. At the same time leachables/extractables testing will become a topic of major concern.

Within the scope of this GMP Education Course, all relevant aspects of FDA/GMP-compliant leachables and extractables testing will be addressed ranging from regulatory requirements to routine extractables testing in quality control.

Experienced industry speakers share their in-depth knowledge with you.

Target Group

The course is designed for personnel of pharmaceutical companies and their suppliers who
- are responsible for qualification of extractables/leachables in quality control,
- perform leachables/extractables testing,
- work in quality control of packaging material,
- choose and define polymeric, glass and rubber materials in process development.

Programme

Introduction to Plastics
- Physical and chemical characteristics
- Different types of additives in plastics

Regulatory Requirements for Extractables / Leachables Testing
- Why should Extractables & Leachables be assessed?
- Regulatory requirements of EMA and US-FDA
- Compendial requirements and foodstuff regulations
- PQRI and other recommendations for Safety Thresholds and Best Practices for Extractables & Leachables testing

Extractables and Leachables Testing in Packaging Material
- Why – Regulatory requirements of FDA and EMEA
- What – Change in primary and secondary packaging material or labels
- How – Global and tailored approaches

Annual Guest Presentation: Challenges in L&E Testing
- Sample preparation – How to avoid pitfalls
- Analytical methods – How to increase analytical performance
- Leachable testing – Method validation approach

The leachables profile should also be determined for compendial plastics and rubber container closure components.

GUIDELINE ON THE PHARMACEUTICAL QUALITY OF INHALATION AND NASAL PRODUCTS, 1 October 2006

Routine Extractables Testing in Quality Control
- Batch-to-batch consistency in composition and purity of packaging components
- Acceptance criteria for extractables profiles
- Quality agreements with suppliers

Plastic-Derived Materials for the Manufacture of Biopharmaceuticals
- Drug Product Perspective
- Plastic Materials: Selection and Characterization
- Use-Specific Testing
- Example

Extractables & Leachables: A Pragmatic Approach
- In-Process Materials with Product Contact
- Elastomeric Drug Product Stoppers
- Experience with Regulatory Agencies
- Questions, Comments

L&E Strategies in Practice
- How to design a reasonable E&L study („to do enough but not too much“)
- The translation of regulatory requirements into analytical lab work

Leachables & Extractables - Testing & Assessment
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The evaluation of extractables data and consequences to leachables studies
How to outsource E&L studies
Illustrative examples

Extractables from Glass
- Glass composition
- Type of extractables from glass
- Risk evaluation of glass extractables
- Concepts to avoid extractables from glass

For plastic material used for container closure systems for active substances or medicinal products, toxicological data should be provided for extractables and leachables, depending on their level and chemical structure.

GUIDELINE ON PLASTIC IMMEDIATE PACKAGING MATERIALS, 1 December 2005

Extractables from Elastomers – Parenteral Packaging Testing Composition of Elastomers used for Pharmaceutical Applications
- Discussion Material Composition and Extractables (Potential Extractable List)
- Approaches to minimize Extractable/ Leachable from Elastomeric Closures
- General Approach to Extractable/ Leachable Studies for Parenterals

Challenges in L&E Testing
- Sample preparation – How to avoid pitfalls
- Analytical methods – How to increase analytical performance
- Leachable testing – Method validation approach

“All surfaces that come in contact with products shall be clean and free of surface solids, leachable contaminants, and other materials that will hasten the deterioration of the product or otherwise render it less suitable for the intended use.” 21CFR, 600.11 (b)

All final containers and closures shall be clean and free of surface solids, leachable contaminants and other materials that will hasten the deterioration of the product or otherwise render it less suitable for the intended use. 21CFR, 600.11 (h)

Leachables during Manufacturing
- Bag-filter-assemblies and other polymer-based materials in the manufacturing process
- Finding the right test approach under consideration of critical success factors for the pharma/biotech industry such as cost efficiency, time-to-market and regulatory compliance
- Model solvent testing versus product and process specific testing
- Evaluation of the test results

Printing Inks as Potential Sources of Extractables & Leachables
- Introduction and basics of printing techniques
- Composition & chemistry of ink systems ("the ink manufacturer’s toolbox")
- Possible interactions of printing ink systems with the packaging material and the drug formulation
- Illustrative examples of extractables from printing
- Relevance of ink components as leachables.

WORKSHOP
In the course of this workshop you will develop a strategy for conducting a compliant and reasonable leachables study. The task will be based on an industry example. It will be your challenge to answer the following questions:
- Which activities are necessary during the development phase?
- How will you deal with quality control during routine production?
- Where will you find useful information about the material you are going to use?

Speakers

Dr Armin Hauk
Intertek Switzerland AG
Dr Armin Hauk studied environmental chemistry. Parallel to his PhD he conducted a 5 year research work in the field of polymer combustion chemistry. He joined the central analytical department of the former Ciba-Geigy Inc. in 1995. Since 2000 he is head of the trace analysis group, the GLP testing facility and the GMP quality control laboratory in Basle. He is responsible for organic trace and ultra trace analysis, special analytics for registration, migration studies, extractable and leachable studies for pharmaceutical packaging, for GMP quality control analysis and stability tests. He is responsible person according HMG and member of the EDQM Working Group „Plastic Containers for Pharmaceutical Use”.

Petra Motzkau
Sartorius Stedim Biotech GmbH
Petra Motzkau has spent several years in various positions focussing on filtration in the company segment Biotechnology within the Sartorius Group, an internationally leading provider of laboratory and process technologies. In her current function as Director Validation Services Asia Pacific she can look back on 10 years experience. Leading validation studies conducted for the pharmaceutical industry she has permanent insight in the critical success factors in the pharmaceutical and biotech market. This enables her to provide guidance with regard to the practical interpretation of current regulatory requirements. She is a PDA Member and has travelled extensively to conduct seminars and trainings on product and process specific validation.
Dr Andreas Nixdorf  
SGS Institut Fresenius GmbH  
Andreas Nixdorf has sixteen years experience with analytical questions. Since 2007, he is responsible for project management at the customer service pharma at SGS Institute Fresenius with focus on development of methods, validation and analysis of leachables and extractables.

Dr Ralph Nussbaum  
Analytical Services  
Ralph Nussbaum is chemist by education. He started his career in 1995 at Grunenthal GmbH in Aachen as Head of Analytical Laboratory. In 2000 he moved to CarboGen AG, a Swiss drug substance manufacturer, as Head of Quality Management and Qualified Person. After 12 years in the pharmaceutical industry, Ralph started with Analytical Services in 2004. Analytical Services is a service provider for the pharmaceutical industry and is specialized in structure elucidation, leachables & extractables and development and validation of HPLC-MS and GC-MS methods.

Gaby Reckzügel  
Boehringer Ingelheim Pharma GmbH & Co. KG  
Gaby Reckzügel is head of a laboratory for chemical characterization of device components and packaging materials within the Drug Delivery Department. Coming with analytical experience in the food industry as a food chemist she started in Research & Development at Boehringer Ingelheim, Germany in 2000. Here she is involved in the choice of materials for packaging and device components and is responsible for chemical analytical aspects during development. She is in charge of development and validation of routine quality control methods.

Dr Mike Schäfers  
West Pharmaceutical Services GmbH & Co. KG  
Dr Mike Schäfers is Vice President Global Marketing Pharmaceutical Packaging Systems at West Pharmaceutical Services. He studied chemistry and business management at the Ruhr University in Bochum. After 4 years of business experience at R. P. Scherer (today Catalent) he joined West Pharmaceutical Services in 2000 where he headed the Scientific & Technical Customer Service Group for the European and Asian-Pacific market. 2005 he became responsible for Marketing and Technical Customer Service in Europe at West. In 2012 he assumed responsibility for West’s global Marketing activities within the Pharmaceutical Packaging System division. He is member of the Parenteral Drug Association (PDA) and the “Arbeitsgemeinschaft für pharmazeutische Verfahrenstechnik” (APV) and a frequent speaker and organizer of conferences.

Karl-Heinz Schneider  
Freelance associate schneideRS Consulting, Germany  
K.-H. Schneider spent more than 18 years in Regulatory Affairs and was involved in the global licensure of biological products with primary focus on U.S. Product and Establishment License Applications. Since late 2005 to 2013 he worked in the Validation Department of CSL Behring and dealt with the validation of aseptic and non-aseptic processes and primarily working on E & L activities. During the last years he has been involved in the creation and implementation of a practical approach for E & L testing of product-contacting plastic derived materials comprising in-process materials and drug product elastomeric stoppers. Responsibilities include the execution of risk assessments, review of manufacturer’s data, planning of in-house and external E & L studies, and presentation of the E & L approach and data during inspections by Regulatory Agencies including the FDA. He has been working for schneideRS Consulting since 2014.

Dr Jörg Zürcher  
Bayer Pharma AG  
Jörg Zürcher is a pharmacist. He studied in Berlin and finished his studies with PhD degree. Since July 1990 he is working for Schering AG (now Bayer Pharma AG), Berlin in the Pharmaceutical Development. His responsibility is the development of containers for new products as well as for the market product in the course of life-cycle management with focus on packaging of liquid dosage forms. In addition, he is responsible for the development of application systems like pre-filled syringes or unique, product-specific devices.

Social Event  
On 26 April 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.
Organisation and Contact

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

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For questions regarding reservation, hotel, organisation etc.:
Ms Katja Kramer (Organisation Manager) at +49 (0) 62 21 / 84 44 16, or per e-mail at kramer@concept-heidelberg.de.

About CONCEPT HEIDELBERG

Founded in 1978, CONCEPT HEIDELBERG is the leading organiser of seminars on pharmaceutical production, quality control, quality assurance and GMP in Europe. This year more than 240 events will be organised by CONCEPT HEIDELBERG.

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 guidelines. 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 a 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.

GMP Certification Programme

This seminar is recognised within the GMP Certification Programme for the module “Certified Packaging 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

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.

Use the GMP App at no costs!

The ECA Foundation has developed a GMP App which offers a comprehensive GMP Guideline database with more than 1,400 GMP Guidelines and ten thousands of pages. Check relevant Guidelines (full text versions) during internal audits, regulatory inspections or GMP compliance meetings – simply on your smartphone or tablet PC. In addition to this wealth of guideline information the GMP App also comprises features like GMP News, a comprehensive GMP Search Engine. To open the app just enter app.gmp-compliance.org in your browser and the WebApp opens immediately.
Date

Tuesday, 26 April 2016, 09.00 – 18.00 h
(Registration and coffee 08.30 – 09.00 h)

Wednesday, 27 April 2016, 08.30 – 16.00 h

Venue
Radisson Blu Scandinavia Hotel
Amager Boulevard 70
2300 Copenhagen S, Denmark
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Fees (per delegate plus VAT)
ECA Members € 1,590
APIC Members € 1,690
Non-ECA Members € 1,790
EU GMP Inspectorates € 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 find details at this event and a registration form on our website www.gmp-compliance.org. Just follow the link "Conferences" on the homepage.

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.

Terms and conditions:
1. 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:
   - until 2 weeks prior to the conference: 10 %
   - until 1 weeks prior to the conference: 50 %
   - within 1 week prior to the conference: 100 %

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Important: Please indicate your company’s VAT ID Number

Registration

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