20 YEARS ECA Academy
Your GMP/GDP Information Source

Leachables & Extractables
Testing & Assessment

Methods and Materials – from Packaging to Single Use Systems

SPEAKERS:


Dr J. Susanne Becker
Intertek Switzerland AG


Dr Bettine Boltres
West Pharmaceutical Services GmbH & Co. KG


Lothar Fruth
Toxicology Expert Services


Dr Armin Hauk
Sartorius Stedim Biotech GmbH


Michael Jahn
Lonza AG


Dennis Jenke
Triad Scientific Solutions/USP


Petra Motzkau
Sartorius Stedim Biotech GmbH


Dr Andreas Nixdorf
SGS Institut Fresenius GmbH


Gaby Reckzügel
Boehringer Ingelheim Pharma GmbH & Co. KG


Dr Alicja Sobantka
Octapharma GmbH


Dr Jörg Zürcher
Bayer AG

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

21 -23 May 2019, Basle, Switzerland

HIGHLIGHTS:

- Current Regulatory Requirements
- Extractables and Leachables Testing in Packaging Material from Glass over Elastomers to Printing Ink
- Practical Approaches for L&E Testing in QC
- Toxicological Assessment
- Leachable Studies for Single Use Systems
- Case Studies for BioDisposable & Single Use Systems
- Influence and Interaction of Leachables in Biopharmaceutical Processes and Quality Testing

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

Leachables & Extractables - Testing & Assessment

21 -23 May 2019, Basle, Switzerland

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 factors associated with leaching substances 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 also 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 and the need to introduce control strategies along the supply chain to avoid unintentional added impurities in materials. 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 Pharmacopoeia/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 Audience

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 materials.
- choose and define polymeric, glass and rubber materials in process development.
- choose and define Single Use Equipment for manufacturing
- develops materials sourcing strategies.

Programme

Introduction to Plastics Construction and related Additives

- Classification of plastics
- Physical and chemical characteristics
- Different types of additives in plastics

Regulatory Requirements for Extractables / Leachables Testing for finished Packagings

- Why should Extractables & Leachables be assessed?
- Regulatory requirements of EMA and US-FDA
- Compendial requirements and foodstuff regulations
- PQRI recommendations and ICH Guidelines: Safety Thresholds and Permitted Daily Exposure
- USP <1663>, <1664>: Best Practices for Extractables & Leachables testing

Determining the Suitability of Packaging Systems for Therapeutic Products: Compendial Perspective

- Rationale and current thinking around USP's packaging standards
- How Chemical Characterization is being integrated into USP packaging standards
- Current, and future, changes to USP plastic, glass and elastomeric standards
- Chemical Characterization of component used to manufacture drug products

Principal Organisation of E&L Assessments - an Overview; Practical aspects beyond Theory

- Extractables & Leachables Study organization for finished packaging's, timely planning
- Extractables study designs as part of material qualification and selection
- Selection of extraction conditions and methods
- Identification categories, trustable identification,
- Semi-quantitation, analytical uncertainty
- Analytical methods, target analysis or screening or both
- Analytical sensitivity adjustment, correlation with analytical evaluation threshold
- Impacts of sterilization methods on materials chemical composition

Extractables and Leachables testing in Packaging Material, Correlation between Extractables & Leachables, Leachables Strategies

- Analytical method requirements, validation of Leachables analytical methods
- Development of Leachables strategies based on Extractable profile and toxicological report
- How to deal with trustable and poorly characterized chemical profiles
  How to establish the "chemical link" between Extractables& Leachables
- Leachables observed only in Leachables study but not in the Extractables Study: What to do?
- OOS case

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
- Change Management

"The leachables profile should also be determined for compendial plastics and rubber container closure components."
EMA Guideline on Pharmaceutical quality of inhalation and nasal products

L&E Strategies in Practice

- How to design a reasonable E&L Study for single and multicomponent CCS including printings and adhesives ("to do enough but not too much")
- The translation of regulatory requirements into analytical lab work
- The evaluation of Extractables data and consequences to Leachables 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."
Eudralex Volume 3 Guideline on Plastic Immediate Packaging Materials

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

"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)

Toxicological Assessment of Leachables and Extractables Studies

- Minimum requirements for a toxicological assessment of E&L substances
- Recommendations for an effective search for toxicological data
- The art of PDE derivation in a nutshell - for non-toxicologists
- How to deal with poorly identified substances or substances without sufficient toxicological information?

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?

A reasonable E&L Design for complex Products

- Summary of the different steps to be addressed for a proper Extractables-Leachables Screening Study
- Illustration of different study designs which may be applied for complex materials consisting of many different parts
- Importance of a Leachables check experiment as part of the formal Extractables screening study
- Case studies/examples of complex materials, such as, nasal spray device, multilayer bag from single use dosage system

USP strategy for developing Standards for Plastic Components and Systems used on the Manufacturing of a Drug Product

- Objective of standard
- Risk-based approach outlined in the standard
- Rationale for solvent chosen for standards

Leachables during Manufacturing

- Single-Use process equipment (e.g. filters, bags)
- Risk-based evaluation and testing strategies under consideration of critical success factors for the pharma/biotech industry such as cost efficiency, time-to-market and regulatory compliance

Interference of Leachables with Biopharmaceuticals during Manufacturing, Storage and Administration

- Influence of leachables on biopharmaceutical process performance
- Influence of leachables on the stability of biopharmaceuticals
- Influence of leachables on the analytics of biopharmaceuticals

E&L Assessment for Aqueous, Protein based Drug Products for Critical Care, Immunotherapy, and Hematology. The Biopharmaceutical Manufacturer´s PerspectiveLimits of regulatory

- Challenges in extractables profiling
- Case studies
- Medical devices / combination products

WORKSHOP SUS

In this workshop you will handle examples of Leachables studies in the field of Biopharmaceutical manufacturing. These examples will base on industrial and contract lab issues and challenges relating to modern process strategies

Speakers

Dr J. Susanne Becker, *Intertek AG, Switzerland*
J. Susanne Becker did her Ph.D. at the University of Konstanz in Analytical Chemistry After seven years' experience in the pharmaceutical industry at Aeropharm and Baxter, she joined Intertek (Schweiz) AG in April 2016, where she is working as Project leader in the area of E&L and Pharma.

Dr Bettine Boltres, *West Pharmaceuticals, Germany*
Bettine studied Biochemistry in Cologne. 2011 she joined Schott as Product Manager Pharmaceutical Tubing. Since 2017 she became Technical Account Manager at West Pharmaceuticals and in her current position she is Principal Scientific Affairs, Packaging & Delivery Systems.

Lothar Fruth, *Toxicological Expert Services, Göttingen*
Lothar Fruth studied Pharmacy at the university of Regensburg and Hamburg. He received his degree as "Specialised Pharmacist for Toxicology and Ecology". He is lecturer for toxicology at the Chamber of Pharmacists in Lower Saxony as well as member of the examinations board for toxicologists.

Dr Armin Hauk, *Sartorius Stedim Biotech*
After his PhD in 1995, Armin joined the central analytical department of Ciba-Geigy Inc., amongst others with focus on E&L investigations. From 2010 on Armin was active as consultant mainly in the area of E&L for Intertek in Basel. Since June 2016 Armin has a position at Sartorius-Stedim Biotech as Lead Scientist E&L.

Michael Jahn, *Lonza AG*
Dr Michael Jahn is leading the group Forensic Chemistry at Lonza's Drug Product Services in Basel, Switzerland. During his previous 11 years in industry Michael was setting up and leading analytical laboratories with a strong focus on E&L testing.

Dennis Jenke, *Chief Executive Scientist at Triad Scientific Solutions*
Dennis got a PhD from Montana State University Bozeman in Analytical Chemistry. He worked over 33 years for Baxter. His primary responsibilities include the development, validation and application of diverse analytical strategies and methods for the discovery, identification and quantification of trace constituents in pharmaceutically relevant solutions and samples. Currently he is Chief Executive Scientist at Triad Scientific Solutions, Inc, which is his own consulting firm

Petra Motzkau, *Sartorius Stedim Biotech GmbH*
Petra Motzkau currently holds a position as Director Validation Services Asia Pacific. Her up to date knowledge ensures business partners receive appropriate advice with regard to emerging industry trends, as well as practical interpretation of current regulatory requirements with focus on filter elements and single-use products.

Dr Andreas Nixdorf, *SGS Institut Fresenius*
He studied organic chemistry at the University of Bielefeld. 2007 to 2010 he joined SGS Institute Fresenius GmbH with focus on development of analytical methods, method transfer and validation. He introduced Extractables & Leachables services at SGS. He troubleshoots and directs the resolution of QC method issues by fostering effective interdepartmental and cross-functional partnerships with clients from pharmaceutical industry.

Gaby Reckzügel, *Boehringer Ingelheim Pharma GmbH & Co. KG*
Gaby Reckzügel is leading the Center of Expertise for Extractables & Leachables within Development.at Boehringer. Here she is involved in the selection of materials and is responsible for chemical characterization of packaging, device, and process equipment components and for leachables studies. She is in charge of development and validation of routine quality control methods.

Dr. Alicja Sobantka, *Octapharma Pharmazeutika Produktionsgesellschaft m.b.H.,*
Alicja studied at the technical Universities of Kaiserslautern and Vienna. She worked for the French National Institute for Agricultural Research (INRA), the Institute for Composite Materials (IVW) in Kaiserslautern and the Centre for Neutron Science (JCNS) At Octapharma she is responsible for the qualification of materials on corporate level. This includes the assessment of Leachables and the design of E&L studies.

Dr Jörg Zürcher, *Bayer AG*
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

In the evening of the frist course 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.

Organisation and Contact

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

CONCEPT HEIDELBERG
P.O. Box 10 17 64
D-69007 Heidelberg
Germany
Phone +49 (0) 62 21/84 44-0
Fax +49 (0) 62 21/84 44 34
E-mail: info@concept-heidelberg.de
www.concept-heidelberg.de

For questions regarding content please contact:
Mr Axel H. Schroeder (Operations Director) at +49 (0) 62 21 / 84 44 10, or per e-mail at schroeder@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc. please contact:
Ms Isabell Neureuther (Organisation Manager), at +49(0)6221 / 84 44 49 or per e-mail at neureuther@concept-heidelberg.de.

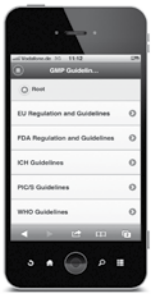
GMP Certification Programme

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
- 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.

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.

Easy Registration

Reservation Form:
CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg
Germany

Reservation Form:
+ 49 6221 84 44 34

e-mail:
info@concept-heidelberg.de

Internet:
www.gmp-compliance.org

If the bill-to-address deviates from the specifications on the right, please fill out here:

Reservation Form (Please complete in full)

+ 49 6221 84 44 34

Leachables & Extractables – Testing & Assessment
21 -23 May 2019, Basle, Switzerland

☐ Mr ☐ Ms

Title, first name, surname

Company Department

Important: Please indicate your company's VAT ID Number **P.O. Number (if applicable)**

Street/P.O. Box

City Zip Code Country

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Fax +49 (0) 62 21/84 44 34

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GERMANY

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- 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: 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)

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

Tuesday, 21 May 2019, 09.30 – 18.00 h
(Registration and coffee 09.00- 09.30 h)
Wednesday, 22 May 2019, 09.00 – 17.00 h
Thursday, 23 May 2019, 09.00 – 16.00 h

Venue

Hyperion Hotel Basel
Messeplatz 12
4058 Basel, Switzerland
Phone +41 61 560 40 00
Email hyperion.basel@h-hotels.com

Fees (per delegate plus VAT)

ECA Members € 1,980
APIC Members € 2,080
Non-ECA Members € 2,180
EU GMP Inspectorates € 1,090
The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the first day, lunch on all days and all refreshments.
VAT is reclaimable.

Important Information
The presentations of the course will be available for download and your print-out one week before and after the course. There will be no print-outs available during the course

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

Registration

Via the 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.