ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Quality Control Manager

Speakers


Dr J. Susanne Becker
Intertek Switzerland


Dr Bettine Boltres
West Pharmaceutical Services


Lothar Fruth
Toxicology Expert Services


Dr Armin Hauk
Sartorius Stedim Biotech


Dr Michael Jahn
Lonza


Dennis Jenke
Triad Scientific Solutions/USP


Petra Motzkau
Sartorius Stedim Biotech


Dr Andreas Nixdorf
SGS Institut Fresenius


Gaby Reckzügel
Boehringer Ingelheim Pharma


Dr Jörg Zürcher
Bayer

Leachables & Extractables

Testing & Assessment from Packaging to Single Use

Live Online Training from 27 - 29 April 2021


Imgage: Agilent

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

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
- Evaluation of Extractables Data
- 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

Methods and Materials –
from Packaging to Single Use Systems

Objective

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 Live Online Training, 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 This Live Online Training 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.
- develop materials sourcing strategies.

Programme

Introduction to Plastics Construction and Related Additives

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

Introduction to Extractables and Leachables - Regulatory and Scientific Perspectives

- 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
- Scientific aspects

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

Principle 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

Extractables and Leachables in Quality Control and Life Cycle Management

- Batch-to-batch consistency in composition and purity of packaging components
- Acceptance criteria for Extractables/Leachables
- 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

The Interpretation and Use of Extractables Data; from Extractables Data to Potential Exposure Estimations

- Physical-chemical principles of extraction versus Extractables protocols
- The use of extractables data in Scaling and Combination exercises
- The use of extractables data in exposure estimations
- Differences in data interpretation for CCS and SUS
- Quantitative mitigation concepts for the assessment of SUS

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

Including Elastomeric Closures in Extractables/ Leachables Assessment

- Composition of Elastomers used for pharmaceutical applications
- Discussion material composition and Extractables (Potential Extractable List)
- Approaches to minimize Extractable/ Leachable from elastomeric closures
- Case Study presentation

§ *"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."* CFR21, 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)

What do the Analytical Results Mean? The Toxicologist as Interpreter

- Expectations to the toxicologist
- Prerequisites for a successful toxicological risk assessment
- Criteria for the quality check of a toxicological risk assessment
- QSAR tools and TTC concept - can they replace a toxicologist?

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 Standard 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 Studies from (Bio)Production Process to Final Formulation – Coordinated Study Design, Typical Pitfalls and Solutions

- How to derive a suitable study design covering all steps from production process to final container closure system
- Extractables from multi-material-equipment and how to clarify their source
- Advantage of a leachables simulation study
- Challenges during leachables method validation
- Justification for leachables monitoring and typical observations
  - Temporary leachables detected during stability study
  - Unknown leachables and how to identify them

Practice Session Bio Manufacturing/SUS

In this session we 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

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 Deutschland GmbH & Co. KG

As Principal Scientific Affairs, Dr Bettine Boltres is supporting the scientific exchange between West and the pharmaceutical industry. This is complementing her work as Product Manager for Schott Pharmaceutical Tubing, where she provided scientific consulting for glass primary packaging and wrote the book "When Glass Meets Pharma". Bettine is member of the USP PDEC as well as the Ph Eur Group of Experts 16 and the Glass Working Party and the ISO TC76/WG 4.

Lothar Fruth
Toxicological Expert Services

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 GmbH

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 Principal Scientist E&L.

Dr Michael Jahn
Lonza AG

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

Speakers

Dennis Jenke
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 Head of 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 GmbH

Dr Nixdorf 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 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 lifecycle 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.

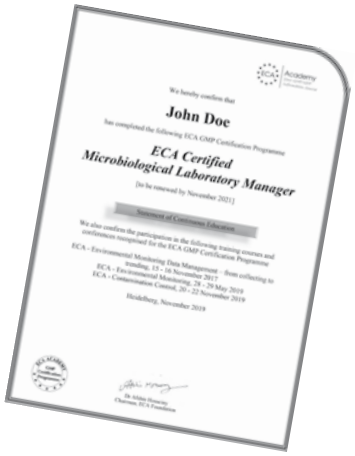
Your Benefits

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.

This Training Course is recognized for the GMP/GDP Certification Scheme

Building on your education the ECA GMP/GDP certification programmes provide you with the appropriate supplement to acquire this qualification. This training course is the first element for your additional certification. Simply choose any three courses within the programme according to your professional interest. Your certificate is then valid for two years. To renew it, you can pick any training from the ECA courses and conferences list within that two-years period – allowing you to broaden your knowledge in GMP and GDP compliance. Please find more information at www.gmp-certification.org


We hereby confirm that

John Doe

has completed the following ECA GMP Certification Programme

ECA Certified
Microbiological Laboratory Manager

[to be renewed by November 2021]

Assessment of Continuous Education

We also confirm the participation in the following training courses and conferences recognized for the ECA GMP Certification Programme

ECA - Environmental Monitoring Data Management – from collecting to trending, 13 - 16 November 2017
ECA - Environmental Monitoring, 28 - 29 May 2019
ECA - Contamination Control, 20 - 22 November 2019

Heidelberg, November 2019

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CONCEPT HEIDELBERG
P.O. Box 101764
Fax +49 (0) 62 21/84 44 34

D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

Leachables & Extractables | Live Online Training from 27 - 29 April 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

E-Mail (Please fill in)

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 %,
- Cancellation until 1 weeks prior to the conference 50 %
- Cancellation within 1 week prior to the conference 100 %.

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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.

Date of the Live Online Training

Tuesday, 27 April 2021, 09.00 – 18.00 h CEST
Wednesday, 28 April 2021, 09.00 – 17.30 h CEST
Thursday, 29 April 2021, 09.00 – 16.00 h CEST

Technical Requirements

For our Live Online Training Courses and Webinars, 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 € 2,080
APIC Members € 2,180
Non-ECA Members € 2,280
EU GMP Inspectorates € 1,140
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.

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
P.O.Box 10 17 64
69007 Heidelberg, Germany
Phone +49(0)62 21/84 44-0
Fax +49(0)62 21/84 44 34
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 at
schroeder@concept-heidelberg.de.

For questions regarding organisation please contact:
Ms Isabell Neureuther (Organisation Manager) at
+49(0)62 21/84 44 49 or at
neureuther@concept-heidelberg.de.