ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Packaging Manager

Speakers


Lothar Fruth
Tox Expert,
Germany


Dr Armin Hauk
Sartorius Stedim Biotech,
Germany


Dr Dennis Jenke
Triad Scientific
Solutions/USP, USA


Dr Ana Kuschel
West Pharmaceutical
Services, Germany


Dr Lukas Mogler
Lonza, Switzerland


Petra Motzkau
Sartorius Stedim Biotech,
Germany


Dr Andreas Nixdorf
SGS Institut Fresenius,
Germany


Igor Petrovic
Intertek, Switzerland


Gaby Reckzügel
Boehringer Ingelheim
Pharma, Germany


Dr Jörg Zürcher
Bayer, Germany

Leachables & Extractables

Testing & Assessment from Packaging to Single Use

Live Online Training from 25 - 27 April 2023


Imgage: Agilent

Addressing all relevant aspects from regulatory requirements to routine testing

Highlights

- Current Regulatory Requirements
- Extractables and Leachables Testing in Packaging Material from Glass to Elastomers to Printing Ink
- Practical Approaches for L&E Testing in QC
- Evaluation of Extractables Data
- Toxicological Assessment
- Leachable Studies for SUS
- Case Studies for BioDisposables & SUS
- Impact of Leachables on Biopharmaceutical Processes and Quality Testing

Methods and Materials –
from Packaging to Single Use Systems (SUS)

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 specific kind of extractable/leachable 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. Therefore, the ICH is currently working on a new ICH Q3E Guideline for Extractables and Leachables (E&L) to *"assist both applicants and regulators by providing focus on critical aspects, and improving transparency in requirements for medicinal products including drug delivery device components"*.

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

This Live Online Training is designed for personnel of pharmaceutical companies and their suppliers who

- are responsible for setting up extractables &leachables studies.
- perform leachables/extractables testing.
- work in quality control of packaging materials.
- specify and select polymeric, glass and rubber materials in process development.
- specify and select Single Use Equipment for manufacturing.
- develop material sourcing strategies.

Programme

Introduction to Plastics used in Medical Applications

- 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

How to Prepare a Successful E&L Study

- 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

Q&A Session 1

Control and Life Cycle Management of Extractables and Leachables

- 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

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

Extractables from Glass

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

Q&A Session 2

§ *„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

How to Prepare a Successful Leachables Study Strategy for Complex Formulated Drug Products

- 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

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)

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

Q&A Session 3

Differences in the Toxicological Evaluation of Substances for Medicinal Products to other Regulatory Fields like Medical Devices explained

- For the same substances often different toxicological thresholds (PDEs) can be found, which may confuse non-toxicologists
- Possible reasons are explained in this session
- Differences in the Derivation of toxicological thresholds for Medicinal Products and Medical Devices are demonstrated by examples
- Criteria for the assessment of the validity of toxicological thresholds are discussed

Practice Session on Strategy for Compliant/ Reasonable Leachables Studies

In the course of this session we will develop a strategy for conducting a compliant and reasonable leachables studies. The task will be based on an industry example and will answer the following questions:

- Which activities are necessary during the development phase?
- How will we deal with quality control during routine production?
- Where will we find useful information about the material we are going to use?

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

Q&A Session 4

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

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

Q&A Session 5

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 on 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.

Q&A Session 6

Speakers

Lothar Fruth
Tox Expert GmbH, Germany

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, Germany

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 Dennis Jenke
Triad Scientific Solutions, USA

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.

Dr Ana Marques Kuschel
West Pharmaceutical Services, Germany

As Sr. Specialist Technical Account, Ana is providing technical support relating to West's packaging components and delivery systems for injectable drugs and healthcare products. This is complementing her previous role as Manager Material Development, where she worked with existing and on the development of new rubber formulations. Ana holds a PhD in macromolecular chemistry from the Universities of Coimbra, Portugal and Wuppertal, Germany.

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

_____

_____

_____

_____

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 25 - 27 April 2023

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 4 weeks prior to the conference 10 %,
- Cancellation until 3 weeks prior to the conference 25 %,
- Cancellation until 2 weeks prior to the conference 50 %,
- Cancellation within 2 weeks 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 HEIDELBERGwill 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 July 2022).
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 https://www.gmp-compliance.org/privacy-policy). 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, 25 April 2023, 09.00 – 18.00 h CEST
Wednesday, 26 April 2023, 09.00 – 17.30 h CEST
Thursday, 27 April 2023, 09.00 – 16.00 h CEST

Technical Requirements

We use Webex for our live online training courses and webinars. At https://www.gmp-compliance.org/training/online-training-technical-information you will find all the information you need to participate in our events and you can check if your system meets the necessary requirements to participate. If the installation of browser extensions is not possible due to your rights in the IT 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 € 1,145
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.

You cannot attend the Live Event?

We also offer many of the training courses and conferences as recordings. This means that you can watch the videos of the event „on demand" – whenever it suits you – on our web server. It is quite uncomplicated and doesn't require any software – you simply watch the video on your browser. You can find all recorded events at www.gmp-compliance.org/recordings.

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:
Dr Andrea Kühn-Hebecker (Operations Director) at
+49(0)62 21/84 44 35, or at
kuehn@concept-heidelberg.de.

For questions regarding organisation please contact:
Mr Ronny Strohwald (Organisation Manager) at
+49(0)62 21/84 44 51 or at
strohwald@concept-heidelberg.de.

Speakers

Dr Lukas Mogler
Lonza AG, Switzerland
After finishing his study of pharmacy in Freiburg (Germany), Lukas did his diploma thesis in breast cancer metabolomics at the Center for Biological Systems Analysis (ZBSA) in Freiburg. During his PhD at the Institute of Legal Medicine in the department of Forensic Toxicology (Freiburg) he further focused on analytical chemistry and metabolism of new synthetic Cannabinoids. Since February 2020 he is working at Lonza DPS, Basel (Switzerland), leading the extractables & leachables group.

Petra Motzkau
Sartorius Stedim Biotech GmbH, Germany
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, Germany
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.

Igor Petrovic
Intertek AG, Switzerland
Igor Petrovic is currently Project Manager / Teamleader E&L – Analytical Testing at Intertek. Previously he worked as Project Chemist / Teamleader Project Lab for Legacy Pharmaceuticals and in different positions for Biotronik, Carbogen Amcis and Genzyme Pharmaceuticals.

Gaby Reckzügel
Boehringer Ingelheim Pharma GmbH & Co. KG, Germany
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, Germany
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.

This could be of interest for you

Would you like to train a larger group of participants in your company?

We offer practice-oriented GMP/GDP training courses on:

- Basic GMP
- APIs (ICH Q7)
- Medicinal Products
- Biopharmaceuticals
- Quality Assurance
- Quality Control
- Validation/Qualification
- Regulatory Affairs
- Sterile Manufacturing
- IT / Computer Validation
- Good Distribution Practice (GDP)
- Data Integrity
- Packaging
- Medical Devices
- Technical Operations

You will find a time schedule for each training course at https://www.gmp-compliance.org/training/gmp-gdp-in-house-trainings.

Your Benefits

Internationally Acknowledged Certificate from ECA Academy


CERTIFICATE

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