ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Packaging Manager

Speakers


Dr Katrin Buss
Bonn


Marcel Dörkes
Eurofins BioPharma


Dr Armin Hauk
Sartorius Stedim Biotech


Dr Dennis Jenke
Triad Scientific Solutions


Dr Ana Kuschel
West Pharmaceutical Services


Dr Andreas Nixdorf
SGS Institut Fresenius


Gaby Reckzügel
Boehringer Ingelheim Pharma

NEWS

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Extractables & Leachables

Challenges and Solutions for Packaging / Devices & Single Use Systems

Live Online Training on 06/07 May 2025


Image: Agilent

Highlights

- Current Regulatory Requirements
- Practical Approaches for E&L Testing
- Evaluation of E&L Data
- Toxicological Assessment
- Leachable Studies for SUS and Devices
- How to use prior Knowledge and IT Solutions

Objectives

In this Live Online Training you will learn

- How to evaluate potential risk factors associated with leaching substances
- How to design extractables studies as part of material qualification and selection
- How to control and manage the life cycle of E&Ls
- How to assess the toxicological risks of E&Ls

You will also get an update on requirements and expectations of E&L testing and risk management from a regulatory perspective.

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&Ls) 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. Recently, particular attention was paid to devices and equipment used in the production process, e.g. filters, bags, tubes.

Target Audience

The course is designed for personnel of pharmaceutical companies and their suppliers who

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

Programme

Day 1

Introduction to Plastics used in Medical Applications

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

Regulatory Perspective (Authority View)

- Applicable Guidelines (EU)
- Update on ICH Q3E
- Experiences in regulatory submissions

Regulatory and Scientific Perspective (Industry View)

- 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 E&L testing
- Scientific Aspects

Q&A Session 1

How to Prepare a Successful E&L Study

- E&L 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
- Impact of sterilization methods on materials chemical composition

Strategies 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

§ *„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

Analytical Challenges and Solutions for Extractables & Leachables

- Essential Analytical Expectations for E&L Studies
- Qualitative Aspects of Extractables and Leachables
- Identification and Good Identification Practices
- Quantitative Aspects of Extractables and Leachables
- Analytical Uncertainty
- When to Quantify –The Analytical Evaluation Threshold (AET)
- How to Quantify –Good Quantitation Practices

Q&A Session 2

Day 2

Elastomeric Closures in E&L Assessment

- Composition of Elastomers used for Pharmaceutical Applications
- Discussion Material Composition and Extractables (Potential Extractable List)
- Approaches to minimize Extractables/ Leachables from Elastomeric Closures
- Case Study presentation

Practical Examples for E&L Testing in Medical Devices

- Key aspects of ISO 10993-1 and ISO 10993-18 for E&L testing of medical devices
- General procedures, challenges, and pitfalls
- Case studies and practical examples

Toxicological Assessment of E&Ls in Medical Devices

- Key aspects of ISO 10993-17 for the toxicological evaluation
- General procedures, challenges, and pitfalls
- Case Studies for different assessment procedures

Q&A Session 3

§ *„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

Control and Life Cycle Management of E&Ls

- Batch-to-batch consistency in composition and purity of packaging components
- Acceptance criteria for Extractables/Leachables
- Quality agreements with suppliers
- Change Management

§ *"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)

E&Ls for SUS as Elements of Process Qualification/ Validation and Safety Assessment

- Single-Use process equipment (e.g. filters, bags)
- Risk-based evaluation and testing strategies
- Influence of leachables on:
  - biopharmaceutical process performance
  - the stability of biopharmaceuticals
  - the analytics of biopharmaceuticals

Simplified E&L Assessment using prior Knowledge and IT Solutions

- Prediction of extractables profiles for SUS of different sizes and complex assemblies
- Calculation of exposure data, with a subsequent automated safety-assessment; including a discussion of deviations and propagation of deviations
- Equivalence study of extractables profiles from an SU assembly before and after a component change, including the evaluation of the impact on the safety assessment
- Using the system to extrapolate extractables data to USP <665> conditions for a safety assessment of a large volume injectable drug product

Q&A Session 4

Speakers

Dr Katrin Buss
Quality Assessor, Bonn, Germany

Katrin Buss is a pharmacist and worked from 2001-2004 as Scientific Project Manager at Memorec/Miltenyi Biotec. Since 2005 she is quality assessor in the department "Pharmaceutical Biotechnology" at the BfArM (since April 2023 Head of the department). She is member of the ICH Q3E EWG on Assessment and Control of Extractables and Leachables.

Marcel Dörkes
Eurofins BioPharma, Germany

Marcel has been working in the field of evaluating the biological safety of medical devices since February 2018 and is now Head of Medical Device Consulting. Marcel Dörkes' expertise includes the biological safety assessment of medical devices and related toxicological issues including strategy planning, chemical characterization procedures and overall biological risk assessments.

Dr Armin Hauk
Sartorius Stedim Biotech GmbH, Germany

Armin has a position as Principal Scientist at Sartorius Stedim Biotech GmbH since 2016. Before that he was over 20 years active as head of laboratories for organic trace-analysis and GLP & GMP analytics in Ciba-Geigy, and Ciba Specialty Chemicals. For Intertek, Switzerland he worked as consultant and Qualified Person (QP). Armin is a lecturer and trainer in E&L at conferences and seminars and is a member of various industry consortia (BPSA, BPOG, DECHEMA, and MIT BioMan). He is chairperson of the Pharmacopeia expert group 16 in the European Directorate for Quality of Medicine (EDQM).

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 Deutschland GmbH & Co. KG, Germany

As Principal Scientific Affairs Europe, Ana is providing technical support relating to West's packaging components and delivery systems for injectable drugs and healthcare products, as well as bridging scientific information through industry outreach. This is complementing her previous role as Manager Material Development, where she worked on both existing and new rubber formulations.

Speakers

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.

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.

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

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Reservation Form (Please complete in full)

Extractables & Leachables | Live Online Training on 06/07 May 2025

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:
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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.

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Date of the Live Online Training

Tuesday, 06 May 2025, 09.00 – approx. 17.30 h
Wednesday, 07 May 2025, 09.00 – approx. 17.30 h
All times mentioned are 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 € 1,890
APIC Members € 1,990
Non-ECA Members € 2,090
EU GMP Inspectorates € 1,045
The fee is payable in advance after receipt of invoice.

Registration

Via the attached reservation form, by e-mail or by fax – or search and register directly at www.gmp-compliance.org under the number 21855.

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.

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