Speakers

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
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 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 first 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.

Lufthansa is Mobility Partner for all ECA Events

As an ECA course or conference attendee, you will receive up to 20% discounted travel fares (according to availability). And as Lufthansa German Airlines offers a comprehensive global route network linking major cities around the world you will most likely be able to benefit from these special prices and conditions.

And this is how it works: Once you registered for a course or conference you will receive a link together with your registration confirmation. Opening that link will take you to the Mobility Partner Program website where you can enter a code in the "Access to Event Booking" area you will also receive. This will take you into an online booking platform* that will automatically calculate the discount offered or provide you with an even better offer if another promotional fare is available.

We look forward to welcoming at one of our next events – and we already wish you a pleasant flight!

*Please note: You may have to enable pop-ups on the Mobility Partner Program website – other-wise the booking platform window will not open.

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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, 26 - 28 May 2020, Barcelona, Spain

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 %
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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 January 2012).
German law shall apply. Court of jurisdiction is Heidelberg.

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Date
Tuesday, 26 May 2020, 09.30 – 18.00 h
(Registration and coffee 09.00- 09.30 h)
Wednesday, 27 May 2020, 09.00 – 17.00 h
Thursday, 28 May 2020, 09.00 – 16.00 h

Venue
Barcelo Sants Hotel
Pl. Països Catalans, s/n
08014 Barcelona, Spain
Phone +34 93 503 53 00
Email sants@barcelo.com

Fees (per delegate, plus VAT)
ECA Members € 2,080
APIC Members € 2,180
Non-ECA Members € 2,280
EU GMP Inspectorates € 1,140
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 receive a room reservation form/POG when you have registered for the conference. 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.

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

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ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Quality Control Manager

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


Dr 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

Leachables & Extractables

Testing & Assessment from Packaging to Single Use

26 - 28 May 2020 | Barcelona, Spain


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 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.
- 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 - Regulations and Recommendations

- 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

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?

WORKSHOP

In the course of this workshop you will develop a strategy for conducting a compliant and reasonable leachables studies.
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 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 Assessment for Biologic Combination Products. The Pharmaceutical Manufacturer's Perspective

- Limits 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

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

Bettine studied Biochemistry in Cologne. 2011 she joined Schott as Product Manager Pharmaceutical Tubing. In 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

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 Principal Scientist E&L.

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.

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.