Leachables & Extractables
Testing & Assessment

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

22-23 April 2015, Basel, Switzerland

SPEAKERS:

Dr Armin Hauk
Intertek Expert Services

Petra Motzkau
Sartorius Stedim Biotech

Dr Andreas Nixdorf
SGS Institut Fresenius

Gaby Reckzügel
Boehringer Ingelheim Pharma

Dr Mike Schäfers
West Pharmaceutical Services

Karl-Heinz Schneider
schneiderRS Consulting

Dr Jörg Zürcher
Bayer Pharma

PROGRAMME:

- Regulatory Requirements for Extractables / Leachables Testing
- Extractables and Leachables Testing in Packaging Material
- Practical Approaches for L&E Testing in QC
- GMP-compliant Approach to a Process Specific Extractable / Leachable Study
- Plastic-Derived Materials for Manufacturing of Biopharmaceuticals
- Extractables from Glass
- Potential Extractables from Elastomers
- Printing Inks as Potential Sources of Leachables and Extractables
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 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 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. 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 FDA/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.

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.

The leachables profile should also be determined for compendial plastics and rubber container closure components.

GUIDELINE ON THE PHARMACEUTICAL QUALITY OF INHALATION AND NASAL PRODUCTS, 1 October 2006

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

Plastic-Derived Materials for the Manufacture of Biopharmaceuticals

- Drug Product Perspective
- Plastic Materials: Selection and Characterization
- Use-Specific Testing
- Example

Extractables & Leachables: A Pragmatic Approach

- In-Process Materials with Product Contact
- Elastomeric Drug Product Stoppers
- Experience with Regulatory Agencies
- Questions, Comments
L&E Strategies in Practice
- How to design a reasonable E&L study („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
- How to outsource E&L studies
- Illustrative examples

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

Potential Extractables from Elastomers
- General definition of rubber
- Composition of elastomers used for pharmaceutical applications
- Discussion material composition and extractables (Potential extractable list)
- Approaches to minimize extractables/leachables from elastomeric closures

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?

Leachables during Manufacturing
- Bag-filter-assemblies and other polymer-based materials in the manufacturing process
- Finding the right test approach under consideration of critical success factors for the pharma/biotech industry such as cost efficiency, time-to-market and regulatory compliance
- Model solvent testing versus product and process specific testing
- Evaluation of the test results

Printing Inks as Potential Sources of Extractables & Leachables
- Introduction and basics of printing techniques
- Composition & chemistry of ink systems („the ink manufacturer’s toolbox“)
- Possible interactions of printing ink systems with the packaging material and the drug formulation
- Illustrative examples of extractables from printing
- Relevance of ink components as leachables

Social Event
On 22 April 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.

Conference Exhibition
The European Compliance Academy offers you the opportunity to present your company, your products and services to your target group almost without any scattering losses. The costs for an exhibition space at this event are € 1,490. You will find details and a registration form on our website www.gmp-compliance.org. Just follow the link „Conferences“ on the homepage.
Speakers

**Dr Armin Hauk**  
*Intertek Switzerland AG*

Dr Armin Hauk studied environmental chemistry. Parallel to his PhD he conducted a 5 year research work in the field of polymer combustion chemistry. He joined the central analytical department of the former Ciba-Geigy Inc. in 1995. Since 2000 he is head of the trace analysis group, the GLP testing facility and the GMP quality control laboratory in Basle. He is responsible for organic trace and ultra trace analysis, special analytics for registration, migration studies, extractable and leachable studies for pharmaceutical packaging, for GMP quality control analysis and stability tests. He is responsible person according HMG and member of the EDQM Working Group „Plastic Containers for Pharmaceutical Use“.

**Petra Motzkau**  
*Sartorius Stedim Biotech GmbH*

Petra Motzkau has spent several years in various positions focussing on filtration in the company segment Biotechnology within the Sartorius Group, an internationally leading provider of laboratory and process technologies. In her current function as Director Validation Services Asia Pacific she can look back on 10 years experience. Leading validation studies conducted for the pharmaceutical industry she has permanent insight in the critical success factors in the pharmaceutical and biotech market. This enables her to provide guidance with regard to the practical interpretation of current regulatory requirements. She is a FDA Member and has travelled extensively to conduct seminars and trainings on product and process specific validation.

**Dr Andreas Nixdorf**  
*SGS Institut Fresenius GmbH*

Andreas Nixdorf has sixteen years experience with analytical questions. Since 2007, he is responsible for project management at the customer service pharma at SGS Institute Fresenius with focus on development of methods, validation and analysis of leachables and extractables.

**Gaby Reckzügel**  
*Boehringer Ingelheim Pharma GmbH & Co. KG*

Gaby Reckzügel is head of a laboratory for chemical characterization of device components and packaging materials within the Drug Delivery Department. Coming with analytical experience in the food industry as a food chemist she started in Research & Development at Boehringer Ingelheim, Germany in 2000. Here she is involved in the choice of materials for packaging and device components and is responsible for chemical analytical aspects during development. She is in charge of development and validation of routine quality control methods.

**Dr Mike Schäfers**  
*West Pharmaceutical Services GmbH & Co. KG*

Dr Mike Schäfers is Vice President Global Marketing Pharmaceutical Packaging Systems at West Pharmaceutical Services. He studied chemistry and business management at the Ruhr University in Bochum. After 4 years of business experience at R. P. Scherer (today Catalent) he joined West Pharmaceutical Services in 2000 where he headed the Scientific & Technical Customer Service Group for the European and Asian-Pacific market. 2005 he became responsible for Marketing and Technical Customer Service in Europe at West. In 2012 he assumed responsibility for West’s global Marketing activities within the Pharmaceutical Packaging System division. He is member of the Parenteral Drug Association (PDA) and the ‘Arbeitsgemeinschaft für pharmazeutische Verfahrenstechnik’ (APV) and a frequent speaker and organizer of conferences.

**Karl-Heinz Schneider**  
*Freelance associate schneideRS Consulting, Germany*

K.-H. Schneider spent more than 18 years in Regulatory Affairs and was involved in the global licensure of biological products with primary focus on U.S. Product and Establishment License Applications. Since late 2005 to 2013 he worked in the Validation Department of Cal Behring and dealt with the validation of aseptic and non-aseptic processes and primarily working on E & L activities. During the last years he has been involved in the creation and implementation of a practical approach for E & L testing of product-contacting plastic derived materials comprising in-process materials and drug product elastomeric stoppers. Responsibilities include the execution of risk assessments, review of manufacturer’s data, planning of in-house and external E & L studies, and presentation of the E & L approach and data during inspections by Regulatory Agencies including the FDA. Since 2014 he worked for schneideRS Consulting.

**Dr Jörg Zürcher**  
*Bayer Pharma AG*

Jörg Zürcher is a pharmacists He studied in Berlin and finished his studies with PhD degree. Since July 1990 he is working for Schering AG (now Bayer Pharma AG), Berlin in the Pharmaceutical Development. 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.
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:
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.:
Ms Jessica Stürmer (Organisation Manager) at +49 (0) 62 21 / 84 44 43, or per e-mail at stuermer@concept-heidelberg.de.

About CONCEPT HEIDELBERG

Founded in 1978, CONCEPT HEIDELBERG is the leading organiser of seminars on pharmaceutical production, quality control, quality assurance and GMP in Europe. This year more than 240 events will be organised by CONCEPT HEIDELBERG.

What are The ECA Foundation and the ECA Academy?

The European Compliance Academy Foundation (ECA Foundation) is an independent professional organisation chaired by a Scientific Advisory Board with members from the pharmaceutical industry and regulatory authorities. The ECA Foundation’s goal is to support the Pharmaceutical Industry and Regulators to promote the move towards a harmonised set of GMP and regulatory guidelines by providing information and interpretation of new or updated guidances. The ECA Academy offers professional basic and advanced education (training) programmes. All services offered by the ECA Academy and with regard to ECA Academy Memberships are solely managed by Concept Heidelberg (a leading European training and information services provider). The ECA Foundation is conceptual sponsor of the ECA Academy.

How Do You Become a Member of ECA?

By participating in one of the ECA Academy Conferences or Courses you will automatically become a ECA Academy Individual Member for two years - free of charge. More information about ECA Academy can be obtained on the Website http://www.gmp-compliance.org

What Are the Benefits of ECA?

During the membership, you enjoy a € 200,- discount on the regular participation fee of any European Conference or Course presented by the ECA Academy. In addition you will receive the GMP Guideline Manager Software with a large number of guidelines, e.g. EC Directives, FDA Guidelines, ICH Guidelines.

GMP Certification Programme

This seminar is recognised within the GMP Certification Programme for the module “Certified Quality Control 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

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.
Leachables & Extractables – Testing & Assessment
22-23 April 2015, Basel, Switzerland

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

Phone/Fax

E-Mail (please fill in)

CONCEPT HEIDELBERG
P.O. Box 101764
Fax +49 (0) 62 21/84 44 34
D-69007 Heidelberg
GERMANY

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 cannot attend the conference 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 notification.

Terms of payment: Payable in advance after receipt of invoice.

Important: If you cannot attend the conference 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 notification.

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 the registration, 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 event 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.

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 Heidelberg will not be responsible for discount airfare penalties or other costs incurred due to a cancellation.

Terms of payment: Payable in advance after receipt of invoice.

Important: If you cannot attend the conference 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 notification.

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 the registration, 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 event 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.

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 Heidelberg will not be responsible for discount airfare penalties or other costs incurred due to a cancellation.

Terms of payment: Payable in advance after receipt of invoice.

Important: If you cannot attend the conference 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 notification.

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 the registration, 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 event 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.

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 Heidelberg will not be responsible for discount airfare penalties or other costs incurred due to a cancellation.

Terms of payment: Payable in advance after receipt of invoice.

Important: If you cannot attend the conference 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 notification.

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 the registration, 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 event 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.

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 Heidelberg will not be responsible for discount airfare penalties or other costs incurred due to a cancellation.

Terms of payment: Payable in advance after receipt of invoice.

Important: If you cannot attend the conference 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 notification.

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 the registration, 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 event 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.

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 Heidelberg will not be responsible for discount airfare penalties or other costs incurred due to a cancellation.

Terms of payment: Payable in advance after receipt of invoice.

Important: If you cannot attend the conference 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 notification.

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 the registration, 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 event 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.