Leachables & Extractables

Testing & Assessment

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

14 – 15 May 2014, Copenhagen, Denmark

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
CSL Behring

Dr Jörg Zürcher
Bayer Pharma

PROGRAMME:

- Introduction to Plastics
- Regulatory Requirements for Extractables / Leachables Testing
- Extractables and Leachables Testing in Packaging Material
- GMP-compliant Approach to a Process Specific Extractable / Leachable Study
- Routine Extractables Testing in Quality Control
- Case Study: Toxicological Evaluation of Extractables & Leachables
- Extractables from Glass
- Potential Extractables from Elastomers
- Leachables during Manufacturing
- Printing Inks as Potential Sources of Leachables and Extractables

ECA
EUROPEAN COMPLIANCE ACADEMY

This education course is recognised for the ECA GMP Certification Programme „Certified Quality Control Manager". Please find details at www.gmp-certification.eu

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Learning 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 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.

Target Group

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.

Programme

Introduction to Plastics

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

DR ANDREAS NIXDORF
SGS Institut Fresenius

Regulatory Requirements for Extractables / Leachables Testing

- Why should Extractables & Leachables be assessed?
- Regulatory requirements of EMA and US-FDA
- Compendial requirements and foodstuff regulations
- PQRI and other recommendations for Safety Thresholds and Best Practices for Extractables & Leachables testing

GABY RECKZÜGEL
Boehringer Ingelheim Pharma

Extractables and Leachables Testing in Packaging Material

- Why – Regulatory requirements of FDA and EMEA
- What – Change in primary and secondary packaging material or labels
- How – Global and tailored approaches

DR ANDREAS NIXDORF
SGS Institut Fresenius

GMP-compliant Approach to a Process Specific Extractable / Leachable Study

- Key regulatory guidances mentioning packaging considerations
- Discussion of the container closure guidance
- General approach to extractable / leachable studies (pre-screening, method development and validation, leachable study in stability samples)
- Sources of extractables/leachables
- Case Studies

DR MIKE SCHÄFERS
West Pharmaceutical Services

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

GABY RECKZÜGEL
Boehringer Ingelheim Pharma

Extractables & Leachables: A Pragmatic Approach

- In-Process Materials with Product Contact
- Elastomeric Drug Product Stoppers
- Experience with Regulatory Agencies
- Questions, Comments

KARL-HEINZ SCHNEIDER
CSL Behring GmbH

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

ARMIN HAUK
Intertek Expert Services

Extractables from Glass

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

DR JÖRG ZÜRCHER
Bayer Pharma

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.
GUIDELINE ON PLASTIC IMMEDIATE PACKAGING MATERIALS, 1 December 2005

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

DR MIKE SCHÄFERS
West Pharmaceutical Services

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

PETRA MOTZKAU
Sartorius Stedim Biotech

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.

DR ARMIN HAUK
Intertek Expert Services

Social Event in Copenhagen

On 14 May 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 year 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 PDA 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
CSL Behring GmbH
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 he works in the Validation Department and deals with the validation of aseptic and non-aseptic processes and primarily working on E | L activities. During the past four 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.

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.

Organisation and Contact

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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.

ECA has entrusted CONCEPT HEIDELBERG with the organisation of its events.

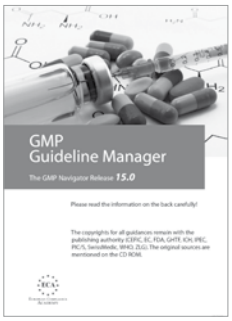
What Is ECA?

The European Compliance Academy (ECA) is an independent educational organisation chaired by a Scientific Advisory Board with members of the pharmaceutical industry and regulatory authorities.

The ECA will provide support to 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.

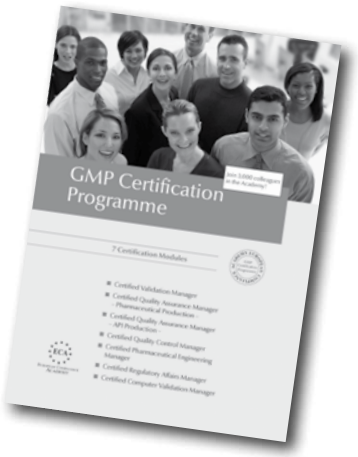
What Are the Benefits of ECA?
First benefit:
During the membership, you enjoy a EUR 200 discount on the regular participation fee of any European Conference organised by ECA in co-operation with CONCEPT HEIDELBERG.

Second benefit:
The GMP Guidelines Manager Software with a large number of guidelines, e.g. EC Directives, FDA Guidelines, ICH Guidelines, will be forwarded to you when you are using your membership for a conference registration.



How Do You Become a Member of ECA?
By participating in one of the European Compliance Conferences or Courses marked with ECA, you will automatically become a member of ECA for two years – free of charge. Conferences and Education Courses organised by ECA will be realised in co-operation with CONCEPT HEIDELBERG.

More information about ECA can be obtained on the Website **http://www.gmp-compliance.org**



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

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.

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

CONCEPT HEIDELBERG
P.O. Box 101764
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D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

+ 49 6221 84 44 34

Leachables & Extractables – Testing & Assessment

14 – 15 May 2014, Copenhagen, Denmark

☐ Mr ☐ Ms

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)

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 %,
- until 1 weeks prior to the conference 50 %
- within 1 week 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 HEIDELBERG will 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 per January 2012)

Easy Registration

Reservation Form:
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Reservation Form:
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Internet:
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Date

Wednesday, 14 May 2014, 09.00 – 18.00 h
(Registration and coffee 08.30- 09.00 h)
Thursday, 15 May 2014, 08.30 – 16.00 h

Venue

Radisson Blu Scandinavia Hotel
Amager Boulevard 70
2300 Copenhagen S, Denmark
Phone +45 33 96 50 00
Or 00 800 3333 3333
Fax +45 33 96 55 55

Fees

ECA Members: € 1,590.– per delegate + VAT
APIC Members: € 1,690,- per delegate + VAT (does not include ECA Membership)
Non-ECA Members: € 1,790.– per delegate + VAT
EU GMP Inspectorates: € 895.– per delegate + VAT

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 when you have registered for the event. Please use this form for your room reservation to receive the specially negotiated rate for the duration of your stay. 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.