# Extractables & Leachables

23 to 24 February 2016
Cologne, Germany

Course no. 6638

## Quality Control/Analytics

### Target audience

This seminar is aimed at pharma professionals engaged in the evaluation and qualification of single-use materials in the pharmaceutical production processes, as well as primary packaging materials for drug sustances and drug products.

The seminar will cover all aspects of this topic starting from relevant guidelines, to considerations for the selection of candidate materials for a given product, how to plan Extractable and Leachable studies, relevant analytical techniques, what to look out for when outsourcing these activities and finally how to evaluate compounds that do migrate into the product.

Relevant case studies presented by experts in the field, will open up the discussion for topics coming from the audience.

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**Arbeitsgemeinschaft für Pharmazeutische Verfahrenstechnik e.V.**
Gemeinnütziger wissenschaftlicher Verein
International Association for Pharmaceutical Technology

# Quality Control/Analytics

A seminar organised by the APV focus group Analytics and Quality Assurance

## Objectives

Compounds migrating into pharmaceutical products, either from single-use materials used during the manufacturing process or during the storage of drug substances or final products from the immediate outer packaging, have been in the spotlight for some time. Since there is no distinct guideline available for extractables and leachables assessments, there are currently best practices for orally inhaled nasal drug products (OINDPs), parenteral and ophthalmic drug products (PODPs) set by the Product Quality Research Institute (PQRI). Furthermore guidance is sought-after in ICH Q3D and M7. Currently there is no binding approach to extractable and leachable assessments and therefore there is some uncertainty but also some degrees of flexibility of how to adopt the available best practices and guidelines mentioned.
The first part of the seminar aims at looking, which guidelines and best practices are available and then presenting case studies by exerts in the field to discuss the strategies available for conducting acceptable E&L-evaluations. Then a manufacturer of single-use devices for the production of biopharmaceuticals will give a rare insight into the efforts made by the industry to evaluate and control the risk of compounds migrating into to the drug substance. The second part will take a different perspective on the topic, discussing what to do in the unfortunate event a leachable is identified and have a toxicologists view of what information is required to make a valid toxicological assessment. Finally, we will take a closer view on materials commonly used in parenterals and which risks are involved and how they can be controlled.
By presenting case studies, this seminar wants to offer strategies and ideas how evaluate and qualify materials from primary packaging and single use devices and how to adopt theses for own, future project. Open discussions about the offered strategies may lead to a consensus approach to E&L-studies and to less uncertainty in the community.

## Speakers

**Dr. David Bohonak** is a senior applications engineer and has 10 years of experience in biopharmaceutical manufacturing. His expertise includes membrane-based separations, filter fouling mechanisms, and membrane characterization. His work experience includes the development of new virus filters and identification of best practices for downstream processes. Dave holds B.S. and Ph.D. degrees in Chemical Engineering from the Pennsylvania State University and a Master of Chemical Engineering degree from the University of Delaware.

**Dr. Roman Föll** was trained in biology at the Ludwig-Maximilians-Universität in Munich. After a degree in zoology and a doctorate in physiology he worked as an assistant professor for zoophysiology at the Westfälische Wilhelms-Universtität in Münster. In 1999 he joined the department for nonclinical drug safety at Boehringer Ingelheim. From there, he changed to the toxicology department of Byk Gulden which later became the institute for preclinical drug safety of Altana AG. Since 2006, he runs his own consulting Company, „Preclinical Services".

**Dr. Ferdinand Haller** studied biochemistry at the Technical University of Munich. During his Ph.D. at the Helmholtz Zentrum München he worked on steroid hormone metabolism, gaining experience in protein characterization and instrumental analytics. He started at Sandoz GmbH in 2010 as an Analytical Specialist supporting the analytical development of several ongoing biosimilar projects. Since 2013 he is head of the extractable & leachable lab for Sandoz Biopharma.

**Dr. Cornelia Lipperheide** is a Pharmacist who graduated from the University of Bonn. After she had received her Ph.D., she worked in several research groups at the university, the pharmaceutical industry and a veterinary laboratory. In 2001, she joined the Federal Institute for Drugs and Medical Devices (BfArM), first in the unit 'Semi-solid dosage forms', since June 2005 in the unit 'Pharmaceutical Biotechnology, Quality Inspections'. Her responsibility is the assessment of Pharmaceutical Quality of medicinal products in European marketing authorization procedures. Furthermore, she was in charge of a research group at the BfArM working on interactions between medicinal products and their primary packaging.

As Vice President Global Marketing, **Dr. Mike Schaefers** is responsible for the global Marketing activities of Wests Pharmaceutical Packaging System Division. Mike joined West in 2000. He previously headed West Pharmaceutical Services Scientific & Technical Customer Service Group for the European and Asia Pacific markets as Director of Technical Customer Service. In 2006 he became Vice President Marketing Europe with responsibilities for Marketing and Technical Support in Europe before he assumed his current position in 2012. Prior to joining West, Mike spent several years with the drug delivery company R.P. Scherer GmbH & Co. KG in Eberbach, Germany, in sales and marketing roles.

After studying biology at the Bielefeld University and graduating with a PhD in genetics and molecular biology in 2005, **Dr. Steven Watt** was granted a position as a postdoctoral candidate. There he was in charge of a mass spectrometry service unit, dealing with proteome and metabolome projects. In 2009 he joined Thermo Fisher Scientific as an instructor for scientific and pharmaceutical mass spectrometry applications. In his current position as a business development manager at A&M STABTEST he is involved in customer relations, marketing and the development of new analytical services in the field of pharmaceutical analysis

# Extractables & Leachables

## Programme

Tuesday, 23 February 2016 13:00 – 17:30 h

**Welcome and introduction**
*Dr. Steven Watt, A&M STABTEST*

**Regulatory requirements**
- Legal basis
- Details on extractables/leachables studies to be submitted in a MAA
- Assessment of leachables
- Case studies

*Dr. Cornelia Lipperheide*

**„Outsourcing of extractable and leachable studies"**
- Criteria for selecting external labs
- Potential issues in selection of labs
- Case studies

*Dr. Ferdinand Haller, Sandoz*

**Conducting E/L-studies in a contract laboratory (Part 1: Extractables)**
- Case study: Introduction into a typical extractable study
- What kind of information is usually made available?
- What kind of extracts and extraction media are sensible?
- How to evaluate the data and results of an extraction study?

*Dr. Steven Watt, A&M STABTEST*

**Conducting E/L-studies in a contract laboratory (Part 2: Leachables)**
- How to plan an leachables study?
- How to prepare reference samples?
- Analysis with validated methods (targeted approach).
- Non-targeted semi-quantitative leachable analysis.

*Dr. Steven Watt, A&M STABTEST*

**Adopting a Fully Single-Use Process:**
A leachables and patient safety evaluation case study
*Dr. David Bohonak, EMD Millipore*

**Get-together**

Wednesday, 24 February 2016 09:00 - 12:00 h

**Toxicological qualification of leachables**
- Which information is required ?
- How is a PDE/ADI for man derived from toxicological data?
- What can (Q)SAR contribute to the hazard identification ?
- A practical approach to qualification of E&L

*Dr. Roman Föll, Preclinical Services*

**Toxicity studies in Qualification of E&L**
- Which toxicological endpoints need to be covered ?
- Which additional data can be used ?
- Genotoxic compounds

*Dr. Roman Föll, Preclinical Services*

**E/L-testing of parenteral primary packaging components**
- Typical extractables from elastomers, glass und plastics
- Guidance and recommendations foreExtractable & leachable testing
- Selection and qualification of primary packaging components for parenterals

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

**Questions and answers**

Programme is subject to change

Optional as added value based on availability and approval
13:00 – 16:00 h

Discussion about leachables in biopharmaceuticals at A&M STABTEST

After the course, A&M STABTEST invites interested individuals to their laboratory site in Bergheim (transfer is provided) to have an in-depth discussion about the risks of leachables for biopharmaceuticals. The already mentioned best practice and relevant guidelines focus on the direct risk leachables pose for patient safety, as they may have toxic or cancerogenic properties. However biopharmaceuticals are more susceptible to structural changes than small molecule drug substances. Therefore leachables, which pose no risk to patients, may have an effect on the structural integrity of the biologic and hence render the product inactive or worse, immunogenic. The discussion will be joined by A&M' s biologics- and E&L-specialists.

**This event will be limited to ten interested individuals.**
Places will be given by date of registration and upon approval of A&M STABTEST in regards to competitor protection rules.

# Registration by fax +49 6131 9769-69

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## Location

Hotel Lyskirchen Cologne
Filzengraben 26-32
50676 Cologne
Germany
T: +49 221 2097-0
F: +49 221 2097-718

I herewith repealable authorise APV to use my E-mail address to send me APV relevant material including current programme information. My acceptance can be cancelled at any time in writing

## Date

Course no. 6638
from 23 Feb. 2016 13:00 h
to 24 Feb. 2016 12:00 h

## Registration fee

APV member 1160 EUR
Non-member 1290 EUR
(free of VAT according to § 4,22 UStG)

Coffee breaks, dinner and electronic proceedings included.

## Registration

APV-Geschäftsstelle
Kurfürstenstraße 59
55118 Mainz/Germany
Phone: +49 6131 9769-0
Fax: +49 6131 9769-69
e-mail: apv@apv-mainz.de

You will receive a confirmation of your registration with the invoice.

Members of authorities pay half of the APV member's and non-member's registration fee respectively.

## Hotel reservation

Hotel Lyskirchen Cologne
Filzengraben 26-32
50676 Cologne
Germany
T: +49 221 2097-0
F: +49 221 2097-718

Participants should make their own hotel reservation referring to the APV seminar.

Deadline for special conference rate: 12 January 2016.

Special rate:
Single room incl. breakfast buffet from 110 EUR per night.

Mainz, October 2015

## Extractables & Leachables, Course no. 6638

**Registration**
As soon as you have found a seminar of your interest, it is very easy to register for it via fax, e-mail or online. We will process your registration promptly and certainly are available for any questions that may arise.

**Registration confirmation**
After your registration was successfully processed, you will receive a confirmation.

**Before the event**
A few days before the event starts, you will receive important information about the seminar, such as time, date, addresses etc.

**After the event**
You will receive a certificate confirming your participation. Furthermore, we would like to ask you to fill-in our evaluation sheet to make sure we get better every time.

**Follow-up**
After the event, we are open to receive any suggestions and critique that might arise during the seminar and will certainly help you with further questions you may have.

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