



Extractables & Leachables Practical Workshop

How to Apply USP Requirements to Design and Execute
Extractable and Leachable Studies.

September 27, 2017, Racquet Club of Philadelphia, PA

The workshop will discuss different analytical approaches related to extractable and leachable testing. Practical recommendations will be presented for designing and executing controlled extractions. Analytical solutions will be explained according to the latest regulatory expectations. The workshop will provide practical guidance and case studies from start to completion. The following topics will be covered:

- Design of extractable studies
- Importance of the AET, how to calculate the AET based on the formulation and the dose of the finished product.
- Extraction studies, practical guidance, solvent based and non-solvent based extraction techniques
 - Practical aspects for selection of extraction time and extraction temperature
 - What to do if the extracts need to be concentrated
 - Compatibility of extraction solvent of choice and analytical instrumentation
 - Comparison of solvent based and solventless extraction techniques
 - Static head-space, dynamic head-space, Solid Phase Microextraction and Twister will be explained with their unique drawbacks and benefits
 - Extraction approaches will be presented for inhalation, injectables, large volume parenterals, transdermal products, and medical devices
- Choice of analytical techniques for characterization of the extracts
 - The drawbacks of "one size fits all" practice
 - Short practical guidance regarding different mass spectrometry techniques
 - Component identification practice according to USP <1663>
- Method validation practice
 - How to design appropriate validation protocol for ppm, ppb and ppt level?
 - How to define and justify appropriate acceptance criteria for low level testing.
 - Method requirements specific to mass spectral based methods
- Instrument qualification and calibration practice.

About the Workshop Leader



Dr. Gyorgy Vas has an M Sc in Analytical Chemistry and a Ph. D. in Mass Spectrometry. He had published 18 research papers that have been cited more than 2500 times. Dr. Vas has several years of experience in E&L testing, pioneering and adopting solventless analytical sample preparation techniques. He has multiple years of experience for developing trace level analytical methods and validating methods at trace level. He worked for Johnson & Johnson for 7 years and was recipient of Johnson & Johnson Outstanding Analytical Scientist Award and the Philip B. Hofmann Research Award. Currently he is holding position in Intertek as a Business-technical Scientific Liasion.



About your conference destination:

The Racquet Club of Philadelphia is located in the heart of downtown Philadelphia, adjacent to beautiful Rittenhouse Square. From the conference venue, you can access many points of interest in Philadelphia including Independence Hall, the Kimmel Center, the Avenue of the Arts, numerous shops, and excellent restaurants!



Registration Information

Register for the conference using one of three options:

Online: www.pharmaedresources.com Phone: (217) 721-5774

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**Extractable Leachable
Practical Workshop, 2017:**

How to apply USP requirements to design and execute extractable and leachable studies

Standard Registration: \$895
Call for government or academic discount.

PAYMENT METHOD

CREDIT CARD REGISTRATION:

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VENUE INFORMATION:

Dates: **September 27, 2017**
 Venue: **The Racquet Club of Philadelphia**
 Venue Address: **215 South 16th Street
Philadelphia, PA 19102**
 Venue Phone: **(215) 735-1525**
 Hotel Room Block: **Radisson Blu Warwick**
 Hotel Address: **220 South 17th Street
Philadelphia, PA 19103**
 Reservations: **(800) 967-9033**
 Hotel Telephone: **(215) 735-6000**

CHECK REGISTRATION:

To pay by check, please provide a purchase order below. Please note that all payments must be received five (5) days prior to the conference to ensure space. Attendees will not be admitted to the conference without full payment.

PURCHASE ORDER #:

PLEASE NOTE:

PharmaEd Resources does not offer refunds. However, if you cannot attend after registering, we are happy to apply your registration fee to another PharmaEd Resources event, or transfer your registration to a colleague. Notice of cancellation must be received at least 5 days prior to the event.