

# Extractables, Leachables, & Elemental Impurities 2019

April 10-11, 2019, Metro Meeting Center, Boston, MA

## Over 16 Featured Speakers, Including:



**Dennis Jenke**  
Chief Executive  
Scientist,  
Triad Scientific  
Solutions



**Daniel Norwood**  
Senior Consultant  
Smithers Rapra



**Andrey Sarafanov**  
Chemist, Principal  
Investigator  
FDA  
(Pending Approval)



**Sherry Parker**  
Toxicology Director  
Fresenius Medical  
Care



**Ted Heise**  
Vice President,  
Regulatory and  
Clinical Services  
MED Institute



**Steve Zdravkovic**  
Senior Research  
Scientist  
PPD



**Ronald Brown**  
Retired  
FDA



**Raymond Colton**  
President  
VR Analytical

## With Comprehensive Coverage On:

- Implementing ICH Q3D, and USP <232> <233> Guidelines Regarding Elemental Impurities: Case Studies and Regulatory Expectations
- Update on ongoing revisions to USP <665> and <1665> for Materials and Components used in Pharmaceutical Manufacturing Systems
- Update on ongoing revisions to ISO 10993 Revised Standards for Medical Devices
- Meeting Regulatory Expectations for E&Ls in Drug Products, Delivery Systems, and Medical Devices
- The Proper Use of Extractables Data
- Toxicology Assessment Approaches for E&L Studies
- E&L Best Practices for Inhaled Products and Inhalation Devices
- E&L Best Practices for Medical Devices & Combination Products
- Designing and Improving Risk-Based Assessment of E&L Data for Drugs, Biologics, and Medical Devices
- GC-MS Applications for Detection of Leachables
- Exploring Biocompatibility Vs. Chemical Assessment in E&L Study Design
- E&L Evaluation for Complex Pharmaceutical Formulations
- Issues Frequently Observed in Analytical Evaluation of Leachables in Drug Products
- E&L Considerations in the Qualification and Validation of Single-Use Systems
- E&L Best Practices for Oral Dosage Forms
- Understanding Leaching Associated with Lyophilized Drug Products Stored in Vial/Stopper Packaging Systems
- Addressing E&Ls from Bioprocessing Equipment & Product Packaging

## Sponsors and Exhibitors Include



**Pre-Conference Special: Register by January 10 for \$300 off Standard Rate!**

Now accepting sponsorships. Contact Kim at [khubbard@pharmaedresources.com](mailto:khubbard@pharmaedresources.com) or (217) 721-5774 for more detail.

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**About your conference destination:**

Boston, Massachusetts, offers a quintessential blend of colonial history and cutting-edge innovation. From the charming cobblestones of Beacon Hill, to the civic landmarks along the Black Heritage Trail and Freedom Trail, to the iconic grounds of Harvard University and Fenway Park, Boston is a treasure trove of Americana. Fun if by land and fun if by sea, Boston is an ideal destination. Explore diverse neighborhoods, enjoy an eclectic array of performing arts and special events, shop in chic boutiques and high-end malls, fall into a foodies' paradise. Boston is a cosmopolitan hub where tradition and innovation interact everyday.



**Registration Information**

Register for the conference using one of three options:

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Please register me for:

**Extractables, Leachables & Elemental Impurities 2019**

Standard Registration: \$1,895  
Early Bird Special (by February 1): \$1,695  
Pre-Conference (by January 10): \$1,595  
Call for Government or Academic Pricing

**PAYMENT METHOD**

CREDIT CARD REGISTRATION:

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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 #:

**VENUE INFORMATION:**

Dates: **April 10–11, 2019**  
Venue: **Metro Meeting Centers–Boston**  
Venue Address: **101 Federal Street**  
**Boston, MA 02110**  
Venue Phone: **(617) 737-1200**

**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.