



## PQRI/USP Workshop on Elemental Impurity Requirements in a Global Environment – Next Steps?

March 31 – April 1, 2015  
USP Meeting Center  
Rockville, Maryland

### Workshop Description

The time to finalize implementation plans is now! This workshop will provide practical solutions to challenges involved in global implementation of the Elemental Impurity (EI) guidelines and standards. Specific topics will include the following:

- Assessment of Ingredients – Excipients & APIs
- Analytical Testing Considerations
- Successful Risk Assessment Methodologies
- Finished Dosage Form Considerations
- Implementation Strategy

This workshop will include global experts from industry, regulatory authorities, pharmacopeias, and academia who are intimately involved in this area.

### Workshop Planning Committee

David R. Schoneker, Chair, Colorcon, IPEC Americas, and PQRI

William Dale Carter, JM Huber

David J. Fillar, Perrigo Co.

John F. Kauffman, Ph.D., US Food and Drug Administration

Andrew Teasdale, Ph.D., Astra Zeneca

Katherine L. Ulman, Dow Corning and IPEC-Americas

Phyllis Walsh, Merck

Kakhashan Zaidi, Ph.D., US Pharmacopeia

Priscilla S. Zawislak, Ashland Inc.

## Preliminary Program Agenda

MARCH 31, 2015

8:00 am – 8:15 am

Registration Check In

8:15 am *Amphitheater*

Welcome and Introductory Remarks

**David R. Schoneker**

Colorcon, IPEC-Americas,  
PQRI Steering Committee, and  
EI Coalition

8:30 am

**Session I: Assessment of Ingredients –  
Excipients and APIs**

FDA Expectations for Archiving Data  
in the Quality System

FDA Speaker TBD

Expectations for APIs and Excipients in the EU

EDQM Speaker TBD

9:30 am

Coffee Break

9:45 am

**Session II: Elemental Impurity  
Measurement and Assessment**

Methods/Validation

**Nancy Lewen**

Bristol Myers Squibb Company,  
USP EI Expert Panel and Chemical Analysis Expert  
Committee

Analytical Challenges/Round Robin Study

**Donna S. Seibert, Ph.D.**

Perrigo  
EI Coalition

Industry Analytical Data Collected by Global  
Groups/FDA-IPEC Excipient Study Data

**Andrew Teasdale, Ph.D.**

Astra Zeneca  
JPAG EI Committee

11:00 am

Lunch

12:00 pm

Breakout Sessions – there will be four concurrent rooms  
utilized to discuss the topic to facilitate small group  
discussion

**Breakout Session I**

Topic: Assessment of Ingredients –  
Excipients and APIs

Facilitators: K. Ulman, D. Carter, D. Schoneker,  
P. Zawislak, and N. Schwarzwaldner

Discussion Points to include:

- Variability of Natural & Mined  
Ingredients – Excursions
- Lack of Predictability for Risk Assessment
- Acid Leach vs. Total Dissolution – Data  
Interpretation
- Appropriate Supplier-User Communication
- How to Assess What is “Likely to be Present”? –  
30% Rule
- Data Sharing – Development of an  
Excipient Elemental Impurity Database

1:15 pm

**Breakout Session II**

Topic: Analytical Testing Considerations

Facilitators: D. Seibert, T. Shelbourn, A. Teasdale and  
K. Ulman

### Discussion Points to include:

- Best Practices
- Method Validation
- Dosage Form Considerations
- Acid Leach vs. Total Dissolution - Sample Prep
- Inter-Laboratory Reproducibility – Coalition Collaborative Study Results
- Instrument Issues – Precision, Accuracy, and Corrections
- Matrix Interferences
- Potential Solutions

2:30 pm

Coffee Break

2:45 pm *Amphitheater*

### Session III: Elemental Impurity Control Strategies for Finished Drug Products

### Successful Risk Assessment Methodologies

EMA Speaker TBD

### General Approaches to Elemental Impurity Product Assessments

Mark G. Schweitzer, Ph.D.

Novartis

ICH Q3D EWG

### Finished Dosage Form Considerations

### Finished Dosage Form Testing

Wilfried Keurentjes

Merck

### Applying Q3D to Other Routes of Administration

John K. Leighton, Ph.D., *Invited*

US Food and Drug Administration

ICH Q3D Expert Working Group

### How to Deal with Other Routes of Administration in the EU

Roland Frötschl, Ph.D.

BfArM

USP EI Expert Panel

4:55 pm

Closing Remarks

David R. Schoneker

Colorcon

PQRI Steering Committee

EI Coalition

5:30 pm – 7:30 pm

Reception

**please note** location is offsite and adjacent to the Twinbrook Metro Station

Held at the Hilton Hotel and Executive Meeting Center  
1750 Rockville Pike  
Rockville, Maryland 20852

APRIL 1, 2015

8:00 am

Registration

8:30 am *Amphitheater*

### Summary of Day 1, Goals for Day 2

David R. Schoneker

Colorcon

PQRI Steering Committee

EI Coalition

8:45 am

### Breakout Session III

Topic: Successful Risk Assessment Methodologies  
Facilitators: D. Fillar, P. Walsh, D. Carter, N. Lewen

### Discussion Points to include:

- Key Considerations and Tools
- Predictability
- When is Testing Needed and When is it Not?
- Case Studies to Demonstrate Appropriate Control Strategies

**10:15 am**  
**Coffee Break**

**10:30 am**  
**Breakout Session IV**

Topic: Finished Dosage Form Considerations  
Facilitators: P. Walsh, A. Teasdale, D. Fillar, N. Schwarzwaldner, T. Shelbourn, J. Poulos

**Discussion Points to include:**

- Finished dosage Form Testing Protocols – What is the Industry Doing?
- Oral, Parenteral, and Inhalation Issues
- How to Deal with Other Routes of Administration with Less Defined Dosing/Exposure (Topicals, etc.)
- Are Reformulations Needed for Some Drug Products or Should Exemptions be Granted?
- How to Apply for an Exemption in Different Regions

**12:00 pm**  
**Lunch**

**1:00 pm Amphitheater**  
**Session IV: Implementation Strategy**

**ICH Training Plans-Implementation Working Group (IWG)**

**John F. Kauffman, Ph.D.**  
US Food and Drug Administration  
ICH Q3D EWG

**Regional and Global Roll-out by Regulatory Authorities –Timing and Compliance**  
**MHLW/JP Speaker TBD**

**Harmonization of Requirements Between ICH Q3D and Pharmacopeias**

**Kakhashan Zaidi, Ph.D.**  
US Pharmacopeia

**Coordination with Requirements in Other Countries (i.e., China, India, Brazil, Taipei, South Korea, etc.)**

**Industry Speaker TBD**

**Regulatory Expectations at Time of Registration and During Ongoing GMP Inspections**

**Danae Christodoulou, Invited**  
US Food and Drug Administration  
EI Implementation Working Group

**3:30 pm**  
**Breakout Summary Reports**

Breakout Session I: Katherine Ulman, Dow Corning and IPEC-Americas

Breakout Session II: Donna Seibert, Perrigo Co.

Breakout Session III: David J. Fillar, Perrigo Co

Breakout Session IV: Phyllis Walsh, Merck

**4:30 pm**  
**Summary of Feedback and Action Plans**

**David R. Schoneker**  
Colorcon, IPEC-Americas  
PQRI Steering Committee, and  
EI Coalition



## **PQRI Mission Statement**

The Product Quality Research Institute (PQRI) is a non-profit consortium of organizations working together to generate and share timely, relevant, and impactful information that advances drug product quality and development. By virtue of its diverse membership, PQRI provides a unique forum to focus critical thinking, conduct research, exchange information, and propose methodology or guidance to pharmaceutical companies, regulators, and standard setting organizations.

## **PQRI Member Organizations**

### **AAPS**

American Association of Pharmaceutical Scientists

### **CHPA**

Consumer Healthcare Products Association

### **FDA/CDER**

U.S. Food and Drug Administration, Center for Drug Evaluation and Research

### **HC**

Health Canada

### **IPEC-Americas**

International Pharmaceutical Excipients Council of the Americas

### **ISPE**

International Society of Pharmaceutical Engineers

### **PDA**

Parenteral Drug Association

### **USP**

United States Pharmacopeia

## **Board of Directors**

Anthony DeStefano, Ph.D., **Chair**

Louis Yu, Ph.D., **Treasurer**

Kevin Hool, Ph.D.

Margaret Szymczak, Ph.D.

Vinod Shah, Ph.D.

## **PQRI Steering Committee**

Margaret Szymczak, Ph.D., **Chair**

Kevin Hool, Ph.D., **Vice Chair**

### **AAPS**

Lynn Van Campen, Ph.D.

### **CHPA**

John Punzi, Ph.D.

### **FDA**

Lawrence Yu, Ph.D.

### **HC**

Anita DiFranco

### **IPEC-Americas**

Dave R. Schoneker

### **ISPE**

Joe Famulare

### **PDA**

Rich Levy, Ph.D.

### **USP**

Kevin Hool, Ph.D.



## Venue and Registration

The workshop is being held at the USP Meeting Center in Rockville, Maryland.

Hotel reservations can be made online at

[https://secure3.hilton.com/en\\_US/hi/reservation/book.htm?ctyhocn=IADMRHF&corporateCode=N2694865](https://secure3.hilton.com/en_US/hi/reservation/book.htm?ctyhocn=IADMRHF&corporateCode=N2694865) using the PQRI corporate discount.

The link allows you to take advantage of that discount when you enter your reservation information. Please note that space is limited so do not delay, make your reservations today!

Registration for the conference can be made by going to the SignMeUp website at [www.signmeup.com/104624](http://www.signmeup.com/104624).

For additional information and/or assistance, please contact Vicki Penn at [pennv@pqri.org](mailto:pennv@pqri.org).