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. Schwarzwalder

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. Schwarzwalder, 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

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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 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.

For additional information and/or assistance, please contact Vicki Penn at pennv@pqri.org .