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

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

Final Program Agenda

March 31, 2015

8:00 am – 8:15 am
Registration Check In

8:15 am Spalding Auditorium

Welcome and Introductory Remarks
David R. Schoneker
Colorcon, IPEC-Americas,
PQRI Steering Committee
EI Coalition

8:30 am

Session I: Assessment of Ingredients – Excipients and APIs

Elemental Impurities in APIs and Excipients – GMP Expectations
Vibhakar Shah
US Food and Drug Administration

Expectations for APIs and Excipients in the EU
Ulrich Rose, Ph.D.
EDQM, Council of Europe

9:30 am
Coffee Break

9:45 am

Session II: Elemental Impurity Measurement and Assessment

Methods/Validation
Nancy Lewen
Bristol-Myers Squibb

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.
AstraZeneca
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 Digestion – 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 Digestion - 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 Spalding Auditorium

Session III: Elemental Impurity Control Strategies for Finished Drug Products

Successful Risk Assessment Methodologies

General Approaches to Elemental Impurity Product Assessments
Mark G. Schweitzer, Ph.D.
Novartis
ICH Q3D EWG
Rapporteur through Step 2 and IWG

Justification for Exceeding the PDE
Doug Ball, Ph.D.
Pfizer
ICH Q3D EWG

Session IV: Elemental Impurity Control Strategies for Finished Drug Products

Finished Dosage Form Considerations

Concept of Elemental Impurities (EI) Assessment in Finished Dosage Forms by Total Extraction Testing
Will J.T.M. Keurentjes
Merck/MSD

Applying Q3D to Other Routes of Administration
John K. Leighton, Ph.D.
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, IPEC-Americas,
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 **Spalding Auditorium**

Summary of Day 1, Goals for Day 2
David R. Schoneker
Colorcon, IPEC-Americas,
PQRI Steering Committee
EI Coalition

8:45 am

<u>Breakout Session III</u>
Topic: Successful Risk Assessment Methodologies
Facilitators: D. Fillar, P. Walsh, D. Carter, N. Lewen

Discussion Points to include:

- Key Considerations and Tools
- Predictability
- How to Address Levels Present in Water?
- How to use a Control Threshold (ie; 30%)?
- 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.)
- Definition of Short-term, Chronic use
- What type of justification may be needed for exceeding the PDE?

12:00 pm
Lunch

1:00 pm **Spalding Auditorium**

Session V: Implementation Strategy

Regulatory Expectations at Time of Registration and During Ongoing GMP Inspections
Danae Christodoulou, *Invited*
US Food and Drug Administration
EI Implementation Working Group

ICH Training Plans-Implementation Working Group (IWG)
John F. Kauffman, Ph.D.
US Food and Drug Administration
ICH Q3D EWG

Harmonization of Requirements Between ICH Q3D and Pharmacopeias
Kahkashan Zaidi, Ph.D.
US Pharmacopeia

Expectations for Implementation from Europe
Henk De Jong, Ph.D.
IPEC Europe
Federation Representative to ICH Q3D EWG

Coordination with Requirements in Other Countries (i.e., China, India, Brazil, Taipei, South Korea, etc.)
Helmut Rockstroh, Ph.D.
F. Hoffman- LaRoche Ltd.

3:30 pm **Spalding Auditorium**

Breakout Summary Reports

Breakout Session I: Katherine Ulman, Dow Corning
Breakout Session II: Donna S. 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
EI Coalition