Product Quality Research Institute

Monday – Tuesday, November 9-10, 2020

LIVE VIRTUAL EVENT

4th PQRI Workshop on ICH Q3D Elemental Impurities Requirements

Day 1 – Monday, November 9, 2020 8:00 AM – 5:00 PM US ET	
8:00 - 8:15 AM ET	***Welcome and Introductory Remarks*** David Schoneker IPEC-Americas, Black Diamond Regulatory Consulting, Chair - PQRI EI Workshop Organizing Committee
Current State of Implementation of ICH Q3D Globally	
8:15 – 8:45 AM	***Global Experience/Survey Results*** Janeen Skutnik Wilkinson, Biogen, Chair - IPEC-Americas
8:45 – 9:15 AM	***Implementation of ICH Q3D in Japan*** Yoshiaki Ogasawara, IPEC Japan
9:15 – 9:45 AM	***Implementation of ICH Q3D in India*** Vishakha Metkar, IPEC India, Colorcon Asia Pvt Ltd.
9:45 – 10:00 AM	**BREAK**
	Regulator Experience - Quality of Risk Assessments and Supporting Data
10:00 – 10:30 AM	***Implementation in the US – FDA Perspective*** Matthew Vera, Ph.D., US Food and Drug Administration
10:30 – 11:00 AM	***Implementation in Europe – EMA Perspective*** Sophie Bertilsson, Ph.D., Swedish Medical Products Agency
11:00 – 11:30 AM	Moderator: David Schoneker ***Q&A Session with above speakers***
11:30 AM – 12:00 PM	**LUNCH BREAK**
	Industry Experience – Implementation Challenges
12:00 – 12:30 PM	***Recent Experiences with Global Implementation of the Principles of ICH Q3D*** Mark G. Schweitzer, Ph.D., Novartis
12:30 – 1:00 PM	***Industry Implementation Challenges - Excipient Company Experience*** Priscilla Zawislak, DuPont Nutrition and Biosciences
Pharmacopeia Approaches to Element Specific Requirements in Monographs	
1:00 – 1:15 PM	***An Update on USP Element Specific Chapters*** Nancy Lewen, Consultant
1:15 – 1:45 PM	***USP Update on Draft Roadmap for Addressing Element-Specific Chapters and Tests in Excipient Monographs*** Galina Holloway, Ph.D., USP
1:45 – 2:15 PM	***European Pharmacopoeia Activities on Elemental Impurities – An Update*** Ulrich Rose, Ph.D., EDQM

2:15 – 2:30 PM	**BREAK**
	Industry Perspectives and Consequences
2:30 – 3:00 PM	***ICH Q3D Industry Perspective and Consequences*** William Dale Carter, MS, Evonik Corporation
3:00 – 3:30 PM	***An Industry Perspective on Managing Specific Elements in Public Standards*** Philip Travis, BSc., Merck and Co., Inc.
3:30 – 3:45 PM	**BREAK** – To connect to breakout rooms
3:45 – 4:55 PM	***Breakout Session 1 - Implementation Problems and Future Needs*** *There will be three concurrent breakouts utilized to discuss the topic to facilitate small group discussion* Moderators: Kathy Ulman, Consultant; Douglas Muse, Eli Lilly and Company; and Janeen Skutnik-Wilkinson, Biogen
4:55 - 5:00 PM	***Day 1 Closing Remarks*** *In breakout sessions*

Day 2 – Tuesday, November 10, 2020 8:45 AM – 5:00 PM US ET	
8:30 – 9:00 AM ET	***Welcome to Day 2 and Review of Day 1*** David Schoneker IPEC-Americas, Black Diamond Regulatory Consulting, Chair - PQRI EI Workshop Organizing Committee
Ongoing ICH Q3D Activities	
9:00 – 9:30 AM	***Update on Transdermal Limits*** Andrew Teasdale, Ph.D., AstraZeneca
9:30 – 10:00 AM	***Lhasa Database Update – Industry Data and Use in DP Risk Assessments*** Laurence J. Harris, Ph.D., Pfizer
10:00 – 10:15 AM	**BREAK**
PQRI Phase 2 Elemental Impurities Collaborative Study Results	
10:15 – 10:45 AM	***PQRI Phase 2 Elemental Impurities Collaborative Study Purpose and Design*** Donna Seibert, Ph.D., Perrigo
10:45 – 11:15 AM	***Phase 2 Study Method Development and Laboratory Participant Perspective*** Denise McClenathan, Ph.D., Procter & Gamble
11:15 – 11:45 AM	***PQRI Phase 2 Elemental Impurities Collaborative Study Results Review and Publication*** Donna Seibert, Ph.D., Perrigo
11:45 AM – 12:15 PM	***XRF Results of Phase 2 Collaborative Study*** Glenn Williams, Ph.D. and Thanh Nguyen, Ph.D., Rigaku Americas Corporations
12:15 - 1:00 PM	**LUNCH BREAK**
	Main Take-Aways
1:00 – 1:30 PM	***Statistical Methods in PQRI Interlaboratory Study Report*** Stephen W. Erickson, Ph.D., RTI International
1:30 – 2:00 PM	***Key Findings*** James Michael Harrington, Ph.D., RTI International
	Implications for Analytical Testing in Laboratories for Elemental Impurities
2:00 – 2:30 PM	***Implications for Analytical Laboratory Testing*** Francine Walker, SGS Chemical Solutions Laboratory
	Implications for Risk Assessments
2:30 – 3:00 PM	***Recent Regulatory Filing Experiences Regarding ICH Q3D Implementation*** Xiaoyi Gong, Ph.D., Merck and Co., Inc.
3:00 – 3:30 PM	**BREAK**

3:30 – 4:30 PM	***Breakout Session 2 – Explore the Impact of the Phase 2 Study on Industry and Regulators*** *There will be three concurrent breakouts utilized to discuss the topic to facilitate small group discussion.* Moderators: James Harrington, RTI International; Donna Seibert, Perrigo; and Denise McClenathan, Procter & Gamble
4:30 – 4:45 PM	**BREAK** – To reconnect from breakout rooms
4:45 – 5:00 PM	***Closing Remarks*** David Schoneker IPEC-Americas, Black Diamond Regulatory Consulting, Chair - PQRI EI Workshop Organizing Committee

Workshop Planning Committee

David R. Schoneker, Chair – Workshop Organizing Committee, Black Diamond Regulatory Consulting, IPEC Americas, PQRI
Dale Carter, Evonik
Danae Christodoulou, US Food and Drug Administration
Dede Godstrey, PQRI Secretariat
James Harrington, RTI
Nancy Lewen, Consultant
Timothy McGovern, US Food and Drug Administration
Doug Muse, Eli Lilly and Company
Donna Seibert, Perrigo
Timothy Shelbourn, Eli Lilly and Company
Janeen Skutnik Wilkinson, Biogen
Andrew Teasdale, AstraZeneca
Katherine Ulman, Consultant
Kahkashan Zaidi, US Pharmacopeia
Priscilla Zawislak, Dupont