Workshop on ICH Q3D Guidance for Elemental Impurities

Agenda

FDA White Oak Campus, Great Room, August 22-23, 2016

DAY 1

Monday, August 22, 2016

Time	Topic	Speaker
8:30 – 9:00 AM	Check-in	
9:00 AM	Opening Remarks	Dr. Michael Kopcha, Director, OPQ
9:10 AM	Introduction to Workshop	John Kauffman, FDA/OPQ, Office of Testing and Research, (Member Q3D IWG)
9:30 AM	Determining safe levels of elemental impurities	Douglas Ball, Pfizer (Member Q3D IWG)
10:10 AM	**BREAK**	
10:30 AM	Administration by other routes and other safety aspects	John Leighton, FDA/OND/OHOP (Member Q3D IWG)
11:10 AM	Panel Discussion and Questions	John Leighton, FDA; Douglas Ball, Pfizer; Tim McGovern, FDA
11:40 AM	**LUNCH**	
1:00 PM	Calculation Options	John Kauffman, FDA
1:20 PM	Risk Assessment and Control - Industry Perspective	Mark Schweitzer, Novartis (Member Q3D IWG)
2:00 PM	**BREAK**	
2:20 PM	Risk Assessment and Control - FDA Perspective	Frank Holcombe, FDA/OPQ/Office of Lifecycle Drug Products (Member Q3D IWG)
2:50 PM	Process-introduced Elemental Impurities and Controls	Edwin Jao, FDA/OPQ/Office of Process and Facilities
3:20 PM	Panel Discussion and Questions	John Kauffman, FDA; Mark Schweitzer, Novartis; Frank Holcombe, FDA; Janeen Skutnik-Wilkinson, Biogen IDEC (Q3D IWG); Kahkashan Zaidi, USP; Alison Ingham, Health Canada (Q3D IWG); Edwin Jao, FDA
4:00 PM	Wrap-up and Adjourn	

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DAY 2

Tuesday, August 23, 2016

Time	Topic	Speaker
8:30 – 9:00 AM	Check-in	
9:00 AM	Opening Remarks	John Kauffman, FDA
9:10 AM	USP <232 & 233> Implementation Strategy	Kahkashan Zaidi, USP (Member Q3D IWG)
9:50 AM	FDA Regulatory Perspective and Expectations	Danae Christodoulou, FDA/OPQ/Office of New Drug Products
10:20 AM	**BREAK**	
10:40 AM	Implementation Challenges Related to LVPs and CCS	Tim Shelbourn, Eli Lilly (USP Elemental Impurities Expert Panel Member)
11:10 AM	Panel Discussion and Questions	Kahkashan Zaidi, USP; Tim Shelbourn, Eli Lilly; Danae Christodoulou, FDA; Douglas Ball, Pfizer; Edwin Jao, FDA
11:40 PM	**LUNCH**	
1:00 PM	Breakout Sessions	
2:30 PM	**BREAK**	
2:50 PM	Reconvene, Debrief and Discussion	
3:50 PM	Wrap-up and Adjourn	

Breakout Session Topics*

1. What challenges do you anticipate during implementation of Q3D and Pharmacopeial requirements?
2. What analytical testing and validation challenges do you anticipate?
3. Are Regulatory expectations clear? If not, what expectations need clarification?
4. Is the relationship between Control Threshold and expectations for specifications clear?
5. Have you had any experience establishing acceptable levels of elemental impurities for other routes of administration? What challenges do you anticipate establishing acceptable levels for other routes?

*Additional questions may be formulated based on panel discussions.