In Vitro Dissolution Profiles Similarity Assessment in Support of Drug Product Quality: What, How, and When

MAY 22, 2019

Day 2 Breakout Session D
1:40 – 3:30 PM

Session D1 (Group G4), Pharmacy Hall N314, Time 1:30-2:30 PM
Session D2 (Group G2), Pharmacy Hall N310, Time 2.30-3.30 PM

Day2 Breakout Session D (Group G2 and G4)

- How to Design a Robust Approach (e.g., Decision Tree) Beyond Statistical Considerations for the Assessment of Dissolution Profile Comparisons -- Part 2
  - Moderators: Poonam Delvadia (FDA), David Lavrich (Merck), Amy (Huizi) Zhang (GSK)
  - Scribes: Dave LeBlond (CMCStats), Michael Cohen (Pfizer), Gao Yi (AbbVie)

Session Background

- Discussion on
  - When to apply decision tree
  - Advantages and disadvantages of decision tree
  - Candidate methods and acceptance criterion(a)
  - Consideration of following elements in decision tree for dissolution similarity assessment:
    - Root cause of variability and control strategy
    - Risk assessment
    - Safe space

Question 1

- Under what situations the application of a decision tree would be helpful?

Question 2

- What are the advantages and disadvantages of having a decision tree?

Question 3

- What are the candidate methods for the decision tree?

Question 4

- What is the criterion(a) for the selection of dissolution similarity assessment method? (e.g., Variability, number of time points, number of appropriate lots)

Question 5

- Should the root cause of observed dissolution variability be considered in the decision tree? If the cause of variability is identified, could it be addressed (e.g., appropriate control strategy)?

Question 6

- Should risk assessment be employed when assessing two profiles and comparison outcome? For example, if dissolution similarity fails, is an in vivo BE study necessary? Can risk assessment be considered for further evaluation of the impact of dissolution similarity failure on in vivo performance of the drug product? How the application of risk assessment should be incorporated in the decision tree?

Question 7

- If the safe space is established, how the application of this could be included in the decision tree?

Action Day 2 BO Session D Q1

Group	Key points discussed (related to the Question)	Consensus or Agreement reached	Possible scenarios or options (if no consensus is reached)	Action items and responsible person(s)
G4				
G2				

Action Day 2 BO Session D Q2

Group	Key points discussed (related to the Question)	Consensus or Agreement reached	Possible scenarios or options (if no consensus is reached)	Action items and responsible person(s)
G4				
G2				

Action Day 2 BO Session D Q3

Group	Key points discussed (related to the Question)	Consensus or Agreement reached	Possible scenarios or options (if no consensus is reached)	Action items and responsible person(s)
G4				
G2				

Action Day 2 BO Session D Q4

Group	Key points discussed (related to the Question)	Consensus or Agreement reached	Possible scenarios or options (if no consensus is reached)	Action items and responsible person(s)
G4				
G2				

Action Day 2 BO Session D Q5

Group	Key points discussed (related to the Question)	Consensus or Agreement reached	Possible scenarios or options (if no consensus is reached)	Action items and responsible person(s)
G4				
G2				

Action Day 2 BO Session D Q6

Group	Key points discussed (related to the Question)	Consensus or Agreement reached	Possible scenarios or options (if no consensus is reached)	Action items and responsible person(s)
G4				
G2				

Action Day 2 BO Session D Q7

Group	Key points discussed (related to the Question)	Consensus or Agreement reached	Possible scenarios or options (if no consensus is reached)	Action items and responsible person(s)
G4				
G2				