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

MAY 22, 2019

**Breakout Session Day 2**

**Session B1, Pharmacy Hall (G2) N310; Time 1:30 – 3:30 PM**
**Session B2, Pharmacy Hall (G4) N314; Time 2:30 – 3:30 PM**

# Breakout Sessions B, Day 2

- Dissolution similarity assessment, requirements and global expectations?

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# Question 1

- **How should we interpret the USFDA guidance and Health Canada guidances for selecting time points for f2 calculation?**
  a) The Guidance for Industry -Dissolution Testing of Immediate Release Solid Oral Dosage Forms says "**only one measurement should be considered after 85% dissolution of both the products**."
  **b) Does it mean that both test and reference products should have one time point with 85% dissolution** included in the calculation?
  c) In contrast, **EMA** guidance is clear for this issue, which recommends **"not more than one mean value of > 85% dissolved for any of the formulations**."
  d) Should the definition **depend on the product/application**?

# Question 2

Which **guidance** should be followed for dissolution **profile comparisons**? Should a **new** global guidance e.g. ICH guidance be considered for best practices in dissolution similarity (e.g. number of sampling points, point after minimum %dissolved, % variability, frequency in sampling times for IR BCS 1/3 vs. BCS 2/4 vs. ER formulations?

# Question 3

Many similarities and differences for comparability criteria **across the regions** have been identified. Based on participants' experience, which **criteria can be standardized** and which must remain, and **why or why not** can those criteria be standardized?

# Question 4

What are the views **across regions** on **post-approval changes**, should it be **based on in-vivo** or **commercial manufacturing experienc**e of a product's dissolution profile space?

# Question 5

What are the scientific and regulatory rationale(s) for **switching from f2 to MSD** based on **intra-lot variability**? Doing so a**lters** the **definition of similarity**?

# Question 6

Is it scientifically appropriate for post-approval changes to be assessed against a **safe space** established based on dissolution **profiles of a range of pivotal clinical batches**?

# Action BO B2, Day 2, Q1

| 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) |
|---|---|---|---|
| Q1 | | | |

# Action BO B2, Day 2, Q2

| 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) |
|---|---|---|---|
| Q2 | | | |