Regulatory Education for Industry (REdI) and CERSI Workshop

Current State and Future Expectations of Translational Modeling Strategies to Support Drug Product Development, Manufacturing Changes and Controls

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College Park, MD

BREAKOUT SESSION A DAY 3:

The Road towards harmonization among regulatory agencies on evidentiary standards for PBBM

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Session Background

harmonization *is the process of minimizing redundant or conflicting standards which may have evolved independently. The concept borrows from the process to harmonize discordant music. The goal is to find commonalities, identify critical requirements that need to be retained, and provide a common standard.*

Key Points from BO Session C, Day 3, Question 1

To attain harmonization, a common and consistent understanding of the associated “risk” when implementing PBBM to support regulatory decision making is needed. Propose actions to supporting a stepwise approach to harmonization be taken with an initial focus on low risk items.

Key Points from BO Session C, Day 3, Question 2

In the current state, what challenges does industry/regulatory agencies face in the absence of harmonized requirements?

A. Does the absence of harmonization discourage development and utilization of PBBM?

B. Are there approaches that should be considered to increase confidence in this emerging field, promote harmonization, and reduce obstacles for the use of PBBM?

C. How do we want the landscape of PBBM to look like in the future?

Key Points from BO Session C, Day 3, Question 3

How can the scientific community (e.g., academics, industry, and regulatory agencies) converge to expand the utility of PBBM?

A. How effective is a position paper with authors from academics, industry and regulatory agencies towards convergence?

B. What are the recommended next steps to achieve a high-impact position paper?

Key Points from BO Session C, Day 3, Question 4

Describe the future state of regulatory application of PBBM. Must guidance be implemented or updated to allow flexibility for regulatory authorities to accept use of PBBM? In the absence of new/updated guidance, what paths are available?

Key Points from BO Session C, Day 3, Question 5

For model development, validation, and application identify fundamental areas of opportunity for harmonization between regulatory agencies.

	AREA NEEDING HARMONIZATION				
	Data Needed	Model Structure	Model Assumptions	Model Parameters	Other
MODEL DEVELOPMENT					

	AREA NEEDING HARMONIZATION				
	Data Needed	Acceptance Criteria	Other	Other	Other
MODEL VALIDATION					

	AREA NEEDING HARMONIZATION			
	Virtual BE Requirements	Safe Space (IVIVR/IVIVC) requirements	Other	Other
MODEL APPLICATION				

Overall Conclusions

SUMMARY of BREAKOUT DISCUSSION QUESTIONS