

Regulatory Update and Overview of BE and BA Testing with an Industry Perspective

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-
- Consultancy Services for Bioequivalence and Bioavailability Studies

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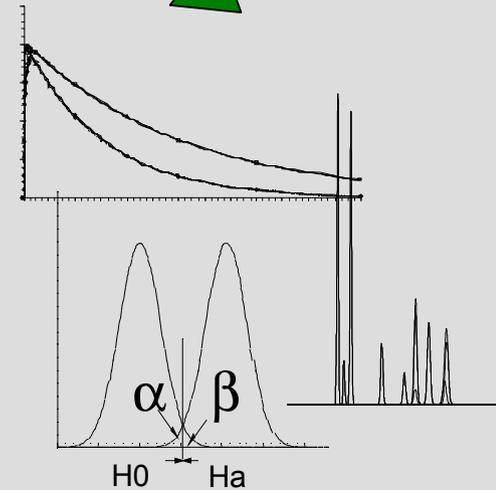
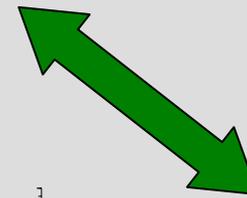
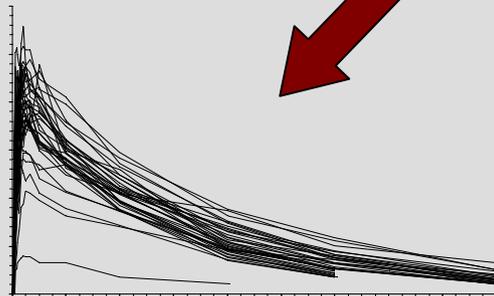
Whenever a theory appears to you as the only possible one, take this as a sign that you have neither understood the theory nor the problem which it was intended to solve.

Karl R. Popper

Even though it's *applied* science we're dealin' with, it still is – *science!*

Leslie Z. Bennet

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■ Overview of Dissolution for BA/BE

-  Biopharmaceutics Classification System based on Solubility/Permeability (Classes I-IV)
- Biowaivers for BCS I Drugs
- Discussion of BCS III Drugs
- Models establishing *in vivo-in vitro* Correlations (IVIVC Levels A-C)

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■ Bioavailability / Bioequivalence



- Selection of CROs
- Selection of a Reference Product
- Metrics (AUC, C_{max}/t_{max} , Shape of Profile)
- Acceptance Ranges (0.80 – 1.25 and beyond)
- Sample Size Planning (Literature References, Pilot Studies)

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■ **Bioavailability / Bioequivalence**

-  Steps in bioanalytical Validation (Validation Plan, Pre-Study Validation, In-Study Validation)
- Study Designs
- Protocol Issues
- Evaluation of Studies
- Advanced Topics
- Avoiding Pitfalls