Session 1 Summary

The Evolution of Biopharmaceutics: Risk Assessment and Clinical Relevance

Helena Engman, MSc, PhD
Senior Principal Scientist, ADME Sciences

April 30, 2026

Session 1 Summary

- Scientific foundation and Principles for the workshop and for future discussions:
  - Integrating dissolution data with in vivo understanding supports patient-centric quality and regulations

- Frameworks proposed by the FDA and Innovators & Generics Industry
  - Sets the stage for more science- and risk-based decision making
  - Going beyond categorical concepts

- Biopharmaceutics is about oral drug absorption: a complex, multi-step process
  - Absorption limitation must be characterized and understood as a continuum (not binary)
  - Level of evidence should be proportionate to level of risk, rather than standardised

Biopharmaceutics Risk Assessment in the Context of Quality Risk Management in Product Development

→ DEFINITIONS ARE IMPORTANT

HAZARD is Unacceptable / Inadequate clinical performance, **i.e., unacceptable bioavailability or non-bioequivalence**

→

RISK is the PROBABILITY of harm to occur and the MAGNITUDE of potential harm

→

Probability of harm depends on the inherent biopharmaceutics properties of the API which may limit the rate and extent of absorption, formulation/process factors along with PK/PD relationship

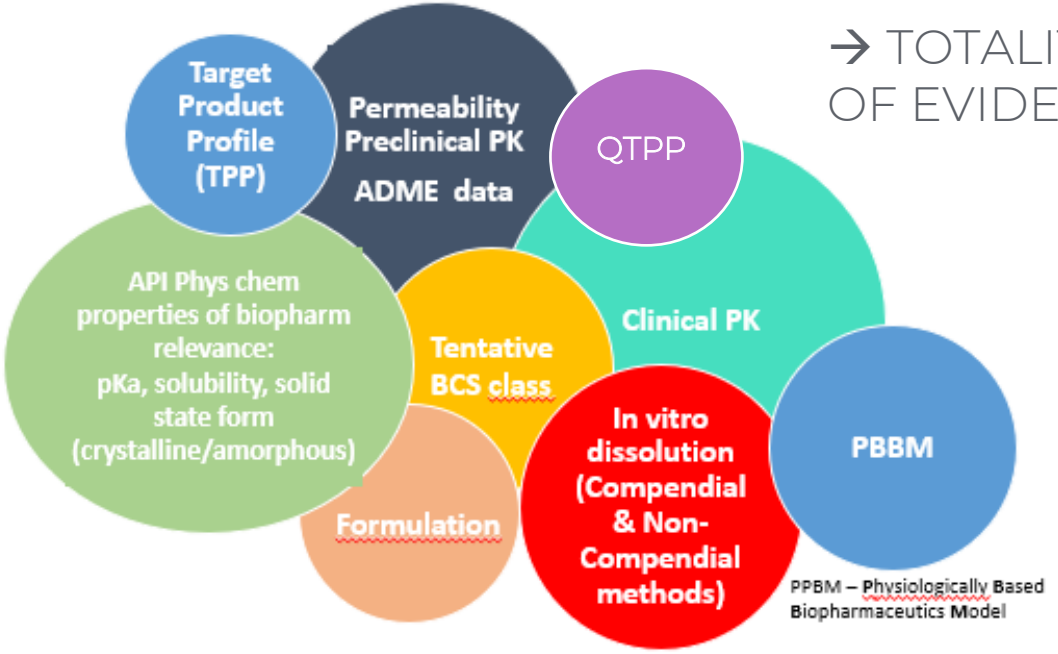
→

Magnitude depends on target disease, patient, PK/PD, etc.

→ ORIGIN in ICH Q8(R2) & ICH Q9(R1)

→ KEY: MECHANISTIC UNDERSTANDING

Very Low & Low Risk	BCS 1 & 3 drugs/ drug products showing high solubility in physiologically relevant media
Medium Risk	BCS 2 & 4, absorption limiting factors known - mechanistic understanding of in vitro dissolution as well as biopharm failure modes:
High Risk	BCS 2 & 4, absorption limiting factors not understood or difficult to detect



→ TOTALITY OF EVIDENCE

TIME FOR A BREAK!

Please be back on time for Session 2, High Risk Category

SEDA
Pharmaceutical Development Services