The Evolution of Biopharmaceutics: Risk Assessment and Clinical Relevance – Day 2 recap

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Day 2 recap

- Moved from risk-based reduction of unnecessary dissolution testing (Session 4) to a forward-looking paradigm where dissolution becomes a predictive, clinically anchored regulatory tool (Session 5)
- Breakouts focused on defining evidence standards for low- and very low-risk products (Breakout E) and strategizing implementation of advanced, risk-based control frameworks (Breakout F).

Day 2 Highlights

- Session 4: Low & Very Low Risk Products – What is needed and what is not
  - Discussed when dissolution was not clinically meaningful for low-risk products
  - Explored opportunities to waive or replace dissolution testing (e.g., disintegration)
  - Emphasized risk-based frameworks using API properties, formulation, and clinical relevance
  - Identified minimum data expectations to justify reduced testing
  - Reinforced aligning specifications with clinical performance rather than legacy QC norms
- Session 5: The Future of Dissolution –Beyond Quality Control
  - Framed dissolution as a predictive, clinically relevant tool rather than a QC check
  - Introduced clinically relevant dissolution specifications (CRDS) and “safe space” concepts
  - Highlighted integration of in vitro, in vivo, and modeling data (totality of evidence)
  - Discussed need for global harmonization of dissolution standards tied to biopharmaceutic risk
  - Positioned dissolution science as enabling regulatory flexibility and lifecycle efficiency

Breakout Sessions

- **Breakout Session E:** Defining Low- and Very Low-Risk Products in Biopharmaceutics - a Framework Based on Physicochemical and Clinical Evidence

- **Breakout Session F:** Strategizing the Future - Implementing Advanced, Risk-Based Control Frameworks

Breakout E – Defining Low- and Very Low-Risk Products in Biopharmaceutics: A Framework Based on Physicochemical and Clinical Evidence

- Discussed criteria for using disintegration in place of dissolution, focusing on when dissolution is not clinically meaningful
- Explored need for a practical framework to classify low vs. very low biopharm risk, beyond traditional BCS
- Emphasized that fit-for-purpose dissolution methods (if used) should demonstrate relevance to product performance
- Discussions on defining evidence needed to justify low-risk designation
- Identified global regulatory alignment as a key need for consistent application of reduced testing approaches

Breakout F – Strategizing the Future: Implementing Advanced, Risk-Based Control Frameworks

- Focused on defining the minimum evidence package needed to establish a clinically relevant dissolution “safe space”
- Explored how QC and clinically relevant (biopredictive) methods should coexist within a control strategy
- Discussed thresholds for decision-making evidence and how expectations scale with risk and lifecycle stage
- Examined barriers to implementation, including regulatory uncertainty and lack of harmonized expectations
- Identified priorities to accelerate progress: shared submission expectations, case examples, and cross-agency collaboration

Key Takeaways – Day 2

- Low-Risk Doesn’t Mean No Science - It Means Right-Sized Science
- Dissolution is Not Always Clinically Relevant
- Risk-Based Approaches Enable Flexibility - but Require Guardrails
- Clinical Relevance is Becoming the Anchor
- Modeling and Mechanistic Understanding are Central Enablers
- Evidence Packages Should Be Fit-for-Purpose
- Opportunity to Reduce Burden Without Compromising Quality
- Alignment Will Drive Implementation

Thank you !!

Merci · Gracias · Danke · Grazie · Obrigado

谢谢 · ありがとうございます · 감사합니다 · धन्यवाद

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Спасибо · Terima Kasih