The Future of Dissolution – An Industry Perspective

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M-CERSI - The Evolution of Biopharmaceutics: Risk Assessment and Clinical Relevance
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Agenda

01	The Future of Dissolution
02	Product Lifecycle
03	Wet Testing
04	Models
05	Control Strategy
06	Requirements

The Future of Dissolution is to evolve from a standalone QC test—to a strategic, model-informed tool for ensuring clinical performance and enabling flexible, efficient product lifecycle management.

Early Development

Formulation Performance

- Focus on formulation performance
- Wet testing for Learning and Understanding
- Models for Learnings and Insight
- Establishing the Scientific Basis for Control - CBAs

Late Development

Method Performance

- Focus on method performance
- Wet testing for Confirmation and Alignment
- Models for Optimization & Alignment
- Translating CBAs into a Clinically Justified Safe Space

Commercial

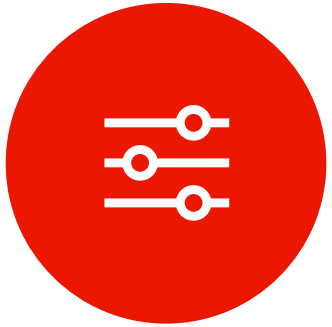
Product Performance

- Focus on product performance
- Wet testing for bridging and maintenance
- Models for Control and Decision Making
- Integrated control strategy ensures lifecycle flexibility and clinical performance

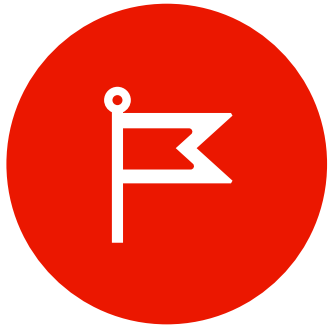
Wet Testing for Learning & Understanding

Early Development – Formulation Performance

Generic and platform specific methods and systems



Physiology based media and systems



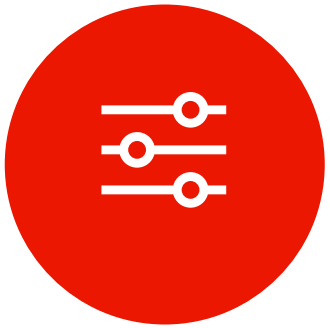
Characterization, learning, and identification of Critical Bioavailability Attributes (CBAs), not for control or release

Outputs inform design of clinically relevant methods, surrogate models, and control strategy

Wet Testing for Confirmation & Alignment

Late Development – Method Performance

Generic, platform specific, and product specific methods and systems



Combination of physiology based and clinically relevant parameters focused on CBAs

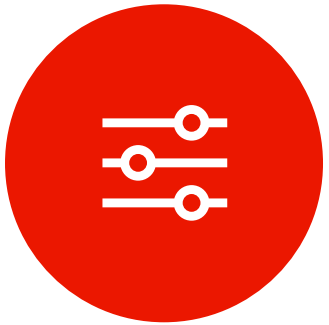
Confirm safe space boundaries and align wet method performance with PBDT/PBBM and surrogate model predictions

Outputs justify clinically relevant specifications and enable regulatory flexibility for post-approval changes

Wet Testing for Bridging & Maintenance

Commercial – Product Performance

Product specific clinically relevant methods and systems



Selected parameter combinations that best predicts in vivo performance

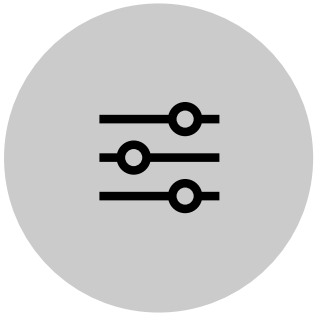
Bridge formulation, process, material, and packaging changes; investigate out-of-model predictions

Outputs maintains and extends the validated control strategy alongside PAT-fed surrogate models and RTRT

Models for Learning & Insight

Early Development – Formulation Performance

BASIC MECHANISTIC AND DATA-DRIVEN MODELS FOR DISSOLUTION AND ABSORPTION



FORMULATION COMPOSITION, PROCESS SETTINGS, API PROPERTIES (PKA, SOLUBILITY, SOLID STATE), PBDT DATA

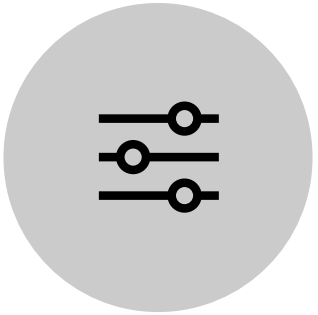
FORMULATION OPTIMIZATION, PROCESS UNDERSTANDING, AND SENSITIVITY ANALYSIS FOR CRITICAL BIOAVAILABILITY ATTRIBUTES (CBAS)

INFORM DESIGN OF CLINICALLY RELEVANT METHODS, SAFE SPACE EXPLORATION, AND STRUCTURE OF COMMERCIAL SURROGATE MODELS

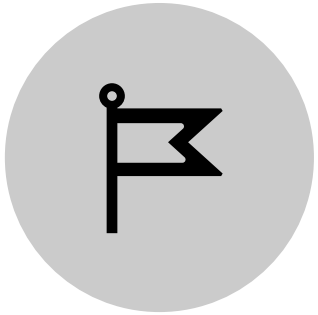
Models for Optimization & Alignment

Late Development – Method Performance

ADVANCED MECHANISTIC, DATA DRIVEN, AND HYBRID MODELS FOR DISSOLUTION AND ABSORPTION



PURPOSEFUL CBA-DRIVEN VARIABILITY, CLINICALLY RELEVANT WET DISSOLUTION DATA, AND PBDT DATA



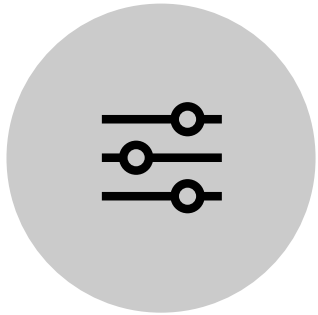
OPTIMIZE DISSOLUTION METHOD CONDITIONS, DEFINE SAFE SPACE BOUNDARIES, AND ALIGN METHOD–MODEL–SPECIFICATION FRAMEWORK

ENSURE ALIGNMENT BETWEEN METHOD PERFORMANCE, CLINICAL RELEVANCE, AND SPECIFICATION SETTING

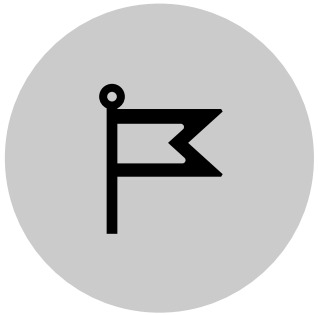
Models for Control & Decision Making

Commercial – Product Performance

VALIDATED SURROGATE DISSOLUTION AND ABSORPTION MODELS



PAT AND PROCESS DATA (E.G., NIR, API PSD, TABLET HARDNESS, PACKAGING, STORAGE CONDITIONS) AND PBDT DATA



PREDICT DISSOLUTION PERFORMANCE AT RELEASE AND ON STABILITY; ENSURE ONGOING COMPLIANCE WITH CLINICALLY JUSTIFIED SAFE SPACE

SUPPORT LIFECYCLE MANAGEMENT, AND FACILITATE CONFIDENT BRIDGING OF POST-APPROVAL CHANGES

Establishing the Scientific Basis for Control

Early Development – Formulation Performance

- Critical Bioavailability Attribute (CBA) identification as the scientific basis for control
- Integration of formulation, process, and material understanding with in vitro methods, system, and absorption sensitivity analysis
- Define what must be controlled to ensure clinical performance; deprioritize non-impactful attributes
- Inform purposeful variability design and safe space exploration

Translating CBAs into a Clinically Justified Safe Space

Late Development – Method Performance

- Purposeful CBA driven variability introduced to explore clinically relevant extremes
- Safe space establishment using PBDT/PBBM (including Virtual BE) and/or targeted in vivo studies
- Translate scientific understanding into clinically relevant discriminative method & model conditions, and acceptance criteria
- Enable calibration and validation of commercial integrated control strategy

Ensuring Clinical Performance Across the Lifecycle

Commercial – Product Performance

Surrogate models and PAT ensure the product remains within the clinically justified safe space at release and on stability

PAT-fed validated surrogate models and Real-Time Release Testing (RTRT)

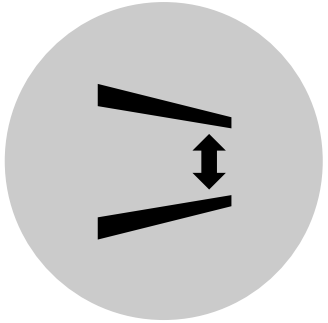
Ensure ongoing compliance with clinically relevant specifications at release and on stability

Support confident post-approval change management and lifecycle flexibility using targeted wet testing only when bridging significant change

Requirements

Global regulatory alignment

Biopharmaceutical risk assessment as the foundation for method and model development



Safe space as the basis for acceptance criteria and bridging changes

Surrogate methods and models to (partly) replace routine wet testing

Thank you

If you have more questions, please contact:
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