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

September 23-25, 2019

College Park, MD

BREAKOUT SESSION D DAY 3:

Strategies for bridging biorelevant and QC dissolution via PBBM

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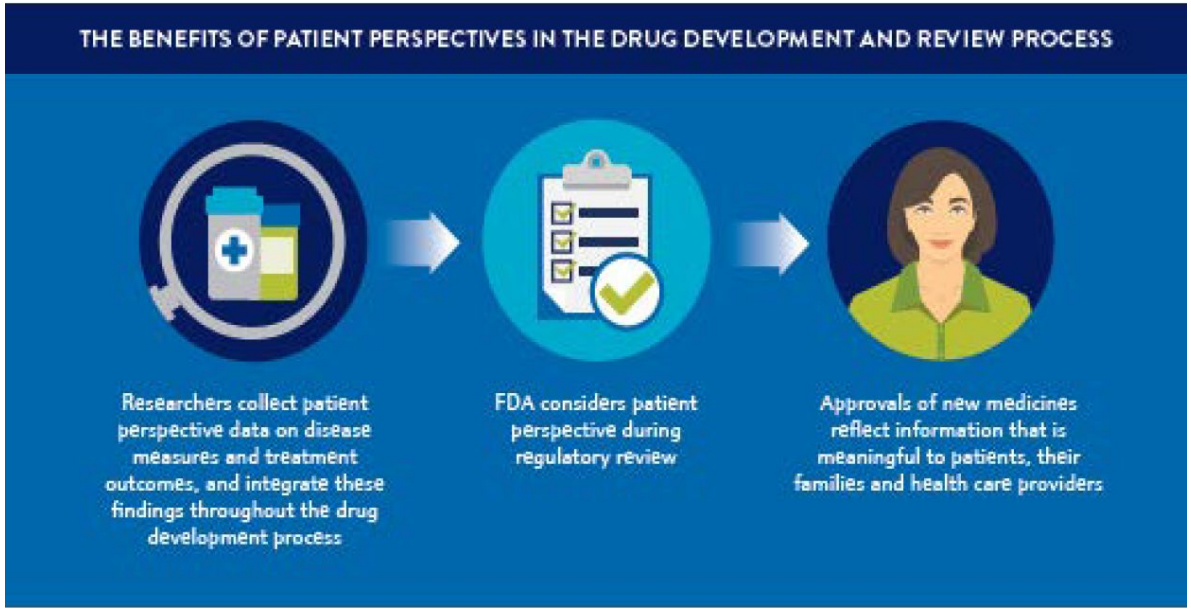
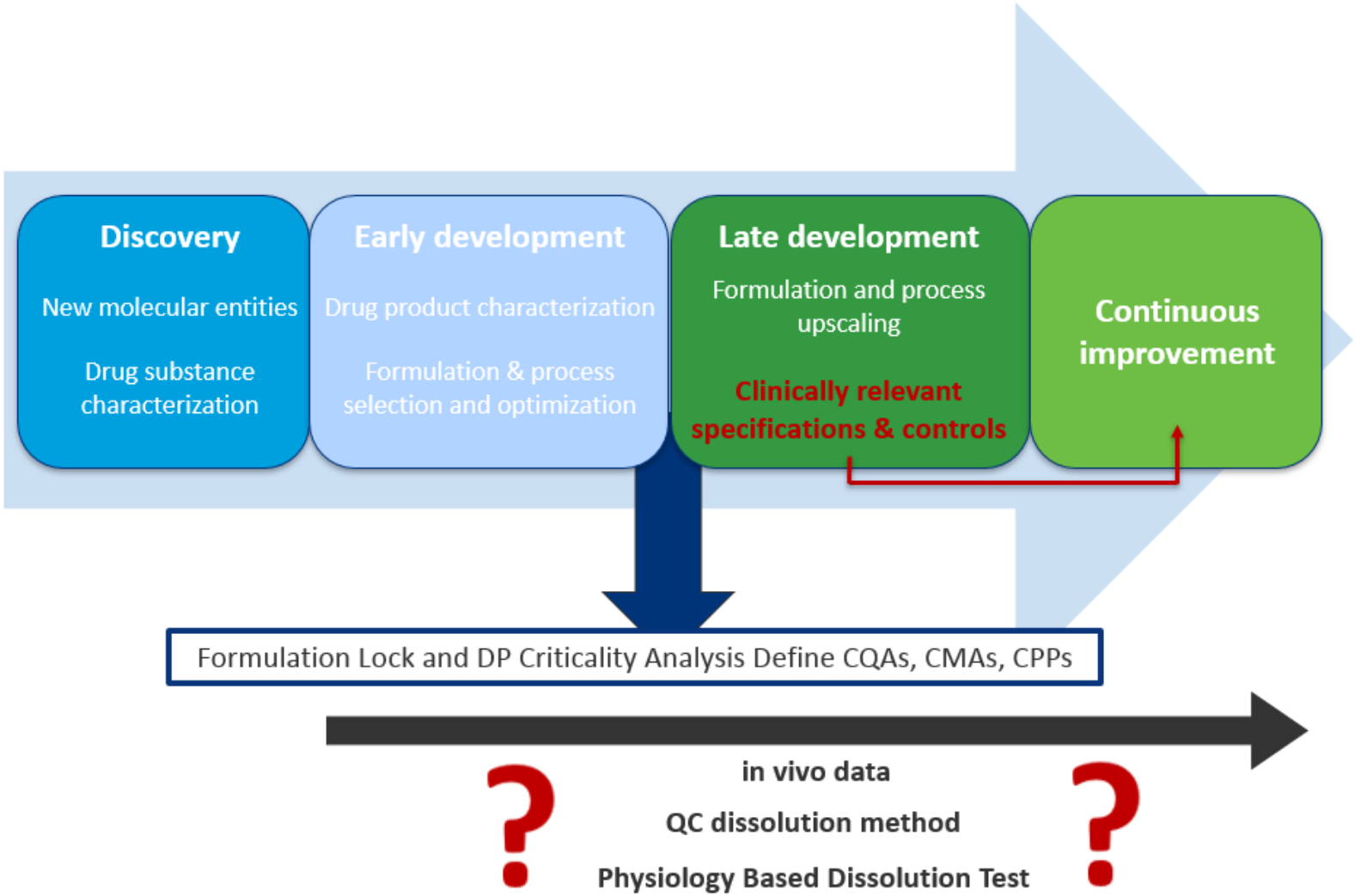
Why Clinically Relevant Drug Product Specifications?

Integral part of Patient-Centric Drug Product Development (PCDPD)

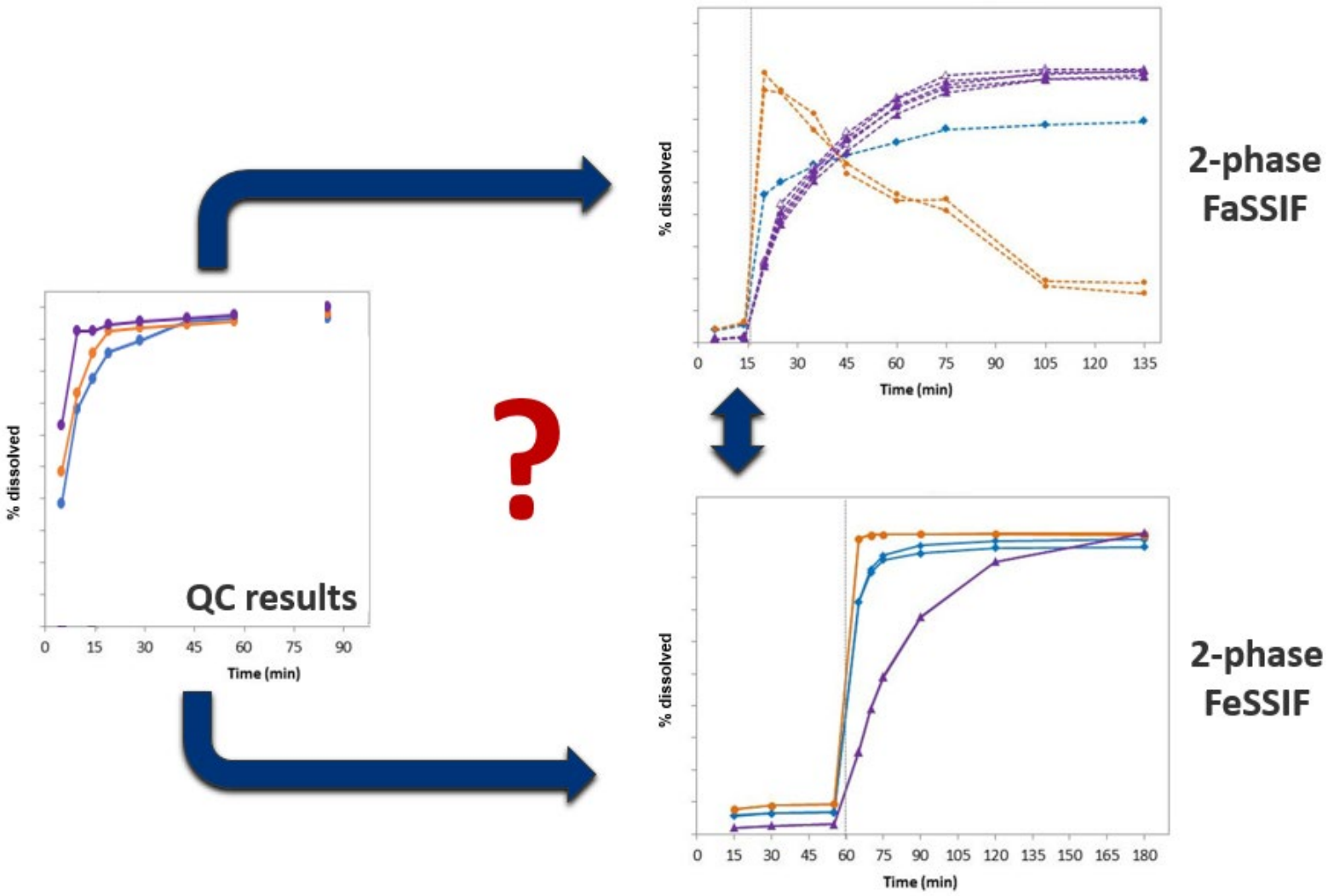
- Science- and risk-based drug product development
- Drug product specifications and control strategies that are clinically relevant



Biorelevant and/or QC dissolution
What? When? How?



How to bridge Biorelevant and/or QC dissolution?



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

Are biorelevant methods for low solubility and MR drug products always needed to increase the likelihood of developing clinically relevant dissolution methods and consequently, clinically relevant drug product specification (CRDPS)?

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

If and when they are, what is the feasibility for implementing these biorelevant methods (i.e, as QC) throughout the drug product life cycle? Does this mean 'replacing the QC method with biorelevant method'?

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

If feasibility is low (e.g., due to potential high cost), what are potential path(s) to bridge biorelevant and other simple/feasible methods? What data should be developed/collected for bridging?

- When (e.g., phase of development) these data should be collected? Is there a value in QC dissolution and /or Biorelevant dissolution and /or PBBM data being generated in earlier phases of development?
- Is there any possibility of collecting these data simultaneously (e.g., in parallel throughout relevant phases of development including phase 3)?
- Are there any situations when biorelevant & QC methods should not be bridged?

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

How can the data collected throughout phases of development be leveraged to construct PBBM to support bridging among dissolution methodologies?

- What specific dissolution data should be collected towards building PBBM for the purpose of bridging the dissolution methods?

Overall Conclusions