Current State and Future Expectations of Translational Modeling Strategies to Support Drug Product Development, Manufacturing Changes and Controls

REdI and CERSI Workshop

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Opinions expressed are personal and do not reflect those of the FDA

Pharmaceutical Quality

A quality product of any kind consistently meets the expectations of the user.

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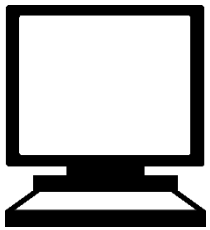


Drugs are no different.


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Patients expect safe and effective medicine with every dose they take.

Pharmaceutical quality is

assuring *every* dose is safe and effective, free of contamination and defects.


It is what gives patients confidence in their *next* dose of medicine.

Pharmaceutical Quality for the 21st Century: What are the Goals?

Patient-Centric Drug Product Development

----21st Century Cures and PDUFA VI

A maximally efficient, ag flexible pharmaceutica manufacturing sector th reliably produces high quality drugs without extensive regulatory oversight"

-----Janet Woodcock MD, Director, CDER FDA

Establishment of acceptance criteria for CQAs based on clinical relevance instead of process capability or manufacturing process control

---FDA Pharmaceutical Quality Oversight-One Quality Voice

Pharmaceutical Quality for the 21st Century: What are (some of) the Challenges?

The manufacture of more affordable drugs

"We're on an unsustainable path, where the cost of drug development is growing enormously, as well as the costs of the new medicines. We need to do something now, to make the entire *process less costly and more efficient"*

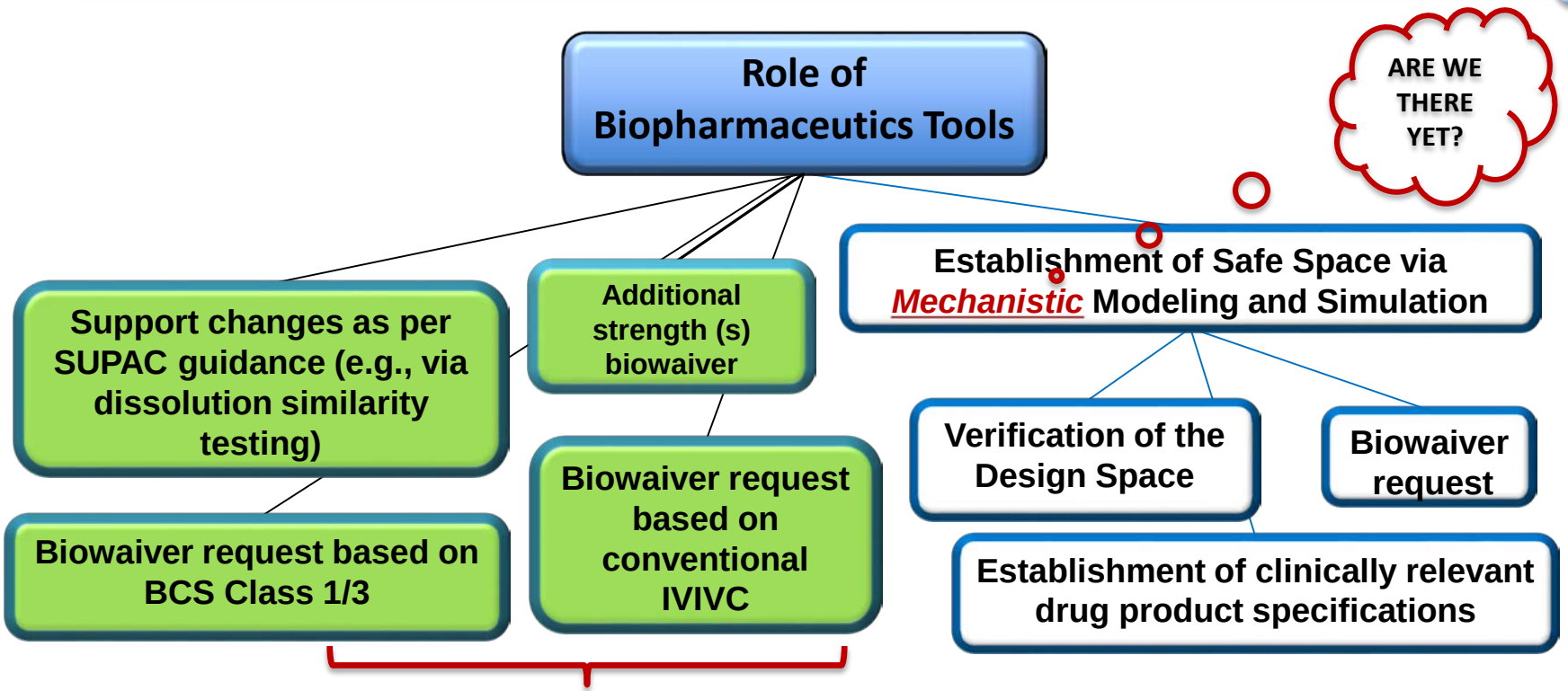
----Dr. Gottlieb's speech to the Regulatory Affairs Professionals Society (RAPS) 2017 Regulatory Conference

The development of efficient strategies to accelerate drug product development without compromising its Quality

The number of post-approval supplements has increased, in part owing to our current practice of "locking in" an applicant's manufacturing process before it is fully optimized leading to potential product recall and defect reporting.

---FDA Pharmaceutical Quality Oversight-One Quality Voice

Current Tools/Strategies: The Role of Biopharmaceutics in Support of Pharmaceutical Quality



Workshop Objectives and Deliverables

OBJECTIVES

1. Provide an opportunity for direct dialogue between Regulatory, Industry and Academic stakeholders to identify the gaps in knowledge and path for collaboration to move the field forward
2. Identify biopharmaceutics and modeling tools to facilitate formulation development and to enhance risk management of bio performance over the product's entire life cycle
3. Demonstrate the rewards and challenges of coupling biopredictive dissolution testing with translational PBPK

DELIVERABLES

1. Identify and list the gaps among in vitro studies, relevant in vivo studies, and current modeling tools (e.g. PBPK) including a discussion of their advantages and remaining challenges
2. Identify and list best practices for model development, verification/validation/Application
3. Identify the appropriate terminology (e.g., PBBM vs. PBAM)
4. Preparation of White Paper (s)

Workshop Themes

- **Day 1:** In Vitro Biopredictive Methods
- **Day 2:** Best Practices for Model Development, Verification and Validation
- **Day 3:** Application of PBBM to Support Drug Product Quality

Workshop Outline, cont.

- Each day will start with logistics, followed by podium presentations that will share current understanding and/ or provide examples of the issues
- We will have four breakout sessions in the afternoon discussing questions/topics developed by Faculty
- Each day concludes with a summary of the breakout discussions
  - Speakers, facilitators, and scribes will meet at the end of the day to capture major discussions, path forward, etc.

Members of Organizing Committee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