Second FDA/PQRI Conference on Advancing Product Quality: Opening Remarks

Lawrence X. Yu, Ph.D.

Deputy Director
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research
Food and Drug Administration

OFFICE OF PHARMACEUTICAL QUALITY

The AAPS Journal, Vol. 17, No. 4, July 2015 (© 2015)
DOI: 10.1208/s12248-015-9754-4

Meeting Report

Advancing Product Quality: a Summary of the Inaugural FDA/PQRI Conference

Lawrence X. Yu,[1,15] Jeffrey Baker,[1] Susan C. Berlam,[2] Ashley Boam,[1] E. J. Brandreth,[3] Lucinda Buhse,[1] Thomas Cosgrove,[1] David Doleski,[1] Lynne Ensor,[1] Joseph Famulare,[4] Mohan Ganapathy,[7] Gustavo Grampp,[5] David Hussong,[1] Robert Iser,[1] Gordon Johnston,[5] Filippos Kesisoglou,[6] Mansoor Khan,[1] Steven Kozlowski,[1] Emanuela Lacana,[1] Sau L. Lee,[1] Stephen Miller,[1] Sarah Pope Miksinski,[1] Christine M. V. Moore,[1] Theresa Mullin,[1] G. K. Raju,[8,9] Andre Raw,[1] Susan Rosencrance,[1] Mark Rosolowsky,[10] Paul Stinavage,[11] Hayden Thomas,[12] Russell Wesdyk,[1] Joerg Windisch,[13] and Sivakumar Vaithiyalingam[14]

Received 24 January 2015; accepted 16 March 2015; published online 4 April 2015

Abstract. On September 16 and 17, 2014, the Food and Drug Administration (FDA) and Product Quality Research Institute (PQRI) inaugurated their Conference on Evolving Product Quality. The Conference is conceived as an annual forum in which scientists from regulatory agencies, industry, and academia may exchange viewpoints and work together to advance pharmaceutical quality. This Conference Summary Report highlights key topics of this conference, including (1) risk-based approaches to pharmaceutical development, manufacturing, regulatory assessment, and post-approval changes; (2) FDA-proposed quality metrics for products, facilities, and quality management systems; (3) performance-based quality assessment and clinically relevant specifications; (4) recent developments and implementation of continuous manufacturing processes, question-based review, and European Medicines Agency (EMA)-FDA pilot for Quality-by-Design (QbD) applications; and (5) breakthrough therapies, biosimilars, and international harmonization, focusing on ICH M7 and Q3D guidelines. The second FDA/PQRI conference on advancing product quality is planned for October 5–7, 2015.

Quality Risk Management and Quality Metrics

- Quality risk management is formally documented in quality assessment of ANDAs, BLAs, and NDAs
- Quality Dashboard based on drug product risk mitigation is being developed as an approach to lifecycle and knowledge management
- FDA published the draft guidance on quality metrics, July, 2015
  - http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM455957.pdf

Performance-based Quality Assessment

- FDA published the draft guidance on dissolution testing of immediate release dosage forms containing BCS Class I and III drugs
  - http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM456594.pdf
- FDA published the draft guidance on established conditions, May, 2015
  - http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM448638.pdf

Innovation in Manufacturing and Assessment

- Continuous Manufacturing and Innovation
  - FDA published a review article
  - FDA approved the first continuous manufacturing application
  - FDA approved a 3D-printed tablet application
- FDA is developing a new quality assessment template (for both review and inspection) using Question-based Review principle

Emerging Regulatory Topics

- Breakthrough Therapeutics
  - FDA approved a total of 10 breakthrough therapeutic drugs and supplements
- Biosimilar
  - FDA approved the first biosimilar application
- FDA finalized the M7 guidance, May, 2015
  - Assessment and control of DNA reactive (mutagenic) impurities in pharmaceuticals to limit potential carcinogenic risk
- FDA published the final Q3D elemental impurity guidance, Sept, 2015

Program Overview, Day 1

MONDAY, OCTOBER 5, 2015				
8:00 AM Continental Breakfast – Salon E				
8:30 – 10:15 AM **Plenary Session – Salon D**				
10:15 -10:30 AM Coffee Break – Salon E				
	Emerging Regulatory Initiatives (White Oak A)	**Regulatory Submission, Assessment, and Inspection (Salon F)**	**Product and Process Development (White Oak B)**	**Manufacturing, Risk Management, and Quality Assurance (White Flint Amphitheater)**
10:30 – 12:15 PM	Biopharmaceutics – BCS Biowaivers	Breakthrough Therapy – CMC Challenges	Current Challenges in the Characterization of Complex Drug Formulations Containing Nanomaterials	How to Prevent, Detect, and Respond to Data Integrity Events
12:15 – 1:15 PM Lunch – Salon E				
1:15 – 3:00 PM	Pharmaceutical Product Lifecycle Management – Q12	Pre-Approval and Surveillance Inspection	Biosimilar Product Assessment – How Similar is Similar?	Continuous Manufacturing
3:00 – 3:15 PM Coffee Break – Salon E				
3:15 – 5:00 PM	Pharmaceutical Product Lifecycle Management – Q12 (cont.)	Pre-Approval and Surveillance Inspection (cont.)	Biosimilar Product Assessment – How Similar is Similar? (cont.)	Continuous Manufacturing (cont.)
5:30 – 7:00 PM Reception – Foyer (outside Salon A-C)				

Program Overview, Day 2

TUESDAY, OCTOBER 6, 2015				
8:00 AM Continental Breakfast – Salon E				
	Emerging Regulatory Initiatives (White Oak A)	**Regulatory Submission, Assessment, and Inspection (Salon F)**	**Product and Process Development (White Oak B)**	**Manufacturing, Risk Management, and Quality Assurance (White Flint Amphitheater)**
8:30 – 10:15 AM	Dissolution Testing and Specification for BCS I and III Drugs in Immediate Release Products	Risk-based Regulatory Assessment	Palatability and Swallowability-Benefits of Transdisciplinary Learning	How to Monitor, Control, and Improve Product Quality using Process Capability
10:15 AM – 10:30 AM Coffee Break – Salon E				
10:30 – 12:15 PM	Dissolution Testing and Specification for Extended Release Products	How Quality Risk Management can Enable a More Effective Pharmaceutical Quality System Resulting in Improved Product Quality	Alternatives for Content Uniformity Acceptance Criteria and Stratified Sampling	How to Monitor, Control, and Improve Product Quality using Process Capability (cont.)
12:15 – 1:15 PM Lunch – Salon E				
1:15 – 3:00 PM	Quality Metrics	FDA Integrated Quality Assessment: Common Deficiencies/Information Request	The Science of Tech Transfer/Scale-up	How to Identify Critical Quality Attributes and Critical Process Parameters
3:00 – 3:15 PM Coffee Break – Salon E				
3:15 – 5:00 PM	Botanical Drug Development and Quality Standards	FDA Integrated Quality Assessment: Common Deficiencies/Information Request (cont.)	The Science of Tech Transfer/Scale-up (cont.)	How to Identify Critical Quality Attributes and Critical Process Parameters (cont.)
5:00 – 6:30 PM	How to Interact and Communicate with FDA on Quality Issues			

Program Overview, Day 3

Wednesday, October 7, 2015
8:30 – 10:15 AM **Breakout Summaries –** Salon E
10:15 – 10:30 AM Coffee Break – Salon E
10:30 – 11:30 AM **Roundtable with FDA Leaders –** Salon E
11:30 AM **Closing Remarks**

Organizing Committee

- Lawrence Yu, *Food & Drug Administration (Chair)*
- Gregory Amidon, *University of Michigan*
- Margaret Caulk, *Food & Drug Administration*
- Dave Doleski, *Food & Drug Administration*
- Joseph Famulare, *Genentech*
- Don Henry, *Food & Drug Administration*
- Ajaz S. Hussain, *NIPTE*
- Robert Iser, *Food & Drug Administration*
- Rob Ju, *AbbVie*
- Emanuela Lacana, *Food & Drug Administration*
- Tandra Latham, *Food & Drug Administration*
- Lisa Matthews, *Food & Drug Administration*
- Ganapathy Mohan, *Merck*
- Moheb Nasr, *GlaxoSmithKline*
- Cecily Nelson, *Food & Drug Administration*
- Roger Nosal, *Pfizer*
- Suzanne Pattee, *Food & Drug Administration*
- Kristin Phucas, *Food & Drug Administration*
- James Polli, *University of Maryland*
- GK Raju, *Light Pharma*
- Arzu Selen, *Food & Drug Administration*
- Vinod Shah, *Pharmaceutical Consultant*
- John Skoug, *AbbVie*
- Margaret Szymczak, *Johnson & Johnson*
- Lisa Tan, *GPhA*
- Tony Tong, *Teva*
- Katherine Tyner, *Food & Drug Administration*
- Martin VanTrieste, *Amgen*
- Russell Wesdyk, *Food & Drug Administration*
- Geoffrey Wu, *Food & Drug Administration*
- Larisa Wu, *Food & Drug Administration*
- Louis Yu, *Perrigo*