Activity Outline
2019 Pharmaceutical Quality Symposium
October 16 - 17, 2019
The Hotel at the University of Maryland College Park 777 Baltimore Ave, College Park, MD 20740

Activity Coordinator
Lisa Misevicz
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Description

Participants will learn about emerging technologies in pharmaceutical design and manufacturing, biologics to include biosimilars & transition products, facility issues impacting application approval, and facilities issues beyond application approval.

References

- The Future of Pharmaceutical Quality: https://www.sciencedirect.com/science/article/pii/S0378517317305471
- The State of Pharmaceutical Quality Report: https://www.fda.gov/media/125001/download
- 2018 OPQ Annual Report: https://www.fda.gov/media/120781/download

Learning Objectives

- Define the term “pharmaceutical quality.”
- Recognize the impact of pharmaceutical quality on drug safety and effectiveness.
- Describe how the FDA addresses pharmaceutical quality over the lifecycle of a drug product.
- Evaluate how to address pharmaceutical quality in regulatory submissions and at manufacturing facilities.
- Predict effective ways to interact with the FDA related to pharmaceutical quality.

Target Audience
This activity is intended for physicians, pharmacists, and nurses.

Agenda
Day 1 October 16, 2019

Time	Topic	Speaker
8:15 - 8:30 AM	Overview	Brenda Stodart, PharmD, BCGP, RAC-US
8:30 - 8:45 AM	Keynote from the Center for Drug Evaluation and Research (CDER)	Patrizia Cavazzoni, MD
8:45 - 9:00 AM	Keynote from the Office of Pharmaceutical Quality (OPQ)	Michael Kopcha, PhD, R. Ph
9:00 - 9:25 AM	The Quality Assessment of Different Application Types	Lawrence Yu, PhD
9:25 - 9:50 AM	Application Manufacturing Assessment	Mahesh Ramanadham, PharmD, MBA
9:50 - 10:10 AM	Policy Initiatives for Pharmaceutical Quality	Ashley Boam, MSBE
10:10 - 10:35 AM	Panel Discussion	Lawrence Yu, PhD Mahesh Ramanadham, PharmD, MBA Ashley Boam, MSBE
10:35 - 10:50 AM	*Break*	
10:50 - 11:15 AM	How Does FDA Execute Preapproval and Postapproval Inspections?	Rahki Shah, PhD
11:15 - 11:40 AM	Integration of Assessment and Inspection: Small Molecule Case Studies	ALLISON ALDRIDGE, Ph.D.
11:40 - 12:05 PM	Integration of Assessment and Inspection: Biological Products Case Studies	Candace Gomez-Broughton, PhD

12:05 - 12:30 PM	Panel Discussion	Rahki Shah, PhD ALLISON ALDRIDGE, Ph.D. Candace Gomez-Broughton, PhD
12:30 - 1:45 PM	*Lunch*	
1:45 - 2:10 PM	The Future of FDA's Quality Assessment and Knowledge Management	GEOFFREY WU, PhD
2:10 - 2:30 PM	Postapproval Change Management: ICH Q12 and Established Conditions	Bhagwant Rege
2:30 - 3:00 PM	Panel Discussion	GEOFFREY WU, PhD Bhagwant Rege
3:00 - 3:15 PM	*Break*	
3:15 - 3:35 PM	Pharmaceutical Quality Surveillance Program	Cindy Buhse, PhD
3:35 - 3:55 PM	Quality-Related Enforcement Actions and Trends	Francis Godwin
3:55 - 4:10 PM	The Importance of Quality Metrics and Quality Culture	Alex Viehmann Tara Gooen, M.BSci.
4:10 - 4:30 PM	Panel Discussion	Cindy Buhse, PhD Alex Viehmann Tara Gooen, M.BSci.

Day 2 October 17, 2019

Time	**Topic**	**Speaker**
8:15 - 8:25 AM	Day 2 Overview	Forest Ford
8:25 - 8:40 AM	Interacting with CDER's Emerging Technology Program	Sau Lee, PhD
8:40 - 9:00 AM	Policy Considerations for Continuous Manufacturing	Tara Gooen, M.BSci. Rapti Madurawe *Not offered for CE*
9:00 - 9:20 AM	Continuous Manufacturing of Drug Product: Case Studies	ARWA ELHAGRASY, PhD
9:20 - 9:40 AM	Continuous Manufacturing of Drug Substance: Case Studies	Vani Mathur Richards, MS
9:40 - 10:10 AM	Panel Discussion	Sau Lee, PhD Rapti Madurawe ARWA ELHAGRASY, PhD Vani Mathur Richards, MS *Not offered for CE*
10:10 - 10:25 AM	*Break*	
10:25 - 10:45 AM	Emerging Technologies for Biologics: Multi-Attribute Method	Sarah Rogstad, PhD
10:45 - 11:05 AM	FDA Research Supporting Emerging Technologies with Case Studies	Thomas OConnor, PhD
11:05 - 11:25 AM	Extramural Research Supporting Emerging Technologies	Salvatore Mascia, PhD *Not offered for CE*
11:25 - 11:45 AM	Panel Discussion	Sau Lee, PhD Sarah Rogstad, PhD Thomas OConnor, PhD Salvatore Mascia, PhD *Not offered for CE*
11:45 - 1:00 PM	*Lunch*	
1:00 - 1:30 PM	FDA's Biosimilars Program	Eva Temkin, JD
1:30 - 1:55 PM	Biosimilars Manufacturing Issues with Case Studies	Rachel Novak, PhD
1:55 - 2:20 PM	Data Quality Expectations for Biosimilars with Case Studies	Merry Christie, PhD

2:20 - 2:50 PM	Panel Discussion	Merry Christie, PhD Rachel Novak, PhD
2:50 - 3:05 PM	*Break*	
3:05 - 3:25 PM	The “Deemed to be a License” Provision of the BPCI Act	Janice Weiner, JD, MPH
3:25 - 3:45 PM	Quality Considerations for Transition Biological Products	Leslie Rivera-Rosado, PhD
3:45 - 4:05 PM	Panel Discussion	Susan Kirshner, PhD Janice Weiner, JD, MPH Leslie Rivera-Rosado, PhD

Continuing Education Accreditation

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In support of improving patient care, FDA Center for Drug Evaluation and Research is jointly accredited by the Accreditation Council for Continuing Medical Education (ACCME), the Accreditation Council for Pharmacy Education (ACPE), and the American Nurses Credentialing Center (ANCC) to provide continuing education for the healthcare team.

IPCE CREDIT™

This activity was planned by and for the healthcare team, and learners will receive 11.00 Interprofessional Continuing Education (IPCE) credit(s) for learning and change.

CME

FDA Center for Drug Evaluation and Research designates this live activity for a maximum of 11.00 *AMA PRA Category 1 Credit(s)*™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

CPE

This knowledge-based activity has been assigned ACPE Universal Activity Number JA0002895-0000-19-081-L04-P for 11.00 contact hour(s).

CNE

FDA Center for Drug Evaluation and Research designates this activity for 11.00 contact hour(s).

Requirements for Receiving CE Credit

Physicians, pharmacists, nurses, and those claiming non-physician CME: participants must attest to their attendance and complete the final activity evaluation via the CE Portal (ceportal.fda.gov). For multi-day activities, participants must attest to their attendance and complete the faculty evaluation each day. Final activity evaluations must be completed within two weeks after the activity - no exceptions.

Pharmacists will need their NABP e-profile ID number as well as their DOB in MMDD format in order to claim CE credit.

Important Note regarding completion of evaluations and receiving credit
Attendees have 14 days from the last day of the activity to log in, complete the required evaluation(s) and attest to your attendance to claim credit.Physicians and nurses may then view/print statement of credit. Pharmacists should log into the CPE monitor 10 weeks after the last session of the activity to obtain their CE credit.

Disclosure

Faculty

- ALDRIDGE, ALLISON, Ph.D., Consumer Safety Officer, OPQ/OPF/DIA - nothing to disclose
- Boam, Ashley, MSBE, Director, CDER/OPQ/OPPQ - nothing to disclose

- Buhse, Cindy, PhD, Director, FDA/CDER/OPQ/OS - nothing to disclose
- Cavazzoni, Patrizia, MD, Deputy director for operations at the Center for Drug Evaluation and Research (CDER) at the Food and, FDA - nothing to disclose
- Christie, Merry, PhD, Chemist Leader, FDA/CDER/OPQ/OBP - nothing to disclose
- ELHAGRASY, ARWA, PhD, Chemist/Quality Assessment Lead (Acting), FDA/CDER/OPQ/OPF - nothing to disclose
- Ford, Forest, CSO, FDA - nothing to disclose
- Godwin, Francis, Office Director (Acting), FDA - nothing to disclose
- Gomez-Broughton, Candace, PhD, Microbiologist, FDA - nothing to disclose
- Gooen, Tara, M.BSci., Senior Science Policy Advisor, FDA/CDER/OPQ - nothing to disclose
- Kirshner, Susan, PhD, Review Chief, CDER/OPQ/OBP - nothing to disclose
- Kopcha, Michael, PhD, R. Ph, Director, Office of Pharmaceutical Quality, CDER - nothing to disclose
- Lee, Sau, PhD, Director, OTR/OPQ/CDER - nothing to disclose
- Madurawe, Rapti *Disclosure not received.*
- Mascia, Salvatore, PhD, CEO, CONTINUUS Pharmaceuticals, Inc. *I received Salary from CONTINUUS Pharmaceuticals for a role as Employee. I received Stocks from CONTINUUS Pharmaceuticals for a role as Board Member.*
- Novak, Rachel, PhD, Supervisory Biologist, Food and Drug Administration - nothing to disclose
- OConnor, Thomas, PhD, Chemist, CDER/OPQ/OTR/DPQR - nothing to disclose
- Ramanadham, Mahesh, PharmD, MBA, Senior Science and Policy Advisor (acting), FDA/CDER/OPQ/OPF - nothing to disclose
- Rege, Bhagwant, Division Director, FDA - nothing to disclose
- Richards, Vani Mathur, MS, Senior Manufacturing Assessor, FDA/CDER/OPQ/OPF - nothing to disclose
- Rivera-Rosado, Leslie, PhD, Product Quality Team Leader, FDA/CDER/OPQ - nothing to disclose
- Rogstad, Sarah, PhD, Chemist, US FDA - nothing to disclose
- Shah, Rahki, PhD, Branch chief, FDA - nothing to disclose
- Stodart, Brenda, PharmD, BCGP, RAC-US, Program Director, FDA - nothing to disclose
- Temkin, Eva, JD, Acting Deputy Director for Policy, CDER/OND/TBBS - nothing to disclose
- Viehmann, Alex, Branch Chief, FDA/CDER/OPQ/OS - nothing to disclose
- WU, GEOFFREY, PhD, Associate Director, CDER/OPQ/OLDP - nothing to disclose
- Weiner, Janice, JD, MPH, Senior Regulatory Counsel, FDA/CDER/Office of Regulatory Policy - nothing to disclose
- Yu, Lawrence, PhD, Deputy Director, Office of Pharmaceutical Quality - nothing to disclose

Planning Committee

- Giroux, Virginia, MSN, FNP-BC, Associate Director for Accreditation, FDA/CDER/OEP/DLOD - nothing to disclose
- Kozlowski, Steven, MD, Director, Office of Biotechnology Products, OPQ, Office of Pharmaceutical Quality, CDER,FDA - nothing to disclose
- Stodart, Brenda, PharmD, BCGP, RAC-US, Program Director, FDA - nothing to disclose

CE Consultation and Accreditation Team

- Miller, Isaac J., CE Consultant, FDA/CDER/OEP/DLOD - nothing to disclose
- Giroux, Virginia, MSN, FNP-BC, Associate Director for Accreditation, FDA/CDER/OEP/DLOD - nothing to disclose
- Zawalick, Karen, CE Team Leader, FDA/CDER/OEP/DLOD - nothing to disclose

Registration Fee and Refunds
Registration is complimentary, therefore refunds are not applicable.

Requirements for Certificate of Completion (Non CE)
Must attend 85% of the activity.