Activity Outline
Topics in Public Health: Clinical Relevance of Product Quality and Drug Manufacturing
March 20, 2020
Webinar

Activity Coordinator:
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Series Description

This series will educate PHS health professionals about topics that are pertinent to their roles within the various agencies within the Department of Health and Human Services and other Public Health Service agencies by presenting topics that directly relate to the HHS Strategic Plan, the Secretary's Strategic Initiatives, current topics for DHHS OPDIVs who utilize PHS health professionals, and/or other topics directly related to the advancement of public health.

Lecture Description
Describe the foundational impact of product quality and drug manufacturing to assure clinical performance (safety/efficacy) of a drug, including how FDA assesses how drugs are made to consistently perform as expected.

References

- 21 U.S.C. § 501 and § 505
- 21 C.F.R. § 314 and § 211
- U.S. Food and Drug Administration. Compliance Program Guidance Manual 7346.832. Pre-approval inspections/Investigations, Silver Spring (MD): 2019. Available from: https://www.fda.gov/media/121512/download

Series Objectives

- Describe scientific evidence supporting the HHS Initiatives, Surgeon General Priorities or any other public health concern
- Explain the multi-disciplinary approach in addressing public health issues
- Identify public health concerns.
- Identify ways Public Health Professionals can impact public health issues.

Learning Objectives After completion of this activity, the participant will be able to:

- Recall the foundational impact of drug quality to assure the clinical performance (safety/efficacy) of the drug.
- Recognize the process for how FDA assesses how drugs are made to ensure consistent performance.

Target Audience
This activity is intended for physicians, pharmacists, nurses, and other public health medical professionals interested in learning more about the initiatives other advances in public health.

Agenda

Lecture 1 March 20, 2020

Time	Topic	Speaker
2:00 - 3:00 PM	Clinical Relevance of Product Quality and Drug Manufacturing	Mahesh Ramanadham, PharmD, MBA

Continuing Education Accreditation

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INTERPROFESSIONAL CONTINUING EDUCATION

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.

This activity was planned by and for the healthcare team, and learners will receive 1 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 1.00 *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 JA0002895-0000-20-009-L04-P, and ACPE Universal Activity Number JA0002895-0000-20-009-L04-T for 1.00 contact hour(s).

CNE

FDA Center for Drug Evaluation and Research designates this activity for 1.00 contact hour(s).

CPH

Up to 1.00 CPH Recertification Credits may be earned at this event.

Requirements for Receiving CE Credit

Physicians, pharmacists, nurses, pharmacist techs, 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

- Ramanadham, Mahesh, PharmD, MBA, Senior Science and Policy Advisor (acting), FDA/CDER/OPQ/OPMA - nothing to disclose

Planning Committee

- Birch-Smith, Postelle, PharmD - nothing to disclose
- Brodhead, LeAnn, PharmD, Health Insurance Specialist, CMS - nothing to disclose
- CHIN, EDWARD, Medical Officer, DNDP - nothing to disclose
- Chan, Vicky, Team Leader, FDA - nothing to disclose
- Janusziewicz, Ashlee, Pharm.D, Compounding Incidents Team Leader, FDA/CDER/OC/OUDLC - nothing to disclose
- La, Thang, PharmD, MPH, Central Triage Unit Manager, FDA/CDER/OSE/RSS - nothing to disclose
- Lal, Renu, Pharm.D., Pharmacist, FDA - nothing to disclose
- Lucero, Karly, RN, DNP, MSN/eD, CCHP, Regional Field Medical Coordinator, DHS - nothing to disclose
- McClain, Rena, PharmD, CMS - nothing to disclose
- Nabavian, Sadaf, Senior Regulatory Project Manager, FDA - nothing to disclose
- Ramanadham, Amy, Senior Regulatory Research Officer, U.S. Food and Drug Administration - nothing to disclose

CE Consultation and Accreditation Team

- Bryant, Traci, M.A.T., CE Consultant, 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.