

Activity Outline
FDA Drug Topics: An Overview of Pharmacovigilance in the Center for Drug Evaluation and Research (CDER)
March 26, 2019
FDA

Activity Coordinator
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Series Description

This series of educational webinars is designed to aid physicians, physician assistants, nurses, pharmacists, pharmacy technicians, students, and other healthcare professionals, to provide better patient care by knowing how to find relevant FDA regulatory information that will improve drug safety.

Lecture Description

This webinar will give an overview of how the FDA conducts pharmacovigilance activities, detect safety signals, and communicates safety findings.

References

- World Health Organization. The Importance of Pharmacovigilance: Safety Monitoring of medicinal products. (2002). Available at: <http://apps.who.int/medicinedocs/pdf/s4893e/s4893e.pdf?ua=1>. Accessed March 8, 2018.
- Textbook of Pharmacoepidemiology 5th edition. Edited by Brian Storm
- Federal Register - Code of Federal Regulations. 21 CFR 314.80 (a); U.S. Food and Drug Administration. FDA Adverse Event Reporting System (FAERS) Public Dashboard. Available at: <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/ucm070093.htm>
- U.S. Food and Drug Administration. MedWatch: The FDA Safety Information and Adverse Event Reporting Program. Available at: <https://www.fda.gov/Safety/MedWatch/default.htm>
- U.S. Food and Drug Administration. MedWatch Consumer Voluntary Reporting (FORM FDA 3500B). Available at: <https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM349464.pdf>
- U.S. Food and Drug Administration. Biosimilar Product Information. Available at: <https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm580432.htm>

Series Objectives

- Explain how to utilize FDA's Drug Information, medication safety resources, and regulatory guidances to improve delivery of patient care and optimize outcomes.
- Describe and inform health care providers of recent labeling, policy and regulatory changes which would impact prescribing and medication management to optimize patient care.

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

- Define pharmacovigilance
- Describe the Division of Pharmacovigilance's (DPV's) key safety roles in FDA's Center for Drug Evaluation and Research (CDER)
- Explain components of postmarketing drug safety surveillance
- Describe the role of MedWatch for reporting postmarketing safety information
- Discuss how adverse event reports are collected and analyzed by FDA/CDER/DPV

Target Audience

This activity is intended for physicians, pharmacists, pharmacy technicians, nurses, and students other healthcare professionals.

Agenda

Lecture 1 March 26, 2019

Time	Topic	Speaker
1:00 - 2:00 PM	An Overview of Pharmacovigilance in the Center for Drug Evaluation and Research (CDER)	kim swank, PharmD

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 1.00 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 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 JA0002895-0000-19-020-L04-P, and ACPE Universal Activity Number JA0002895-0000-19-020-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).

AAPA



This activity is designated for 1.00 AAPA Category 1 CME credits. FDA Center for Drug Evaluation and Research has been authorized by the American Academy of PAs (AAPA) to award AAPA Category 1 CME credit for activities planned in accordance with AAPA CME Criteria. PAs should only claim credit commensurate with the extent of their participation.

CPH

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

Requirements for Receiving CE Credit

Physicians, physician assistants, 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, physician assistants, 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

- swank, kim, PharmD, pharmacist, FDA *May reference off-label use.*

Planning Committee

- Burke, Kara, PharmD, Team Leader/Pharmacist, FDA/CDER/OCOMM/DDI - nothing to disclose
- Cao, Christian, MPAS, PA-C, Safety Evaluator Team Leader, FDA/CDER/OSE/DPV - nothing to disclose
- DeFronzo, Kimberly, RPh, MS, MBA, Consumer Safety Officer, FDA/CDER/OCOMM/DDI - nothing to disclose
- Giroux, Virginia, MSN, FNP-BC, Associate Director for Accreditation, FDA/CDER/OEP/DL0D - nothing to disclose
- Navin, Lesley, RN, MSN, Consumer Safety Officer, FDA/CDER/DDI - nothing to disclose
- Weinstein, Edward, M.D., Ph.D., Medical Officer, CDER FDA *My spouse received Salary from EndoCentre of Baltimore for a role as Employee.*

CE Consultation and Accreditation Team

- Lisa Thompson, MSHA, MBA, CE Consultant, FDA/CDER/OEP/DL0D - nothing to disclose
- Giroux, Virginia, MSN, FNP-BC, Associate Director for Accreditation, FDA/CDER/OEP/DL0D - nothing to disclose
- Zawalick, Karen, CE Team Leader, FDA/CDER/OEP/DL0D - nothing to disclose

Registration Fee and Refunds

Registration is complimentary, therefore refunds are not applicable.