Activity Outline
CDER Small Business and Industry Assistance 1-Hour Webinar Series: Electronic Submission of Adverse Event Reports to FDA Adverse Event Reporting System (FAERS) using International Council for Harmonisation (ICH) E2B(R3) Standards
October 11, 2019
Webinar

Activity Coordinator
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Series Description

FDA's CDER Small Business and Industry Assistance (SBIA) sponsors a series of educational webinars targeting the needs of health care professionals working in the pharmaceutical industry. Subject matter experts from the FDA explain trending drug development topics, new guidances or regulations, and/or FDA regulatory processes. These webinars support FDA's mission of promoting and protecting public health by bridging knowledge gaps about emerging regulatory issues or areas with frequently asked questions.

Lecture Description
The purpose of this webinar is to provide information on the plans, progress, and technical specifications on enhancements to electronic submission of premarket and postmarket Individual Case Safety Reports (ICSRs) in FAERS using ICH E2B(R3) standards. This webinar will enhance healthcare professionals' knowledge of the processes needed to implement ICH E2B(R3) into their systems.

References

- Public Meeting Page: Electronic Submission of Adverse Event Reports to FDA Adverse Event Reporting System (FAERS) using International Council for Harmonisation (ICH) E2B(R3) Standards https://www.fda.gov/drugs/news-events-human-drugs/electronic-submission-adverse-event-reports-fda-adverse-event-reporting-system-faers-using

Series Objectives

- Solve FDA drug regulatory issues as they arise.
- Explain new FDA regulatory initiatives.

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

- Recognize FDA’s regional data elements for the implementation of ICH E2B(R3).
- Integrate processes needed to implement ICH E2B(R3) and regional data elements into home systems.

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

Agenda

Lecture 1 October 11, 2019

Time	Topic	Speaker
12:00 - 1:00 PM	Electronic Submission of Adverse Event Reports to FDA Adverse Event Reporting System (FAERS) using International Council for Harmonisation (ICH) E2B(R3) Standards	Suranjan De

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 1.00 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 JA0002895-0000-19-076-L04-P for 1.00 contact hour(s).

CNE

FDA Center for Drug Evaluation and Research designates this activity for 1.00 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

- De, Suranjan, SUPERVISORY HEALTH SCIENCE, FDA - nothing to disclose

Planning Committee

- Giroux, Virginia, MSN, FNP-BC, Associate Director for Accreditation, FDA/CDER/OEP/DLOD - nothing to disclose
- Kleppinger, Cynthia, MD, Medical Officer, 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.