Activity Outline
CDER Small Business and Industry Assistance 1.5 Hour Web Series: FDA - EMA Parallel Scientific Advice (PSA) Program
March 16, 2022
Webcast

Activity Coordinator:
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Series Description

FDA's CDER Small Business and Industry Assistance (SBIA) educational webinars target the needs of health care professionals working in the pharmaceutical industry. Subject matter experts from the FDA explain trending drug development topics, (e.g. labeling, adverse events, quality) new guidance's 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 Parallel Scientific Advice (PSA) program shared by the European Medicines Agency (EMA) and the US Food and Drug Administration (FDA) provides a mechanism for experts to concurrently engage in scientific discourse with sponsors on key issues during the development phase of new medicinal products (drugs, biologicals, vaccines, advanced therapies).

References

- FDA link for General Principles EMA-FDA Parallel Scientific Advice (Human Medicinal Products) https://www.fda.gov/media/105211/download
- EMA link for General Principles EMA-FDA Parallel Scientific Advice (Human Medicinal Products) https://www.ema.europa.eu/en/documents/other/general-principles-european-me dicines-agency-food-drug-administration-parallel-scientific-advice_en.pdf
- European Medicines Agency Guidance for Applicants seeking scientific advice and protocol assistance https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/euro pean-medicines-agency-guidance-applicants-seeking-scientific-advice-protoco l-assistance_en.pdf

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:

- Describe the Parallel Scientific Advice (PSA) program.
- Discuss the present findings from a 5-year PSA program review.
- Identify best practice recommendations for those considering a PSA request.

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

Agenda

Lecture 1 March 16, 2022

Time	Topic	Speaker
10:00 - 11:30 AM EDT	FDA - EMA Parallel Scientific Advice (PSA) Program	Sandra Kweder, MD Shannon Thor Thorsten Vetter, MD Anabela Luis De Marcal, Ms

Continuing Education Accreditation

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 1.5 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 1.50 *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 JA0002895-0000-22-028-L04-P for 1.50 contact hour(s).

CNE

FDA Center for Drug Evaluation and Research designates this activity for 1.50 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.

Attention Pharmacists and Pharmacy Techs: Failure to provide your correct NABP AND Date of Birth information, in the required format, may result in the loss of credit for this activity. NABP profile number should be the 6-7 digit profile number assigned by the CPE Monitor and your birth date should be in the MMDD format (e.g. 0721) Do not provide your pharmacy license number. Please click the "My Account" tab and then navigate to "Edit Contact Information" to verify that your information is correct.

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 8 weeks after the last session of the activity to obtain their CE credit.

Disclosure

Faculty

- Kweder, Sandra, MD, Deputy Director, Europe Office - *nothing to disclose*
- Marcal, Anabela Luis De, Ms, EMA Liaison Official to FDA, European Medicines Agency - *nothing to disclose*
- Thor, Shannon, pharmacist, FDA - *nothing to disclose*
- Vetter, Thorsten, MD, Senior Scientific Officer, EMA - *nothing to disclose*

Planning Committee

- Kweder, Sandra, MD, Deputy Director, Europe Office - *nothing to disclose*
- Paraoan, Dianne, MPH, RN, Associate Director for Regulatory Affairs, FDA/ CDER/ OMP - *nothing to disclose*
- Stodart, Brenda, PharmD, BCGP, RAC, Program Director, FDA - *nothing to disclose*

CE Consultation and Accreditation Team

- Catherine Harrison, CE Consultant, FDA/CDER/OEP/DLOD - nothing to disclose
- Zawalick, Karen, CE Team Leader, FDA/CDER/OEP/DLOD - nothing to disclose

All of the relevant financial relationships listed for these individuals have been mitigated.

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