**Activity Outline**
**FDA Drug Topics: Development and U.S. Regulation of Preventive Vaccines**
**September 27, 2022**
**FDA**

**Activity Coordinators:**
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**Description**
This webinar will provide an overview of the development and federal regulations for vaccines in the United States. We will discuss key statutes that grants the Food and Drug Administration authority to regulate vaccines, precipitating historical events, and current regulatory requirements for vaccine licensure and marketing approval. The basic vaccine development process and key regulatory milestones will also be covered.

**References**

- Science and the Regulation of Biological Products - From a Rich History to a Challenging Future. US Food and Drug Administration, Center for Biologics Evaluation & Research. September 2002. (https://archive.org/details/scienceregulatio00cent/page/n11/mode/2up).
- Baylor, Norman and Midthun, Karen. "Regulation and testing of vaccines", Chapter 73 in Vaccines, Fifth Edition. Plotkin, SA, Orenstein, WA, and Offit, PA. Philadelphia: Elsevier (2008).
- Shapiro, Stuart Z., The HIV/AIDS vaccine researchers' orientation to the process of preparing a US FDA application for an investigational new drug (IND): what it is all about and how you start by preparing for your pre-IND meeting. Vaccine 20:1261-1280, 2002.
- Federal Food Drug and Cosmetic Act (FD&C Act), June 25, 1938. Codified at 21 U.S.C. Ch. 9. (http://uscode.house.gov/browse/prelim@title21/chapter9&edition=prelim).
- Public Health Service Act, July 1, 1944. Codified at 42 U.S.C. Sec. 262. (https://uscode.house.gov/view.xhtml?req=(title:42%20section:262%20edition: prelim).
- Code of Federal Regulations, Title 21, Food and Drugs, Parts 312 and 601 Washington, DC, Office of the Federal Register, National Archives & Records Administration, 2021. (https://www.ecfr.gov/current/title-21).


**Learning Objectives**
- Identify the legislative Acts leading to and authorizing FDA to regulate preventive vaccines and discuss the historical context of each.
- List basic regulatory requirements and types of data needed to support vaccine licensure and marketing approval.
- Outline the usual vaccine development process from conception to marketing and explain key regulatory milestones during the process.

**Target Audience**
This activity is intended for physicians, pharmacists, pharmacy technicians, nurses, Certified Public Health Professionals (CPH), and physician assistants.

**Agenda**
**Day 1 September 27, 2022**

| Time | Topic | Speaker |
|---|---|---|
| 1:00 - 2:00 PM EDT | FDA Drug Topics: Development and U.S. Regulation of Preventive Vaccines | Julienne Vaillancourt, MPH, R. Ph |

**Continuing Education Accreditation**

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This knowledge-based activity has been assigned ACPE Universal Activity Number JA0002895-0000-22-073-L03-P, and ACPE Universal Activity Number JA0002895-0000-22-073-L03-T for 1.00 contact hour(s).

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

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**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.

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, physician assistants, 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**
- Vaillancourt, Julienne, MPH, R. Ph, Rare Disease Liaison/Policy Advisor, FDA/CBER/OD - nothing to disclose

**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, R. Ph, RPh, MS, MBA, Consumer Safety Officer, FDA/CDER/OCOMM/DDI - nothing to disclose
- Kapoor, Rama, MD, Senior Physician, FDA - nothing to disclose
- Nguyen-Chu, Thanh Tam, PharmD, Pharmacist, FDA/CDER/OCOMM/DDI - nothing to disclose
- Paraoan, Dianne, MPH, BSN, RN, Associate Director for Regulatory Affairs, FDA/ CDER/ OMP - nothing to disclose

**CE Consultation and Accreditation Team**
- Darlise Henderson, MBA, Training Specialist,FDA/CDER/OEP/DLOD - nothing to disclose
- Zawalick, Karen, CE Team Leader, FDA/CDER/OEP/DLOD - nothing to disclose

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All relevant financial relationships have been mitigated.

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

**Requirements for Certificate of Completion (Non CE)**
Must attend 100% of the activity.