Activity Outline

FDA Grand Rounds:
Vaccine adjuvants: New ways to evaluate their safety and effectiveness

March 30, 2017
12:00 PM-1:00 PM
Bldg 2, Rm 2047E

Series Description
The FDA Grand Rounds is webcast every other month to highlight cutting-edge research underway across the agency and its impact on protecting and advancing public health. Each session features an FDA scientist presenting on a key public health challenge and how FDA is applying science to its regulatory activities.

Session Description
Effective vaccines should generate specific and strong immune responses against disease-causing microorganisms. In the past, live weakened or killed whole organisms were often used for vaccination. Many provided long-lived protective immunity, but a few were associated with reactogenicity, that is, adverse reactions like fever, in a low percentage of vaccinated individuals.

New vaccines against emerging and re-emerging diseases often contain well-defined proteins designed to elicit more targeted immune responses against microorganisms, while also being safer. However, such vaccines are often weakly immunogenic (they produce a short and mild immune response).

Adjuvants are compounds designed to improve the immunogenicity of vaccines by triggering early innate responses--that is, immediate, generic responses in cells such as monocytes and dendritic cells. These cells transfer vaccine components to lymph nodes, where they activate specific B cell and T cell populations that target the microorganism. However, in some cases, excessive activation of the innate response leads to local and systemic toxicities, including fever.

Hana Golding's laboratory has developed new cellular assays to evaluate the safety of new adjuvants using human cells. Additionally, the lab developed new molecular tools to analyze the antibody responses elicited by adjuvanted vaccines and compare them with responses of unadjuvanted vaccine recipients, as well as with patients who have recovered from the infection. The insights gained from her group research could improve the evaluation of future adjuvanted vaccines against diverse disease-causing microorganisms and identify biomarkers of safety and efficacy.

Session References:
S. Khurana, W. Chearwae, F. Castellino, J. Manischewitz, L. R. King, A. Honorkiewicz, M. T. Rock, K. M. Edwards, G. Del Giudice, R. Rappouli, and H. Golding 2010. Vaccines with MF59 adjuvant expand the antibody repertoires to target protective sites of H5N1 pandemic influenza virus. Sci. Transl. Med. 2(15), 15ra5 (2010).

S. Khurana, N. Verma, J. W. Yewdell, A. K. Hilbert, F. Castellino, M. Lattanzi, G. Del Giudice, R. Rappuoli, and H. Golding . 2011. MF59 adjuvant affects human epitope repertoire, augments affinity maturation, and neutralization titers to pandemic influenza in all age groups Sci. Transl. Med. (2011) 3, 85ra48

Series Objectives:
1. Discuss the research conducted at the FDA
2. Explain how FDA science impacts public health

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

1. Explain adjuvants and how they work
2. Describe how adjuvants improve the quality of immune responses
3. Discuss whether adjuvanted vaccines elicit broader (cross-reactive) immunity against pandemic influenza
4. Examine safety concerns related to adjuvants
5. Discuss whether in vitro assays complement pre-clinical studies in animals

Target Audience
This activity is intended for physicians, pharmacists, nurses and other scientists within the agency and external community.

Schedule

Date/Time/Place	Lecture Title	Lecturer
Thursday, March 30, 2017 12:00 PM-1:00 PM Bldg 2, Rm 2047W	FDA Grand Rounds: Vaccine adjuvants: New ways to evaluate their safety and effectiveness	Hana Golding, PhD

Continuing Education
The Food and Drug Administration, Center for Drug Evaluation and Research is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

The Food and Drug Administration – Center for Drug Evaluation and Research designates this live activity for a maximum of 1 *AMA PRA Category 1 Credit(s)*™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

The FDA-Center for Drug Evaluation and Research is accredited by the Accreditation Council for Pharmacy Education as a Provider of continuing pharmacy education. (ACPE Universal Activity No. 0601-0000-17-043-L04-P). This program meets the criteria for 1 contact hour(s) of pharmacy education.

This activity is a knowledge - based activity**.** These CE activities are primarily constructed to transmit knowledge (i.e., facts). The facts must be based on evidence as accepted in the literature by the health care professions.

FDA, Center for Drug Evaluation and Research is an approved provider of continuing nursing education by the Maryland Nurses Association, an accredited approver by the American Nurses Credentialing Center's Commission on Accreditation.
This 1 contact hour Education Activity is provided by FDA, Center for Drug Evaluation and Research. Each nurse should claim only the time that he/she actually spent in the educational activity.

Requirements for receiving CE credit
Physicians, pharmacists, nurses and those claiming non-physician CME: attendance is verified by a sign-in sheet and completion of the final activity evaluation. For multi-day activities, participants must sign in every day. Final activity evaluations must be completed within two weeks after the activity.

Pharmacy participants: partial credit cannot be awarded therefore you must attend the entire activity to receive CPE credit. 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.

Statements of Credit
Physicians and Nurses Statements of Credit for CE will be issued 10 weeks after the last session of this activity. Pharmacists should log into the CPE monitor 10 weeks after the last session of the activity to obtain their CE credit.

Disclosure

Faculty
Hana Golding, PhD, Chief, Laboratory of Retroviruses, CBER/FDA, has nothing to disclose.

Planning Committee
Virginia Giroux, MSN, ARNP, CE Program Administrator, CDER/DLOD, has nothing to disclose.
Emannuel Fadiran, PhD, RPh, Intramural Research Program Director, FDA/OC/OWH, has nothing to disclose.
Rokhsareh Shahidzadeh, MSN, RN, Senior Regulatory Health Education Specialist, OC/OCS/OSPD, has nothing to disclose.
Eileen Parish, MD, Medical Officer, FDA/OC/OCS/OSPD, has nothing to disclose.
Leslie Wheelock, MS, RN, Director OSPD, FDA/OC/OCS/OSPD, has nothing to disclose.

CE Consultation and Accreditation Team
Traci Bryant, MAT, Education Specialist, FDA/CDER/OEP/DLOD, has nothing to disclose.
Karen Zawalick, CE Team Leader, FDA/CDER/OEP/DLOD, has nothing to disclose.

Registration Fees and Refunds
Registration is complimentary therefore refunds are not applicable.

Requirements for Certificate of Completion (Non CE)
Must attend 80% of the lectures (verified by a sign-in sheet).

Initial Release Date: March 30, 2017

Remote Access Instructions:

To register for the webcast, please click the link below and click the link that says "please click here to register." Then follow the instructions. After you register you will receive a link to access the live webinar by logging in with your username and password which you create when you register.

Remote access registration link: https://collaboration.fda.gov/mar92017reg/event/registration.html

For technical assistance please contact Jeffery Rexrode at Jeffery.Rexrode@fda.hhs.gov.

LMS Registration link:
https://lms.learning.hhs.gov/Saba/Web/Main/goto/RegisterCatalog?offeringId=class000000000123427&oneClickLearningON=true

Reasonable Accommodations

The FDA provides reasonable accommodations for all individuals with disabilities who apply for training or developmental opportunities. If you need a reasonable accommodation for any part of the training application process please notify the training contact for this particular event. Reasonable accommodation requests are granted on a case-by case basis. Should you need sign language interpretation to attend this event, please send the request to Interpreting.Services@oc.fda.gov.