Activity Outline FDA Grand Rounds: Polio Vaccines: Past, Present and the Future September 8, 2022 Virtual

Activity Coordinators:

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Series Description

The FDA Grand Rounds is webcast monthly 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.

Lecture Description

FDA regulatory science played a leading role in the evaluation and the development of state-of-the-art quality control methods for the new generation of polio vaccines. The presentation will discuss the evolution of vaccines against poliomyelitis driven by the change in disease epidemiology, socio-economic circumstances, and advances in biotechnology.

References

- Chumakov KM, Powers LB, Noonan KE, Roninson IB, Levenbook IS. Correlation between amount of virus with altered nucleotide sequence
 and the monkey test for acceptability of oral poliovirus vaccine. Proceedings of National Academy of Sciences of USA 1991; 88:199-203.
- Chumakov K, Ehrenfeld E, Wimmer E, Agol VI. Vaccination against polio should not be stopped. Nature reviews 2007; 5:952-8.
- Neverov A, Chumakov K. Massively parallel sequencing for monitoring genetic consistency and quality control of live viral vaccines. Proc Natl Acad Sci U S A 2010; 107:20063-8.
- Konopka-Anstadt JL, Campagnoli R, Vincent A, et al. Development of a new oral poliovirus vaccine for the eradication end game using codon deoptimization. NPJ vaccines 2020; 5:26.

Series Objectives

- Discuss the research conducted at the FDA
- · Explain how FDA science impacts public health

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

- Describe the concept of biotechnology product evolution in response to changes of epidemiology and socio-economic factors.
- Examine genetic changes occurring in live viral vaccines and their impact of safety and efficacy.
- Discuss the efforts to create a new generation of polio vaccines.

Target Audience

This activity is intended for physicians, pharmacists, nurses, and other scientists within the agency external scientific communities.

Agenda

Lecture 1 September 8, 2022

TIME	торіс	SPEAKER
12:00 - 1:00 PM EDT	Polio Vaccines: Past, Present and the Future	Konstantin Chumakov, PhD, D.Sc

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 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) $^{^{\infty}}$. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

CPF

This knowledge-based activity has been assigned ACPE Universal Activity Number JA0002895-0000-22-006-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.

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

Chumakov, Konstantin, PhD, D.Sc, Associate Director for Research, CBER/FDA Office of Vaccines Research and Review - nothing to disclose

Planning Committee

- Dinatale, Miriam, Team Leader, Food and Drug Administration nothing to disclose Pfundt, Tiffany, PharmD, Senior Advisor, HHS/ASPR nothing to disclose
- Wheelock, Leslie, RN, MS, Director, OSPD, FDA, OC, OCS, OSPD nothing to disclose

CE Consultation and Accreditation Team

- Bueide, Rachel E., MPhil, Training Specialist, FDA/CDER/OEP/DLOD nothing to disclose
- Zawalick, Karen, CE Team Leader, FDA/CDER/OEP/DLOD nothing to disclose

Any relationship shown above in italics has been divested within the last 24 months and is therefore considered mitigated. All relevant financial relationships have been mitigated.

Registration Fee and Refunds

Registration is complimentary, therefore refunds are not applicable.