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Medical Countermeasures Initiative Update

August 14, 2019

FDA Science Forum

Transforming Health: Innovation in FDA Science

September 11-12, 2019



Join us at FDA's White Oak campus in Silver Spring, Maryland, or online. [Sessions](#) include advanced manufacturing, food defense, cybersecurity of medical devices, predictive tools (e.g., biomarkers), and other scientific advancements to help counter emerging infectious disease threats including influenza and Zika.

[Learn more and register](#)

[Forward Into the Past With FDA's New History Exhibit](#)



From the “Poison Squad” to AIDS activism, the FDA’s new history exhibit brings the Agency’s past to life while informing its future work. [Read more from Acting Commissioner Ned Sharpless, MD.](#)

Events

- **August 19-22, 2019: [Military Health System Research Symposium](#)** (Kissimmee, FL) - Hosted by the Department of Defense (DoD), this symposium provides a venue for presenting new scientific knowledge resulting from military-unique medical research and development. FDA will provide regulatory updates, and FDA and DoD representatives will discuss [FDA/DoD collaborations](#), regulatory communications, and product development in an interactive panel discussion.
 - **September 11-12, 2019: [2019 FDA Science Forum](#)** (Silver Spring, MD) - [Agenda](#) and registration now available.
 - **September 16-17, 2019: [Identification and Use of Biomarkers to Advance Development of Preventive Vaccines Public Workshop](#)** (Rockville, MD and webcast) - Hosted by the FDA Center for Biologics Evaluation and Research (CBER), the National Institutes of Health, and the Coalition for Epidemic Preparedness Innovations, the purpose of the public workshop is to exchange information with stakeholders from industry, academia, and government about the scientific, clinical, and regulatory challenges encountered in the identification, characterization, and qualification of biomarkers for use in the development of preventive vaccines for infectious diseases indications. [Register](#) by **August 28, 2019**.
 - **New! September 18, 2019: [Implementing FDA’s Predictive Toxicology Roadmap: An Update of FDA Activities](#)** public workshop (Silver Spring, MD and webcast) Register by **September 16, 2019**.
 - **New! September 25-26, 2019: [2019 Complex Generic Drug Product Development Workshop](#)** (College Park, MD and webcast) - FDA will link GDUFA science and research on complex products to product-specific guidance development, discuss pre-ANDA meetings and review, and examine various areas of complex product science, hosted by [CDER Small Business & Industry Assistance](#).
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Information for industry

- Draft guidance - [E8\(R1\) General Considerations for Clinical Studies](#) - The draft guidance was prepared under the auspices of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) and describes internationally accepted principles and practices for the design and conduct of clinical studies of drug and biologic products. In addition, the draft guidance provides an overview of the types of clinical studies that sponsors may perform and data sources they may use during the product's life cycle. The draft guidance intends to promote the quality of the studies submitted to regulatory authorities, while allowing for flexibility. Comment by **September 30, 2019**. (*July 31, 2019*)
 - FDA is requesting that any industry organizations interested in participating in the selection of a nonvoting industry representative to serve on the Vaccines and Related Biological Products Advisory Committee (VRBPAC) [notify FDA in writing](#). FDA is also requesting nominations for a nonvoting industry representative(s) to serve on the VRBPAC. Letters of interest/nomination materials are due by **September 6, 2019**.
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In case you missed it

- Funding opportunity, from the National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL): [Project Call 3.1](#) - Seeks proposals addressing technology, workforce development, and global health priority areas identified by NIIMBL members. Concept papers are due by **September 10, 2019**. To inquire about partnering with FDA on a concept paper for submission to this project call, contact james.coburn@fda.hhs.gov as soon as possible. Also see: [Advanced Manufacturing](#)
- From HHS: [BARDA Industry Day](#) will be **October 15-16, 2019**. Online registration coming soon. BARDA is [accepting applications](#) for Lightning Talks from industry through **September 6, 2019**.
- You want to make a difference. FDA wants to hire you. Follow [@FDAJobs](#) on Twitter, or visit www.fda.gov/jobs.



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