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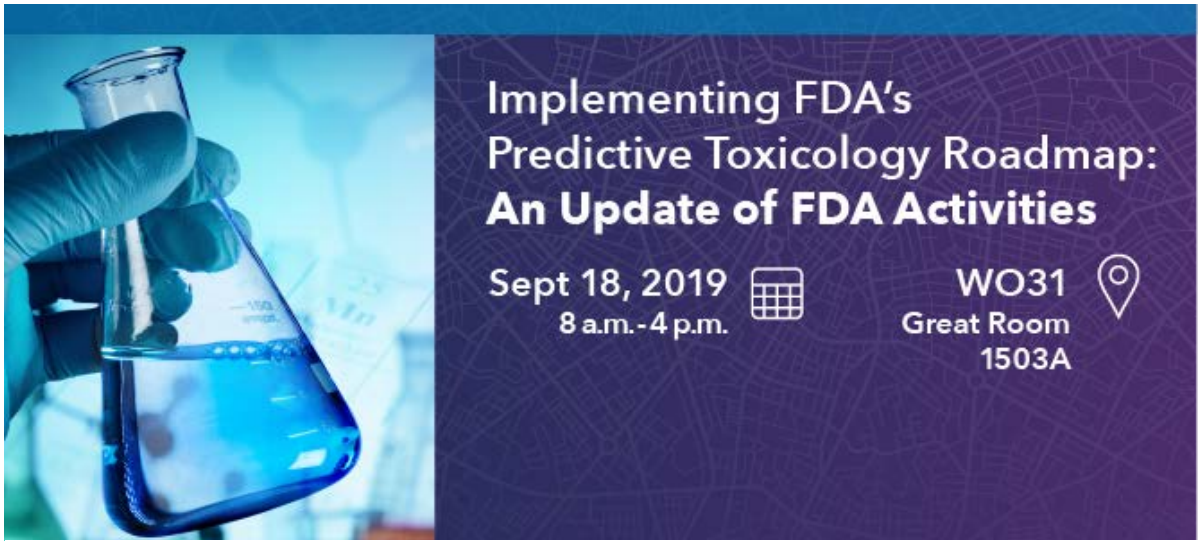
U.S. FOOD & DRUG ADMINISTRATION

Medical Countermeasures Initiative Update

August 28, 2019

Implementing FDA's Predictive Toxicology Roadmap Workshop

September 18, 2019 - Silver Spring, MD and webcast



Join us for a public workshop to highlight the work FDA is doing to support and implement FDA's Predictive Toxicology Roadmap. Toxicology-related research in progress at FDA includes microphysiological systems (including tissue chip technology), computational technology, and *in vitro* alternative methods.

Register by September 16, 2019.

Learn more

Related links:

- Agenda for the September 18, 2019 workshop (PDF)
- FDA's Predictive Toxicology Roadmap (PDF, December 2017)
- 2018 Annual Report on FDA's Predictive Toxicology Roadmap (PDF, June 2019)

Events

- **New! September 9-10, 2019:** 7th Annual FDA Scientific Computing Days (Silver Spring, MD) - This year's event theme is Scientific Computing and Health Data Flows: The Heart and Lifeblood of Public Health Innovation.
- **September 11-12, 2019:** 2019 FDA Science Forum (Silver Spring, MD) - Agenda and registration now available. Don't miss the Oubreak! track.
- **New! September 12, 2019:** HHS Tick-Borne Disease Working Group (online) - The Working Group will receive reports from the eight subcommittees that were formed during the June 4, 2019, meeting and continue to focus on plans to develop the next report to the HHS Secretary and Congress on federal tick-borne activities and research.
- **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 **today** **August 28, 2019**.
- **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**.
- **September 25-26, 2019:** **Link updated** - 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.
- **New! October 3, 2019:** Developing Real-World Data and Evidence to Support Regulatory Decision-Making (Washington, DC) - Through extensive engagement with the stakeholder community, FDA published a framework (PDF) for the Agency's RWE Program in December 2018. This conference will bring together leading experts to discuss questions about and topics addressed in the framework, as well as emerging topics in the development of real-world data and evidence.
- **New! October 9, 2019:** Vaccines and Related Biological Products Advisory Committee (Silver Spring, MD and webcast) - The committee will meet in open session to discuss and make recommendations on the selection of strains to be included in an influenza virus vaccine for the 2020 southern hemisphere influenza season.
- **New! October 16-17, 2019:** Regulatory Education for Industry (REdI): Pharmaceutical Quality Symposium (College Park, MD and webcast) - FDA will discuss the latest developments in pharmaceutical quality and provide case studies that illustrate the most effective ways to address quality issues and interact with the agency.
- **New! November 8, 2019:** Vaccines and Related Biological Products Advisory Committee public meeting (Silver Spring, MD and webcast) - The committee will discuss and make recommendations on the development of chikungunya vaccines.

Information for industry

- FDA released the updated version of the Clinical Outcome Assessment Compendium (COA Compendium) to encourage the development and implementation of patient-focused clinical outcome assessments (COAs) in clinical trials to support drug approvals and labeling claims. The COA Compendium is a communication tool that organizes and summarizes COA information for many different diseases and conditions into a single resource. FDA hopes this will facilitate communication with industry and researchers and provide clarity and transparency to drug developers and the research community. The COA Compendium is intended to be used as a starting point when considering how COAs might be utilized in clinical trials and will likely be most informative early in drug development. *(August 21, 2019)*
- FDA is requesting nominations for voting members to serve on the Blood Products Advisory Committee. Nominations received on or before **October 21, 2019** will be given first consideration.
- **Reminder:** 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**.

In case you missed it

- **Antimicrobial resistance updates:** FDA approves new antibiotic to treat community-acquired bacterial pneumonia *(August 19, 2019)* and a new drug for treatment-resistant forms of tuberculosis that affects the lungs *(August 14, 2019)*. *For more information, see Antimicrobial Resistance Information from FDA.*
- A Cross-Disciplinary Training Program for the Advancement of Medical Countermeasures (*Health Security*, open access) *(August 2019)*
- From HHS/ASPR:
    - BARDA Industry Day will be **October 15-16, 2019**. Registration is now open. BARDA is accepting applications for Lightning Talks from industry through **September 6, 2019**.
    - The Evolution of the Strategic National Stockpile (SNS) - For the last two decades, experts at the SNS have worked to stockpile lifesaving products and build partnerships so we are ready to respond when disaster strikes. As a result, today's SNS has the capacity to get the right medicines, supplies and devices to the right people at the right time. *(August 21, 2019)*
    - HHS Funds an Additional Year of Ebola Vaccine Manufacturing *(August 21, 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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