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Medical Countermeasures Initiative Update

January 8, 2020



REGISTER NOW!

Registration is now open.
Apply to attend by February 28, 2020.

Achieving Data Quality and Integrity in Maximum Containment Laboratories

APRIL 20-24, 2020
Bethesda, Maryland

Attendance is free, but seating is limited.

Training course registration now open

Achieving Data Quality and Integrity in Maximum Containment Laboratories

April 20-24, 2020, Bethesda, Maryland

National Institutes of Health ([NIH](#))

This course offers a unique opportunity for the regulatory and scientific communities to discuss complex issues in an interactive environment and identify and share best practices for ensuring data quality and integrity in high-containment (i.e., BSL-4) facilities. It is designed for researchers who conduct studies intended to support approval under the [Animal Rule](#), which may be used to grant marketing approval of certain products when human challenge studies would not be ethical or feasible.

Registration closes **February 28, 2020**.

[Learn more and apply to attend](#)

Events

- **January 28-30, 2020: [ASM Biothreats](#)** (Arlington, VA) - Hosted by the American Society for Microbiology, to offer professionals in biodefense, biosecurity, and biological threats the opportunity to exchange knowledge and ideas, and explore the latest developments and emerging technologies. *(fee)*
- **January 28-29, 2020: [HHS Tick-Borne Disease Working Group public meeting](#)** (Washington, DC and webcast) - The Working Group will 1) hear presentations from the eight subcommittees on their findings and potential actions for the TBDWG to consider; 2) hear updates from the Public Comment and Inventory Subcommittees; and 3) further discuss plans for developing the 2020 report to the HHS Secretary and Congress on federal tick-borne activities and research. [Register](#) in advance.
- **February 3, 2020: [Advancing EUA IVD Products Toward Full Marketing Status workshop](#)** (Silver Spring, MD) - Hosted by the Medical Device Innovation Consortium (MDIC), this workshop will explore key considerations for using real world data (RWD) to generate real world evidence (RWE) to help support *in vitro* diagnostic (IVD) products available under FDA's Emergency Use Authorization (EUA) to advance to full marketing status.
- **February 25-26, 2020: Public Workshop - [Evolving Role of Artificial Intelligence in Radiological Imaging](#)** (Bethesda, MD and webcast) - Through this workshop, FDA is seeking to engage with stakeholders to explore benefits and risks of evolving applications of artificial intelligence (AI) in radiology. Register by **4:00 p.m. ET February 12, 2020**.
- **February 25-26, 2020: [Developing Medical Countermeasures To Treat the Acute and Chronic Effects of Ocular Chemical Toxicity](#)** (Rockville, MD) - Development of MCMs that mitigate acute and chronic corneal manifestations in response to ocular toxicants relies on the development of well-characterized experimental models with defined pathophysiology that allow for effective bridging to humans. Such models are also essential to demonstrate therapeutic efficacy. This meeting, sponsored by the NIH [Chemical Countermeasures Research Program](#) (CCRP), will bring together subject matter experts from the civilian and military research communities to discuss the current state of the field, including potential therapeutic approaches and available models. Register by **January 31, 2020**.
- **March 3, 2020: Public workshop - [Facilitating End-to-End Development of Individualized Therapeutics](#)** (Silver Spring, MD and webcast) - To foster development of individualized therapeutic products for the treatment of one individual or a very small number of patients, based on engineering a product aimed at the specific molecular mechanism underlying a patient's (or small group of patients') illness. To attend in person, register by **February 18, 2020**.
- **March 18-19, 2020: [Joint Civil & DoD CBRN Symposium](#)** (Alexandria, VA) - Hosted by the Defense Strategies Institute, to provide a forum for CBRN stakeholders to discuss the latest updates in advancing a government-wide approach to improving CBRN defense, readiness and response strategies and capabilities. *(fee)*
- **March 31 - April 3, 2020: [Preparedness Summit](#)** (Dallas, TX) - Hosted by the National Association of County & City Health Officials (NACCHO), the Summit offers a unique learning and networking

opportunity for current and aspiring emergency management, public health, and healthcare professionals, and their partners, to share perspectives and engage in dialogue on key public health preparedness and response issues. *(fee)*

Information for industry

- Final guidance - [Considerations for the Development of Dried Plasma Products Intended for Transfusion](#). This guidance provides recommendations for the development of safe and effective dried plasma products intended for transfusion; it finalizes the guidance of the same title dated October 2018. *(December 19, 2019)*
 - Draft guidance - [Demonstrating Substantial Evidence of Effectiveness for Human Drug and Biological Products](#) - To provide guidance to applicants planning to file new drug applications (NDAs), biologics license applications (BLAs), or applications for supplemental indications on the evidence to be provided to demonstrate effectiveness. Comment by **February 21, 2020**. *(December 19, 2019)*
 - **Reminder:** comment by **February 12, 2020** on the draft guidance [Qualification Process for Drug Development Tools Guidance for Industry and FDA Staff](#).
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In case you missed it

- [First FDA-approved vaccine for the prevention of Ebola virus disease, marking a critical milestone in public health preparedness and response](#) - FDA announced the [approval](#) (PDF, 57 KB) of Ervebo, the first FDA-approved vaccine for the prevention of Ebola virus disease (EVD), caused by *Zaire ebolavirus*, in individuals 18 years of age and older. Cases of EVD are very rare in the U.S., and those that have occurred have been the result of infections acquired by individuals in other countries who then traveled to the U.S., or health care workers who became ill after treating patients with EVD. Because of the public health importance of a vaccine to prevent EVD, FDA worked closely with the company and completed its evaluation of the safety and effectiveness of Ervebo in less than six months. *(December 19, 2019)*
- The FDA [Office of Infectious Diseases](#) is accepting proposals focused on updating susceptibility test interpretive criteria (breakpoints). Specifically, research proposals focused on evaluating microbiologic and pharmacokinetic data that could be utilized by standards development organizations and the FDA to update breakpoints will be prioritized. Proposals should be submitted to the [FDA Broad Agency Announcement](#), priority area 2.4.4. Quad charts and white papers are due by **February 28, 2020**. [Additional information about applying](#) (PDF, 99 KB)
- From HHS/ASPR - [The health security threat in my backyard: how my garden proved that the U.S. needs more, rapid, diagnostics for antimicrobial resistant infections](#) *(December 17, 2019)*



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