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U.S. FOOD & DRUG ADMINISTRATION

Medical Countermeasures Initiative Update

**December 18, 2019**


# Save the dates for these popular training courses

### Achieving Data Quality and Integrity in Maximum Containment Laboratories

**April 20-24, 2020, Bethesda, Maryland**
National Institutes of Health (NIH)
Registration opens January 6, 2020, and closes February 28, 2020

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.

Learn more about this course

### Achieving Data Quality and Integrity in Clinical Trials Involving High-Consequence Pathogens

**July 27-31, 2020, Omaha, Nebraska**
National Ebola Training and Education Center (NETEC)
Registration opens April 6, 2020, and closes when the course is full

Attendees will learn to apply best practices for clinical trials during an outbreak involving high-consequence pathogens, and recognize and prevent potential risks to data quality and integrity. Professionals who have experience with high-consequence pathogen clinical trials are encouraged to apply to attend.

Learn more about this course

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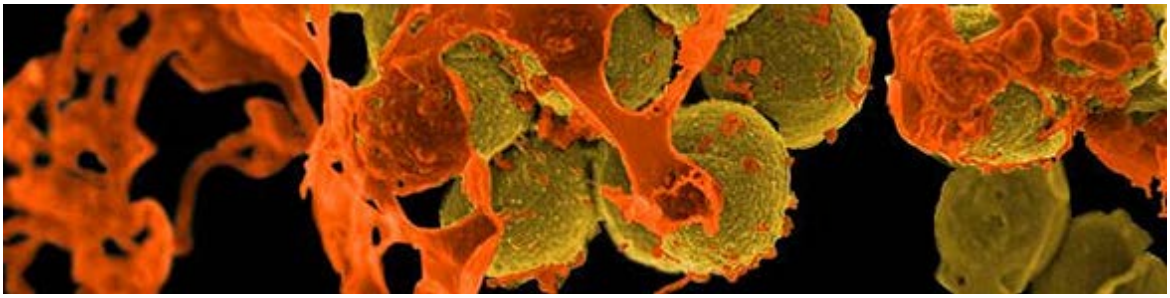

# FDA authorizes marketing of diagnostic test that uses novel technology to detect MRSA bacteria

On December 5, 2019, FDA authorized marketing of a new culture-based diagnostic test that uses novel technology to detect Methicillin-resistant *Staphylococcus aureus* (MRSA) bacterial colonization, a widespread cause of hospital-acquired infections. The cobas vivoDx MRSA diagnostic test may allow health care professionals to evaluate patients for colonization with MRSA bacteria more quickly than traditional culture-based techniques when such testing is needed.

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## 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)*
- **New! 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.

- **New! 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**.
- **New! 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)*

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## Information for industry

- FDA published a new web page, **Availability of Regulatory Management Plans**. The Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (PAHPRA), as amended by the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019 (PAHPAIA), furthered FDA's mission of fostering the development and availability of medical countermeasures (MCMs) by codifying the development of Regulatory Management Plans (RMPs) for certain high-priority MCMs. Under section 565(f) of the Federal Food, Drug, and Cosmetic (FD&C) Act, sponsors or applicants of eligible MCMs can request an RMP, setting forth a formal process for obtaining scientific feedback

and agency interactions regarding the development and regulatory review of eligible MCMs. This page provides information about RMPs for MCM sponsors or applicants. *Also see: MCM-Related Counterterrorism Legislation (December 6, 2019)*

- Draft guidance - Qualification Process for Drug Development Tools Guidance for Industry and FDA Staff - Provides FDA's current thinking regarding the qualification process for drug development tools (DDTs) for a specific use, as defined in the 21st Century Cures Act. Qualification is a voluntary process that permits use of a DDT for its context of use— the defined boundaries within which the available data justifies use of the DDT(s)—across multiple drug development programs. DDTs are methods, materials, or measures that have the potential to facilitate drug development, including, for example, an animal model used for efficacy testing of medical countermeasures under the Animal Rule. Comment by **February 12, 2020**. *(December 13, 2019)*
- FDA issued a final rule, Medical Device Submissions: Amending Premarket Regulations that Require Multiple Copies and Specify Paper Copies to be Required in Electronic Format. The new rule requires medical device premarket submissions to be sent in electronic format, eliminating the need for multiple paper submissions. FDA is also publishing a revised eCopy Guidance, eCopy Program for Medical Device Submissions. The update to the eCopy guidance reflects the amendments to the regulations. *(December 13, 2019)*

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## In case you missed it

- FDA launches app for health care professionals to report novel uses of existing medicines for patients with difficult-to-treat infectious diseases - FDA announced the global launch of CURE ID, an internet-based repository that will allow the clinical community to report their experiences treating difficult-to-treat infectious diseases with novel uses of existing FDA-approved drugs through a website, a smartphone or other mobile device. The platform enables the crowdsourcing of medical information from health care providers to guide potentially life-saving interventions and facilitate the development of new drugs for neglected diseases. *(December 5, 2019)*
- FDA Consumer Update: Having Naloxone on Hand Can Save a Life During an Opioid Overdose *(December 11, 2019)*
- From HHS - HHS Invests in Modernizing U.S. Manufacturing Capacity for Pandemic Influenza Vaccine - The U.S. Department of Health and Human Services (HHS) issued a six-year, $226 million contract to increase capacity to produce recombinant influenza vaccine in the United States. The contract is in accordance with the September 19, 2019, presidential executive order to enhance national security and the public health by modernizing influenza vaccines and technologies. *(December 9, 2019)*


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