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Medical Countermeasures Initiative Update



July 31, 2019

New agreement to support advanced manufacturing innovations

Research centers: partner with FDA to apply for new funding

In July 2019, FDA entered into a Collaborative Research and Development Agreement (CRADA) with the University of Delaware on behalf of the [National Institute for Innovation in Manufacturing Biopharmaceuticals \(NIIMBL\)](#). This CRADA creates a research partnership, in the pre-competitive space, to support research, development, testing, and training in the field of advanced manufacturing innovations to enhance the biopharmaceutical manufacturing ecosystem.

Advanced manufacturing is a collective term for new medical product manufacturing technologies that can improve drug quality, address shortages of medicines, and speed time-to-market. Examples of advanced manufacturing include continuous manufacturing and additive manufacturing, like 3D printing.

These innovations in manufacturing and technology support public health emergency and pandemic preparedness and response.

[Learn more: Advanced manufacturing information from FDA](#)

Related information

- [NIIMBL and FDA Sign Agreement to Support Innovation in Biopharma Manufacturing](#) (*NIIMBL news release, July 31, 2019*)
- [Funding opportunity: 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**.
- [Project Call 3.1 Concept Phase Webinar slides](#) (PDF, 558 KB, July 23, 2019)
- To inquire about partnering with FDA on a concept paper for submission to this project call, contact james.coburn@fda.hhs.gov.

Image: An FDA researcher completes a 3D print of several clinical and research tools for patient-specific medicine. (FDA photo)

First medical product cleared in U.S. for use on certain injuries caused by sulfur mustard

"FDA plays an important role in preparing our nation for a range of threats, including chemical, biological, radiological, and nuclear threats, providing guidance and support for the development of medical countermeasures that can be used safely, effectively, and reliably during public health emergencies," said Acting FDA Commissioner Ned Sharpless, MD.

"The expanded indication for this first-of-its-kind wound contact dressing to include management of certain injuries caused by sulfur mustard vapor exposure demonstrates our commitment to working closely with our federal partners, including BARDA, to expedite the availability of medical countermeasures essential for managing responses to chemical weapons attacks in both civilian and battlefield settings."

Related links:

- [Silverlon](#) - Expanded indication for this first-of-its-kind wound contact dressing to include management of certain injuries caused by exposure to sulfur mustard vapor, commonly known as mustard gas (*July 2019*)
 - [First medical product cleared in U.S. for use on certain injuries caused by sulfur mustard](#) (*HHS press release, July 22, 2019*)
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EUA updates

Second Zika diagnostic cleared

- **July 17, 2019:** FDA [cleared](#) the ADVIA Centaur Zika test. This is the second Zika diagnostic test FDA has allowed to be marketed in the U.S. for detecting Zika virus IgM antibodies. Previously, the test had been authorized only for emergency use under FDA's EUA authority.

EUA revocations

- **FDA has added a new section about [EUA Termination or Revocation](#) to our web page [Information for Laboratories Implementing IVD Tests Under EUA](#).**
- Historical information about revoked or terminated EUAs is available on the [Emergency Use Authorization--Archived Information](#) page.
- Also see Zika Virus Response Updates from FDA, [Updates by Date](#), for information about recent Zika diagnostic EUA actions.



Events

- **August 13, 2019:** [Webinar - FDA Innovation Challenges: Identify Sterilization Alternatives and Reduce Ethylene Oxide Emissions](#), 3:00 - 4:30 p.m. ET - FDA will host a webinar on two FDA Innovation Challenges to spur the development of new approaches to device sterilization. FDA's Center for Devices and Radiological Health will accept applications for this challenge through **October 15, 2019**. Also see: [Preventing Medical Device Shortages by Ensuring Safe and Effective Sterilization in Manufacturing](#)
 - **New! 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. Topic areas include: Outbreak! FDA's approach to prevention and response, including prevention through cybersecurity and promoting medical product and food security, and rapid response to infectious disease and foodborne pathogen outbreaks, e.g. the use of the Animal Rule, emergency communication devices, rapid diagnostic tests, antimicrobial resistance.
 - **New! 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, 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**.
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Information for industry

- [FDA seeks public feedback on biomarker and study endpoint glossary](#) - FDA issued a Federal Register notice, [21st Century Cures: Announcing the Establishment of the BEST Resource Taxonomy](#), to open a docket for public comment. In 2015, the FDA-NIH (National Institutes of Health) Joint Leadership Council identified the harmonization of terms used in translational science and medical product development as a priority need, with a focus on terms related to study endpoints and biomarkers. This resulted in the [BEST glossary of terms](#). FDA is seeking comments concerning the utility of BEST; including edits, additions, and removal of terms along with a rationale supporting these proposed changes. Comment by **September 23, 2019**. Also see: [BEST Resource Taxonomy \(July 24, 2019\)](#)
 - [Submitting Next Generation Sequencing Data to the Division of Antiviral Products Guidance for Industry Technical Specifications Document](#) - The purpose of this technical specifications document is to provide the current thinking of FDA's Division of Antiviral Products in regard to the submission of next generation nucleotide sequence analysis procedures and data in support of resistance assessments for the development of antiviral drug products. Providing accurate resistance information is imperative for protecting public health to prevent the emergence of novel resistant and cross-resistant viral variants that have the potential to infect others and cause major outbreaks of disease that cannot be controlled by approved drug products. *(July 18, 2019)*
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In case you missed it

- [FDA approves new treatment for complicated urinary tract and complicated intra-abdominal infections](#) - FDA has approved Recarbrio (imipenem, cilastatin and relebactam), an antibacterial drug product to treat adults with complicated urinary tract infections (cUTI) and complicated intra-abdominal infections (cIAI). It is important that the use of Recarbrio be reserved for situations when there are limited or no alternative antibacterial drugs for treating a patient's infection. *(July 17, 2019)*
- To help build next-generation sequencing infrastructure, the [FDA-ARGOS](#) database makes publicly available quality-controlled microbial reference genomes for diagnostic use. Learn more in this new [Nature Communications article](#) (PDF, *July 25, 2019*). The FDA-ARGOS team is looking for unique, hard-to-source microbes like biothreat organisms, emerging pathogens, and antimicrobial resistance-related pathogens to help improve the FDA-ARGOS database. We encourage the research community to [share microbe samples](#).
- From HHS/ASPR: [Project BioShield Evolution: Fifteen Years of Bridging the 'Valley of Death' in the Medical Countermeasures Pipeline](#) *(July 17, 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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