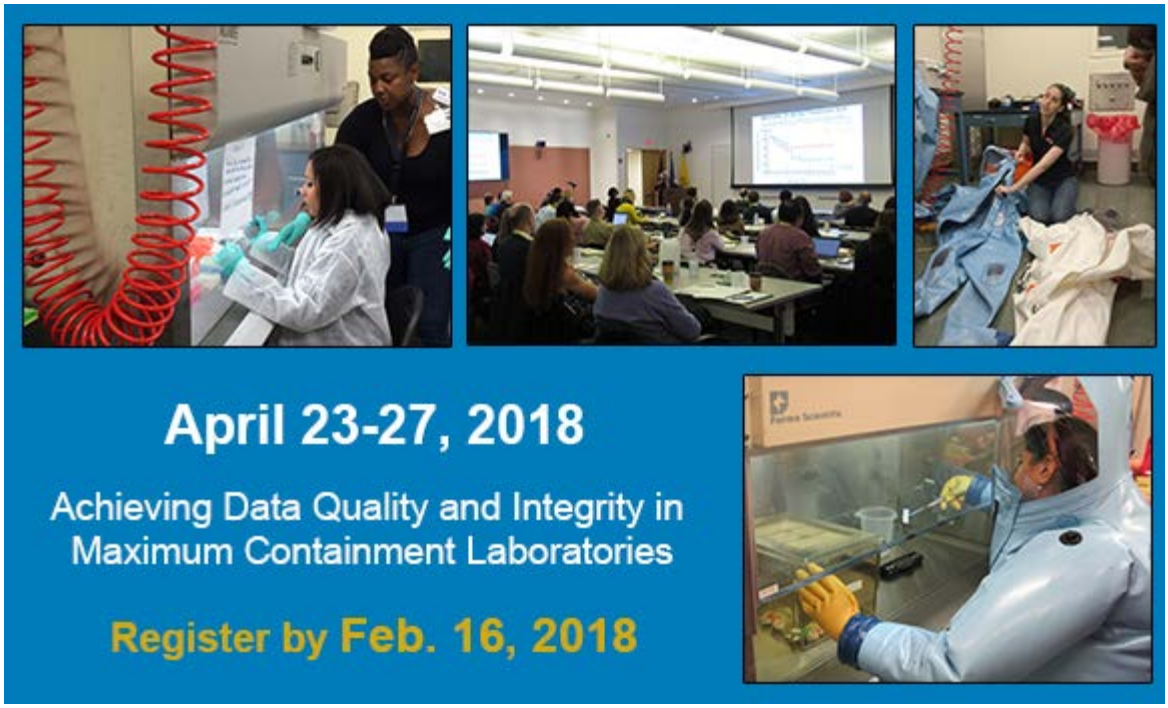
U.S. FOOD & DRUG ADMINISTRATION

Medical Countermeasures Initiative Update

January 31, 2018

Take our email survey



Register now!

Course designed for researchers who conduct studies to support approval under the Animal Rule

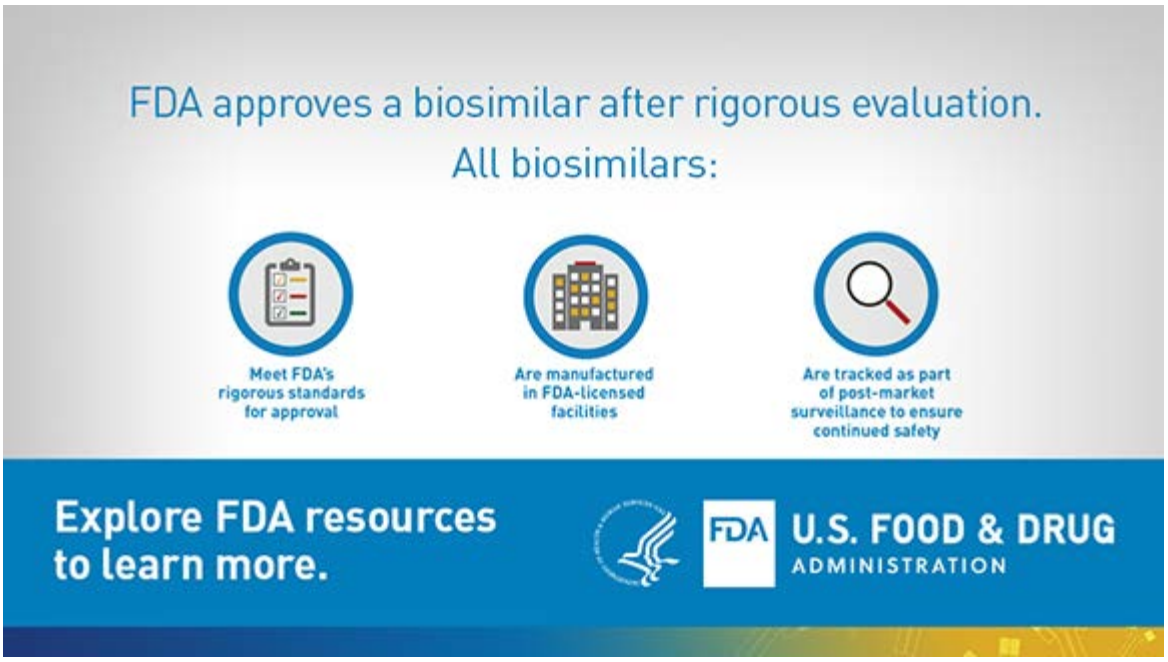
Early registration is recommended, as this course quickly fills to capacity. FDA sponsors this course as part of our work to advance the development and availability of medical countermeasures. There is no registration cost. **Register by February 16, 2018**.

Related links:

- Course FAQs and how to register
- About MCMi professional development
- What are medical countermeasures?

Image: Course attendees participate in lectures and hands-on activities during previous courses. More course photos are available on Flickr.

New biosimilar resources

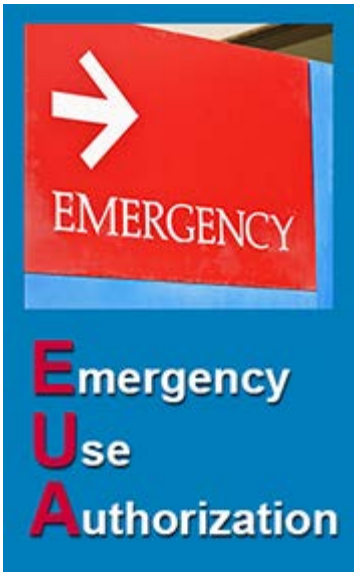


Have questions about biosimilars? Check out FDA's new biosimilar resources – they include biosimilar definitions, information about prescribing them, and details on their rigorous approval standards.

Image: FDA approves a biosimilar after rigorous evaluation. All biosimilars meet FDA's rigorous standards for approval, are manufactured in FDA-licensed facilities, and are tracked as part of post-market surveillance to ensure continued safety.

EUA updates

EUA amendment



- **January 24, 2018:** In response to CDC's request, FDA concurred (PDF, 33 KB) with amendments to the Rafa Atropine Auto-Injector EUA (1) to clarify that the authorized product (0.5 mg, 1 mg, and 2 mg) may be administered through clothing, and (2) for changes to certain Rafa-planned manufacturing processes. The Rafa Atropine Auto-Injector was initially authorized for emergency use for initial treatment of nerve agent or certain insecticide (organophosphorus and/or carbamate) poisoning in April 2017. *Additional information, including updated fact sheets*

Reminder:
Laboratory personnel using Zika diagnostic assays under EUA are encouraged to report performance concerns directly to FDA at CDRH-EUA-Reporting@fda.hhs.gov, in addition to reporting concerns to the manufacturer.

Information about Zika EUAs and amendments is available on the FDA Zika virus response updates page. Also see the latest CDC Zika Laboratory Guidance, last updated July 24, 2017.

Events

- **February 7-8, 2018:** Tenth Annual Sentinel Initiative Public Workshop (Bethesda and Silver Spring, MD, and webcast) - The stakeholder community will discuss a variety of topics on active medical product surveillance. To attend in-person or via webcast, register here for Day 1 and/or here for Day 2 by **February 6, 2018**. To attend both days, please register separately for each.

New! February 12, 2018: HHS Tick-Borne Disease Working Group meeting (webcast), 12:00 - 4:00 p.m. ET - For this third meeting, the Working Group will focus on mapping out the work of the six Subcommittee Meeting Working Groups that were established on December 12, 2017. Additional information, including how to attend, will be posted to the Working Group web page one week before the meeting.

- **New! February 12-14, 2018:** American Society for Microbiology (ASM) Biothreats meeting (Baltimore, MD) - FDA experts will present during sessions including Beyond the Animal Rule and Animal Models as Drug Development Tools *(fee)*
- **February 15-19, 2018:** American Association for the Advancement of Science annual meeting (Austin, TX) - FDA's RADM Carmen T. Maher, MA, BSN, RN, RAC, will present on FDA's role in medical countermeasure development February 18, 2018 at 9:00 a.m. CT *(fee)*
- **April 17-20, 2018:** Preparedness Summit (Atlanta, GA) - The theme for the conference is Strengthening National Health Security: Mastering Ordinary Responses, Building Resilience for Extraordinary Events. Registration is now open. *(fee)*
- **April 23-27, 2018:** Achieving Data Quality and Integrity in Maximum Containment Laboratories course (Bethesda, MD) - Register by **February 16, 2018**.

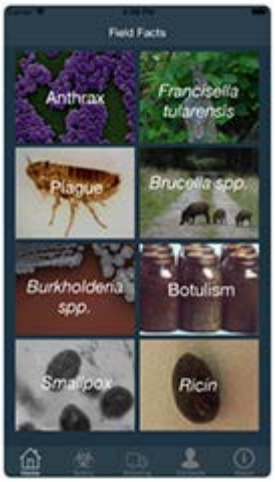
Information for industry

- FDA has issued a direct final rule (and companion proposed rule) that amends the general biologics regulations to remove outdated requirements and help eliminate inconsistencies and duplicative processes – specifically, how frequently the FDA is inspecting certain facilities and the actual duties of the inspector. Comment by **April 11, 2018**. *Also see: FDA issues new rule to improve efficiency, effectiveness of oversight over biologics manufacturing (January 25, 2018)*
- FDA released draft guidance on its policies and procedures related to the designation of a qualified infectious disease product (QIDP) under the Generating Antibiotic Incentives Now (GAIN) Act: QIDP Designation Questions and Answers (PDF, 390 KB). Comment by **April 2, 2018**. *(January 29, 2018)*
- The FDA Office of Pharmaceutical Quality (OPQ) released a new white paper (PDF, 461 KB) on how sponsors can improve the use of a Quality Overall Summary (QOS) submitted as part of drug marketing or licensing applications.*(January 23, 2018)*
- Federal Policy for the Protection of Human Subjects: Delay of the Revisions to the Federal Policy for the Protection of Human Subjects - This interim final rule delays until **July 19, 2018**, the effective date and general compliance date of the final rule published in the Federal Register on January 19, 2017. *(January 22, 2018)*
- Reminder: Comment by **March 20, 2018** on draft guidance Material Threat Medical Countermeasure Priority Review Vouchers (PDF, 174 KB) *Also see: FDA takes steps to spur development of medical countermeasures needed to protect, prepare for emerging threats to public health and national security and 21st Century Cures Act: MCM-Related Cures Provisions*

More: MCM-Related Guidance by Date

In case you missed it

- Extension of Shelf Life Provided by Baxter Healthcare Corporation to Assist with IV Solution Shortages - Due to the ongoing critical shortage of IV solutions used in critical care, FDA is alerting health care professionals of extension of shelf life through which some of these products, manufactured by Baxter Healthcare Corporation, may be used beyond the manufacturer's labeled expiration date. *(January 22, 2018)*
- Statement from FDA Commissioner Scott Gottlieb, MD, on new policy steps for strengthening public warning and notification of recalls - *Also see: FDA Voice: FDA to Expedite Release of Recall Information (January 18, 2018)*
- FDA launched the Clinical Data Summary Pilot Program, a new program to



evaluate whether disclosing certain information included within clinical study reports (CSRs) following approval of an NDA improves public access to drug approval information. *Also see: FDA Commissioner Scott Gottlieb, MD, on new steps FDA is taking to enhance transparency of clinical trial information to support innovation and scientific inquiry related to new drugs (January 16, 2018)*

- FDA's Center for Devices and Radiological Health (CDRH) published accomplishments (PDF, 260 KB) from its 2016-2017 strategic priorities, and its 2018-2020 Strategic Priorities (PDF, 410 KB) - *Also see: FDA Voice: Charting Our Course for 2018-2020 (January 17, 2018)*
- CDC has released a new app for bioterrorism responders, Field Facts (screenshot at right), which provides fast access to information during a possible bioterrorism response. Available for Apple and Android. *(January 17, 2018)*

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FDA Medical Countermeasures Initiative

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