U.S. Food and Drug Administration
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FDA's Remote Interactive Evaluations - Expectations and Way Forward

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Disclaimer

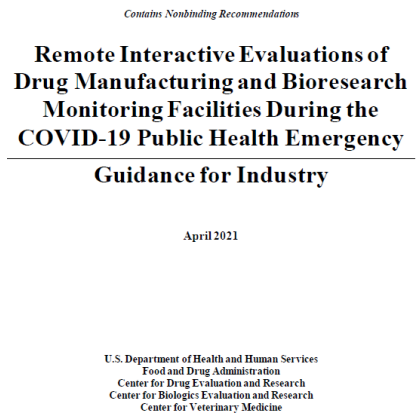
I understand this webinar is an informal discussion, my remarks are consistent with that, and for official FDA statements of law and policy, refer to the statute, regulations, and agency guidance.

Topics for Today's Discussion

- Overview of FDA's Remote Interactive Evaluation (RIE) Guidance
- Statutory context for drug inspections
- How does a remote interactive evaluation compare to an in-person inspection?
- Steps a facility can take to prepare for an RIE
- Tips for aiding in a successful RIE

Overview of the RIE Guidance

- Issued to provide information to industry on how FDA will request RIEs, what firms can expect when one is performed, and how FDA will share RIE outcomes with them.
- Applies to facilities where drugs are manufactured, processed, packed, or held; facilities covered under FDA's bioresearch monitoring (BIMO) program; and outsourcing facilities registered under section 503B of the FD&C Act
- Issued in April 2021 and intended to remain in effect for the duration of the COVID-19 Public Health Emergency (PHE)



Contains Nonbinding Recommendations

Remote Interactive Evaluations of Drug Manufacturing and Bioresearch Monitoring Facilities During the COVID-19 Public Health Emergency

Guidance for Industry

April 2021

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research
Center for Biologics Evaluation and Research
Center for Veterinary Medicine

Meaning of "Remote Interactive Evaluation"

- ✓ any interaction with a facility other than inspection or a record request under section 704(a)(4) of the FD&C Act
- ✓ t-cons, livestreaming video of facility/ops, screen-sharing of records/info, disclosing records, and similar activities
- ✓ always voluntary

Guidance Recommendation Highlights

- FDA will contact facility to request interest in allowing remote evaluation (facilities should not send requests to FDA)
- FDA must host remote interactions using FDA version of Microsoft Teams, Zoom, or Adobe
- FDA communications with facility about RIEs typically include
  - schedule for remote evaluation
  - issue written list of "observations"
  - prepare final report describing coverage/findings; shared following RIE
- FDA will not issue Form FDA 483, *Inspectional Observations*

Guidance Recommendation Highlights (cont.)

- FDA may use remote evaluation outcomes to, e.g.:
  - decide approvability of a pending application
  - determine future CGMP surveillance inspection timing, scope, depth
  - resolve a "for-cause" need to inspect, e.g., assess defect report
  - evaluate outsourcing facility (503B) for CGMP compliance
- Does not specify equipment to use in livestreaming operations or data/info; need only be fit for purpose

Statutory context for drug inspections

- FDC Act says we "**shall inspect**"(§510(h))
  - drug manufacturing facilities (incl. processing, testing, packing)
  - on a risk-based schedule after establishment registers
  - in accordance with §704
- FDC/PHS Acts do not explicitly require inspections of facilities named in pending applications
  - we can and do inspect as we decide necessary
  - therefore, we can use alternatives to inspection to evaluate ops/facilities
- §704(a)(4) says we can request records and other info "in lieu of or in advance of an inspection"
  - drugs only, and only at places where a drug is "manufactured, processed…"
  - does not extend to ***remote interactions***

How does a remote interactive evaluation compare to an in-person inspection?

- RIEs are not the same as an inspection
- FDA does not intend to replace traditional inspections with remote interactive evaluations.
- Ideally, inspections supplemented by additional tools, including records requests under 704(a)(4) and remote interactive evaluations, would provide FDA the greatest depth and breadth of information to inform regulatory decisions and support oversight while allowing for the most prudent use of resources and ensuring the safety of both FDA staff and industry.

What are some steps a facility can take to prepare for an RIE?

- Internet connection
- Portable equipment (phone, tablets)
- Electronic documents and other information
- Translators
- Paper records

What are some tips for during an RIE?

- Clarify with the FDA representative any requests you don't fully understand or will require submission of a particularly high volume of records
- Have subject matter experts available to explain operations and answer questions

Questions?