Land O' Lakes Bioanalytical CONFERENCE
JULY 12-14, 2021

Are Remote Audits Here to Stay?

David Schumacher, RQAP-GLP
Quality Assurance Director

Alturas Analytics, Inc.
The LC-MS Experts

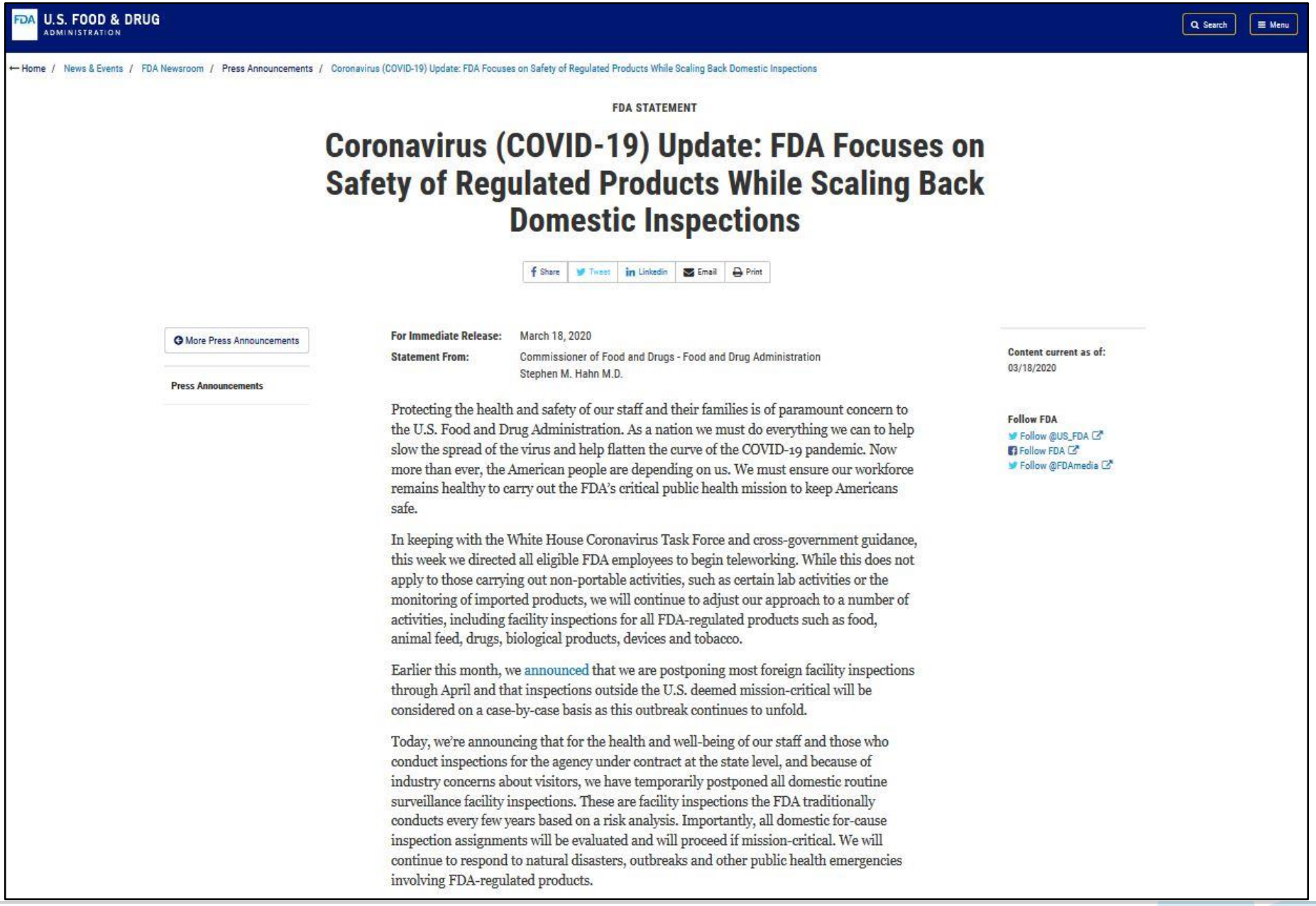
Description & Objectives

Description

COVID-19 disrupted supplier and regulatory audits. Remote audits were implemented to fulfill the void left by in-person audits and are likely here to stay.

Objectives

- Performing a successful remote audit.
- Review the FDA Remote Audit Guidance Document.
- Describe why remote audits are likely here to stay.



U.S. FOOD & DRUG ADMINISTRATION

Search Menu

← Home / News & Events / FDA Newsroom / Press Announcements / Coronavirus (COVID-19) Update: FDA Focuses on Safety of Regulated Products While Scaling Back Domestic Inspections

FDA STATEMENT

Coronavirus (COVID-19) Update: FDA Focuses on Safety of Regulated Products While Scaling Back Domestic Inspections

Share Tweet LinkedIn Email Print

More Press Announcements

Press Announcements

For Immediate Release: March 18, 2020

Statement From: Commissioner of Food and Drugs - Food and Drug Administration
Stephen M. Hahn M.D.

Protecting the health and safety of our staff and their families is of paramount concern to the U.S. Food and Drug Administration. As a nation we must do everything we can to help slow the spread of the virus and help flatten the curve of the COVID-19 pandemic. Now more than ever, the American people are depending on us. We must ensure our workforce remains healthy to carry out the FDA's critical public health mission to keep Americans safe.

In keeping with the White House Coronavirus Task Force and cross-government guidance, this week we directed all eligible FDA employees to begin teleworking. While this does not apply to those carrying out non-portable activities, such as certain lab activities or the monitoring of imported products, we will continue to adjust our approach to a number of activities, including facility inspections for all FDA-regulated products such as food, animal feed, drugs, biological products, devices and tobacco.

Earlier this month, we announced that we are postponing most foreign facility inspections through April and that inspections outside the U.S. deemed mission-critical will be considered on a case-by-case basis as this outbreak continues to unfold.

Today, we're announcing that for the health and well-being of our staff and those who conduct inspections for the agency under contract at the state level, and because of industry concerns about visitors, we have temporarily postponed all domestic routine surveillance facility inspections. These are facility inspections the FDA traditionally conducts every few years based on a risk analysis. Importantly, all domestic for-cause inspection assignments will be evaluated and will proceed if mission-critical. We will continue to respond to natural disasters, outbreaks and other public health emergencies involving FDA-regulated products.

Content current as of:
03/18/2020

Follow FDA
Follow @US_FDA
Follow FDA
Follow @FDAmedia

How does one conduct a remote audit? Where is the manual?

Remote Audit Basics

- Zoom (or other suitable platform) for discussions and interviews
- Initial group meeting with all of the key staff and auditor(s).
- Provide a cell phone video tour.
- Share PDF documents (e.g., SOPs, QA Manual, etc) by passing screen control on Zoom to auditor for review.
- Final closeout meeting with all the key staff members and auditor(s).

The First Remote Audit

FDA Remote Inspection – 14 April 2020

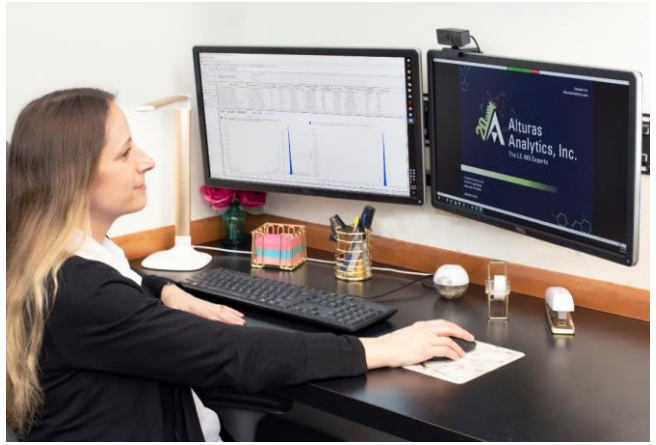
- Lasted 16 business days.
- Operated very much like we had initially envisioned with two exceptions:
  - FDA was in control of the WebEx video platform.
  - Documents were uploaded to a Box.com file sharing application.
- A 482 was presented at the initial meeting.
- A 483 was issued at the final closeout meeting.
- EIR and closeout letter issued 25 June 2020.

Beyond the Basics

- Establish a time frame that recognizes the differing time zones.
- Establish a solid Wi-Fi throughout the facility being audited.
- Ensure plenty of bandwidth at the facility and also at the auditor's location during peak periods.
- Remote audits are not standardized; be sure to summarize the process up front (e.g., secure site, document management system, email, etc.) so the auditor knows what is expected and can prepare.

Beyond the Basics

- Know how the application functions whether it be Zoom, WebEx, Teams or other. New features are continuously being added to improve functionality.
- Use a good quality video camera (older or inexpensive cell phones are lower cost for a reason).
- Understand lighting and camera angles (e.g., portrait vs landscape) to show areas.



Beyond the Basics

- Provide the viewers a floor plan document prior to the video tour so the viewer may print out and easily follow along.
- Provide viewers other key documents (e.g., organization chart, SOP Index) so these may also be printed out and easily available for the auditor.
- Close-ups (labels, forms, etc) sounds simple but can be challenging; must be steady and move slowly; practice
- Consider using a hand-held gimbal device to stabilize the camera.

Beyond the Basics

Gimbal in Portrait

Or Landscape Modes

Beyond the Basics

- Will this be an interactive tour? Need the ability to speak and listen during the video tour.
- Use a good quality speaker phone or Bluetooth device; the voice quality of some is poor; avoid the echo chamber effect.

Beyond the Basics

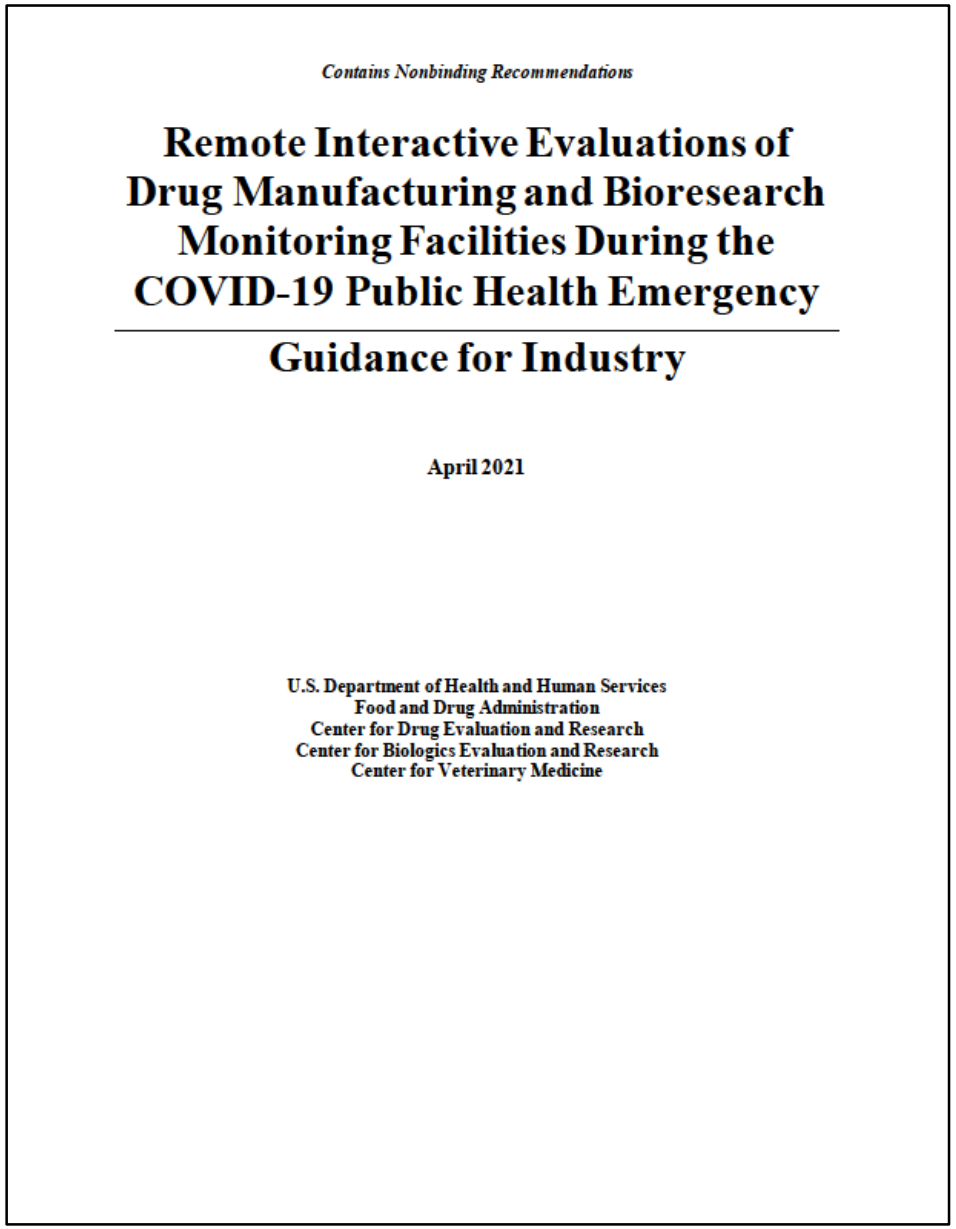
- Be aware of noisy environments that will make speaking or listening difficult; warn the viewers up front if entering these areas.
- Auditors tend to approach remote audits in different ways. Some want to be largely left alone while they review documents and save questions for the end while others prefer to ask questions as they go along. Be prepared to adapt to the auditor's preferences.
- Be aware of what is behind you; even a virtual background can fail at times.

Beyond the Basics

- Use an online file sharing site to provide access to documents. Box.com, OneHub or others enable auditors to view documents securely but not able to print or download.
- Be sure key individuals are available and have a link to the online meeting.
- During a virtual tour, be aware of confidential information that may appear on desktops, white boards or other postings.

Beyond the Basics

- Remote auditing is probably going to be slower than on-site. Adjust your expectations or allotted time to complete.
- Qualifications, validations, equipment maintenance may be paper based. Create PDFs beforehand or have the ability to quickly generate.
- Predict what an auditor may ask for and have readily available.



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

- Describes how the FDA will request voluntary remote interactive audits.
- Policy only remains in effect during the health emergency.

FDA Remote Guidance

- FDA will apply risk management methods and tools to determine when to request a remote interactive evaluation
- The company will be contacted by phone call from the FDA to inquire if you are capable of hosting a remote evaluation
- No 482/483 will be issued
  - Time zone differences and translation services (i.e., spoken and written translation), if applicable. Virtual interactions, including remote observation of manufacturing operations or livestream assessment of data, usually will occur during the facility's normal business hours.
  - The agency will provide methods for sharing requested information, including sharing documents and the use of video-streaming technology.

FDA Remote Guidance

- Technological limitations that could impair or prevent FDA's remote interactive evaluation of the facility.
- Check of the internet connection throughout the facility to verify that the signal strength is adequate to support livestreaming video and audio during the actual remote interactive evaluation.
- FDA expects appropriate staff to be available at scheduled times for interview and virtual interactions.

FDA Remote Guidance

- For security reasons, FDA will use its own IT platforms and equipment to host virtual interactions during remote interactive evaluations (e.g., videoconferences, livestreaming video of the facility and operations in the facility). FDA currently uses the following conferencing platforms:
  - FDA Microsoft Teams
  - FDA Zoom for Government
  - FDA Adobe Connect
- FDA will provide a secure means to send requested information during a remote interactive evaluation.
- Note: Keep track of document uploads along the way so you may easily search for when uploaded.

FDA Remote Guidance

- Requested documents maintained in paper format should be scanned as searchable Portable Document Format (PDF) files when possible.
- Upon completion of a remote interactive evaluation, FDA will have a closeout meeting with the facility's management. During this meeting, FDA will usually present a written list of observations, if any, and describe and discuss any observations in sufficient detail to enable understanding and foster an appropriate response.

FDA Remote Guidance

- FDA encourages facilities to respond during the discussion and/or provide responses in writing to the observations within 15 U.S. business days.
- After the remote interactive evaluation concludes, FDA will provide a copy of the final remote interactive evaluation report to the facility. A remote interactive evaluation report and any written list of observations may be subject to a disclosure request under the Freedom of Information Act.

Resiliency Roadmap for FDA Inspectional Oversight

FDA U.S. FOOD & DRUG ADMINISTRATION

FDA Inspections

Fiscal Year	Planned Inspections	Completed Inspections	Percentage
2019	18,000	16,920	94
2020	21,000	13,000	61
2021	26,250[1]	2953[2]	11

- [1] Includes rollover from 2020
- [2] As of March 2021

Inspectional Priority/Tier by Regulated Commodity

COMMODITY	TIER 1: MISSION CRITICAL	TIER 2: HIGHER PRIORITY	TIER 3: LOWER PRIORITY
Human and Animal Food	Agency crisis or emergency response For-cause work	For-cause but not considered mission critical	Routine-surveillance, including non-high-risk inspection and sampling assignment
	Other mission-critical special assignment	High-priority and high-risk inspection and sampling	
Human and Animal Drugs	**SEE REPORT FOR DETAILS**		
Medical Devices and Radiological Health			
Biologics			
Bioresearch Monitoring			
Tobacco			

On-site vs Remote

On-site vs Remote

On-site Inspection	Remote Inspection
Limited number of participants	Unlimited participation; individuals can "stop by" for a short conversation
Facility clearly visible	Visibility limited by what the camera is pointed at
Start/end times usually driven by business hours	Start/end times challenging depending on time zones
Viewing of documents on-site dictated by business hours	Online file sharing (e.g., Box, OneHub) can be viewed at any time

On-site vs Remote

On-site Inspection	Remote Inspection
Can communicate directly with individuals; can note body language	Communication via video or phone call; difficult to read body language
Can lay out multiple binders and easily compare data on different pages	Must utilize PDF copies and video monitors; more difficult to view unrelated pages
Can utilize all senses	Unable to utilize more than a limited visual sense
Greater security of IP materials	Must trust online viewers to abide by confidentiality agreements

On-site vs Remote

On-site Inspection	Remote Inspection
No risk of internet security	Zoom-bomb or other possible hacking
Must be on-site	Zoom participants can join from anywhere
Typical desktop or notebook computers	Should have good microphone and video camera
Internet connectivity usually not an issue	Internet bandwidth critical to avoid screen freeze

On-site vs Remote

On-site Inspection	Remote Inspection
Can utilize applications directly or easily observe a trained user operate the system	Access to applications may be challenging or need to have someone navigate – more challenging to follow
Live tour – very interactive	Video tour – may be live or recorded
Document access only while on site	Document access before and after audit via a secured file sharing site
Flights, hotel, car rental and meals must be secured	Stay at home or office – minimal expense
Travel time lost in airports, planes or automobile	Minimal travel time – increased productivity

On-site vs Remote: Benefits and Limitations

In the end – do you perform an on-site or remote inspection?

- Is this an initial qualification or follow-up?
- Can the type of audit be adequately performed remotely?
- Are there time or financial constraints to consider?
- Does the facility have the infrastructure and ability to conduct a good remote audit?

Conclusions

- Remote audits can be successfully executed in many situations.
  - Weigh the pro/con of each situation.
- Remote audits are likely to continue for vendor assessments.
- FDA has laid the groundwork for remote inspections through the emergency use declaration in March 2020 – may become a permanent tool; there may be legal considerations to overcome once the health emergency is no longer in effect.

Acknowledgments

I wish to thank the following individuals at Alturas Analytics for their contributions towards the remote audit process and content of this presentation:

- Staci Loughney, QA Associate
- Rachel Walker, QA Associate
- Bo Cheng, PhD, Director of Information Technology
- Cody Hawkins, Marketing Associate

Contact Information

David Schumacher, RQAP-GLP
QA Director
dschumacher@alturasanalytics.com
1324 Alturas Drive
Moscow, ID 83843
(208) 883-3400

Alturas Analytics, Inc.
The LC–MS Experts