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Conducting Remote Regulatory Assessments

AMDM Fall Focus Meeting

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About AdvaMedDx

- AdvaMedDx – a Division of the Advanced Medical Technology Association (AdvaMed)
  - https://www.advamed.org/advameddx/
- Represents over 75 manufacturers of IVDs in the U.S. and abroad, including multiple instrument manufacturers

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Presentation Agenda

- What is an RRA?
- Current Legal Status
- Device Pilot
- Legislative Proposals
- FDA Draft Guidance
- AdvaMed Comments to Draft

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What is an RRA?

- Remote Regulatory Assessments (RRAs) include
  - Remote Records Review
  - Remote Evaluation

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Current Legal Status

- Statutory Authority for Mandatory RRAs for Drugs and FSMA (food)
- No Statutory Authority for Devices
  - CDRH/ORA Would Need New Legislation for any Mandatory RRA

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Device Pilot

- During pandemic, ORA initiated voluntary device RRA pilot
- Pilot implemented by implemented by FDA's Office of Medical Device and Radiological Health Operations (OMDRHO).
- Records review but not remote evaluation

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Device Pilot, cont.

- "Refusal to provide information requested during an RRA is not a refusal under FDA's inspection authority"
- At the conclusion of the RRA, "the investigator will request a meeting with your firm's management to go over any concerns identified during their document review and provide you an opportunity to respond."
- "RRA findings will be considered by management during future routine FDA workplans and will be a factor in deciding the need for an onsite inspection."

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Device Pilot, cont.

- "If significant concerns are found during the RRA, an on-site inspection of your firm may be scheduled, or communication with Compliance Branch may be considered."
- Since an RRA is not an inspection, FMD-145 does not apply and a copy of the report will not automatically be provided to you. If you wish to obtain a copy of this report, please submit a request using the FDA Freedom of Information Act (FOIA) process…"

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Device Pilot, cont.

- Experience of device manufacturers participating in pilot informed comments to draft guidance
- Not yet used for IVDs (OHT7 Mgt, August 2022)
- Questions about current status of pilot

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Legislative Proposals

- House
  - Mandatory device RRA authority included in prior House version of user fee legislation; not included in final package
- Senate
  - Mandatory device RRA authority included in Senate HELP Committee passed PREVENT

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Draft Guidance

- July 2022 Draft Guidance for Industry: Conducting Remote Regulatory Assessments: Questions and Answers.
  - https://www.fda.gov/media/160173/download
- Agency-wide and includes discussions tailored to both mandatory RRAs, e.g., food and drugs, and voluntary, e.g., medical devices.
  - CDRH is included in the list of organizations within the Agency that prepared the draft guidance.

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AdvaMed Comments

- Submitted Sept. 23, 2022
- Developed with input from ADx members
- Support concept of RRAs
- Appreciate guidance outlining thinking
- Need to reinforce voluntary nature

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AdvaMed Comments Cont.

- Propose refinements to acknowledge the differences between on-site inspections and voluntary RRAs, particularly regarding staffing levels necessary to support RRAs by both FDA and industry.
- Concerned that, as structured in the current draft, some manufacturers may not participate because the benefits will not be perceived to be strong enough to outweigh potential burdens associated with participation and the removal of key protections provided in a traditional in-person inspection.

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AdvaMed Comments, cont.

- Address who at FDA is authorized to initiate a request for an RRA, the mechanism for tracking RRAs within the Agency, and intra-Agency coordination.
- Highlight throughout the document the potential benefits of less frequent or reduced duration/scope of inspection
- Engage in an interactive discussion with the company detailing the contours of the RRA in advance of requesting a company to agree to participate
- Provide daily, interactive, updates during the RRA
- Outline protections for documents and data received from the establishment

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AdvaMed Comments, cont.

- Need for issuance of report for all voluntary RRAs and understanding public availability of report
- Closing any RRA before any inspection, or specifying than an RRA will automatically close with the initiation of an inspection.
- Provide additional public documents outlining the RRA process and internal procedures.

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Questions and Thank you

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