









Center for Drug Evaluation and Research (CDER)

Remote Regulatory Assessments and Expectations

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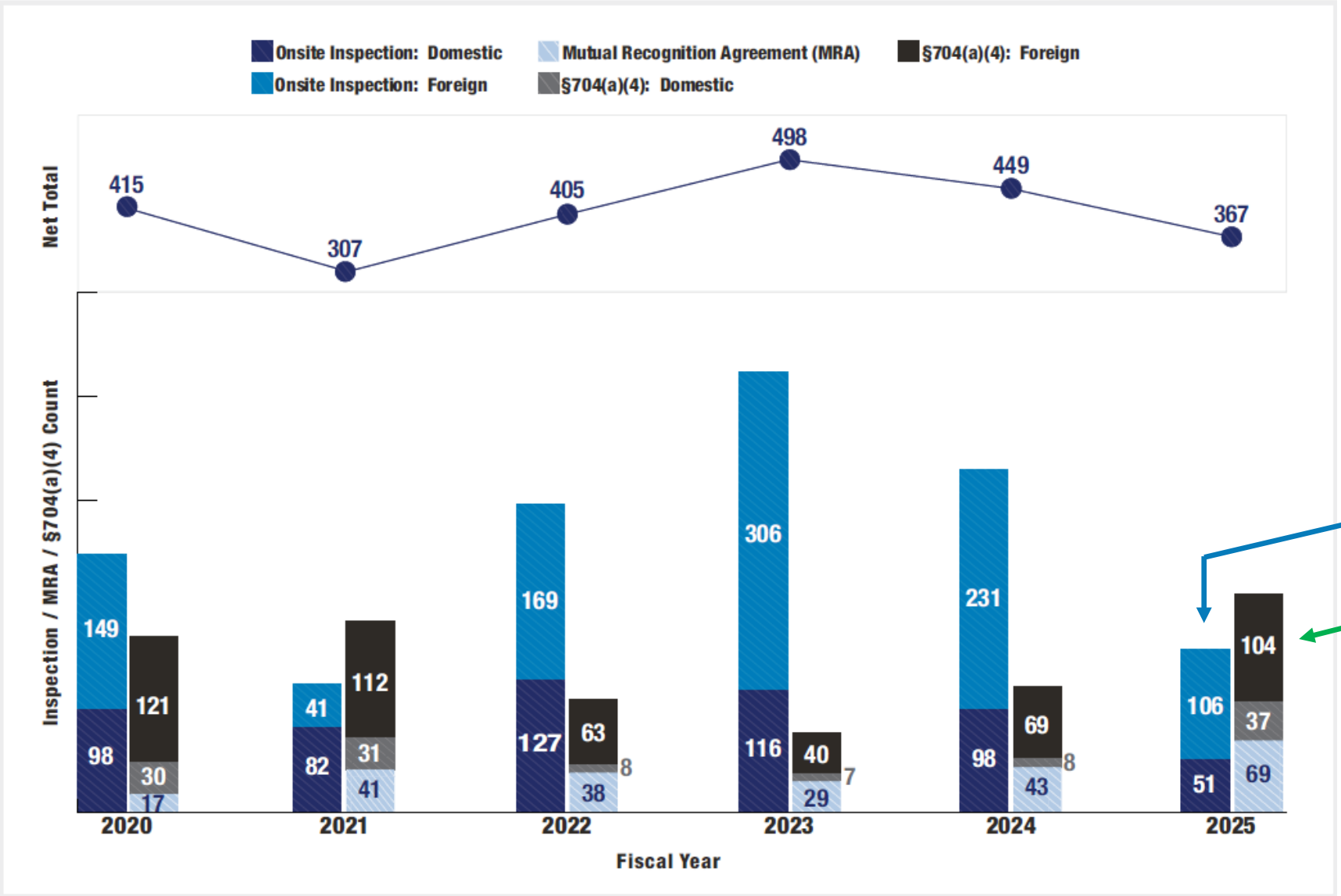
November 2, 2026

Recent Trends in the Use of Alternative Tools



On-site Inspection

Alternative Tools

Report on the State of Pharmaceutical Quality FY2025 https://www.fda.gov/media/188153/download

Remote Regulatory Assessment as Alternative Tools

- FDA may use remote regulatory assessments (RRAs) for an application's facility evaluation, as appropriate and on a case-by-case basis.
  - §704(a)(4) Records Request **in advance** or **in lieu** of a PAI or a PLI.
  - Voluntary Remote interactive evaluation (RIE)
- Decision to initiate or request an RRA is made by FDA.
  - RRAs may be used at any point in the application assessment cycle.
  - One or more tools may be used to aid the assessment.
- RRA is not considered an inspection.
  - Credentials not displayed; FDA Form 482 (Notice of Inspection) or FDA Form 483 (Inspectional Observations) not issued.
- Appropriate use of RRAs helps FDA to maximize facility evaluation efficiency for approval or authorization of marketing submissions.

RRA and Sterility Assurance Tips

- Smoke study videos:
  - Evaluate airflow for turbulence or eddy currents that can act as a channel or reservoir for air contaminants.
  - Should be conducted at the critical areas to demonstrate unidirectional airflow and sweeping action over and away from the product under dynamic conditions.
  - Aseptic manipulations (e.g., interventions) and equipment design should be evaluated.
- Environmental Monitoring Data
  - Trend reports should include data generated by location, shift, room, operator, or other parameters.
  - The quality control unit should investigate results beyond established levels and identify appropriate follow-up actions.
  - Appropriate corrective action should be implemented, as necessary, to prevent future deviations.
- Deviations
  - Deviations are recorded.
  - Appropriate responses to deviations initiated.
- Change controls initiated
  - Written change control program established and the need for revalidation or requalification evaluated.
  - Change control procedures should adequately address issues, as necessary, to prevent future deviations.

Guidance for Industry Sterile Drug Products Produced by Aseptic Processing — Current Good Manufacturing Practice - 2004

Alternative Tools for Facility Assessment Resources

Alternative Tools: Assessing Drug Manufacturing Facilities Identified in Pending Applications Guidance for Industry – September 2025

Conducting Remote Regulatory Assessments Questions and Answers Guidance for Industry – June 2025

Remote Interactive Evaluations of Drug Manufacturing and Bioresearch Monitoring Facilities Draft Guidance for Industry – October 2023

Please attend Science and Regulatory Learning Track: Enhancing Inspection and Remote Assessment Efficiencies to Reduce Approval Delays on Tuesday, November 3, 11:30 a.m. – 12:15 p.m. for additional details from Yiwei Li, Ph.D.