









Center for Drug Evaluation and Research (CDER)

# Facility Assessment for Drug Applications: Inspections and Remote Assessments

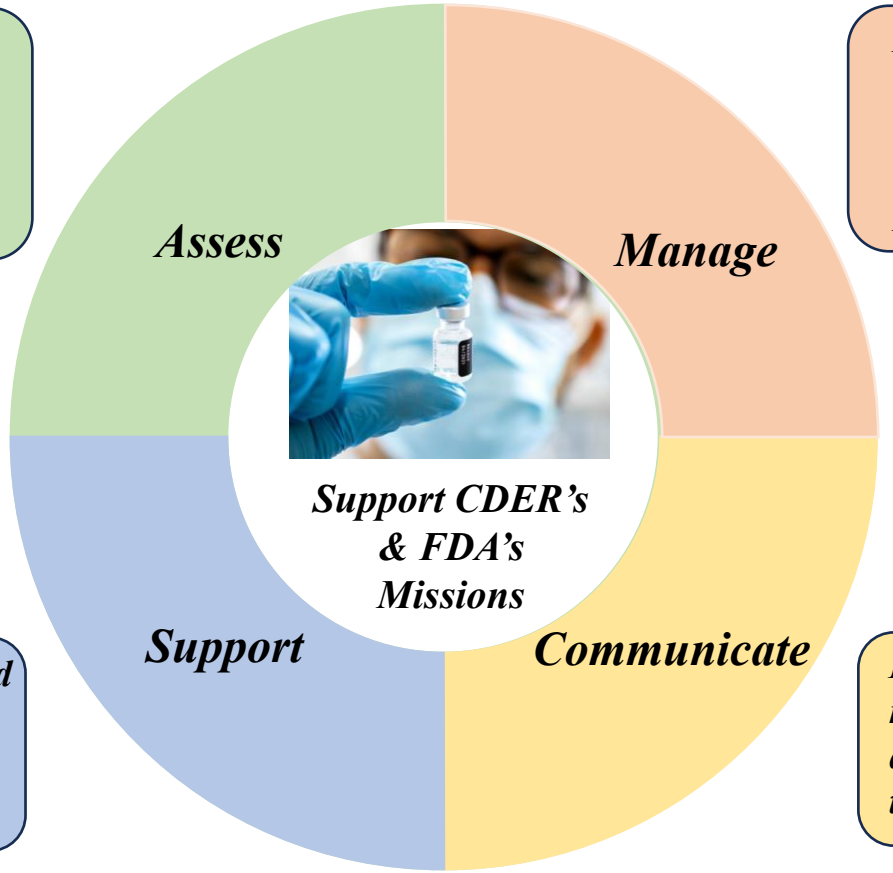
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# Office of Pharmaceutical Manufacturing Assessment

***Assess manufacturing processes, facilities, microbial controls, and sterility assurance for drug product applications; conduct remote regulatory assessment (RRA).***

***Manage and coordinate pre-approval inspections (PAI), pre-license inspections (PLI), and post-approval inspections (PoAI). Participate/lead PAI/PLI/PoAI as needed.***

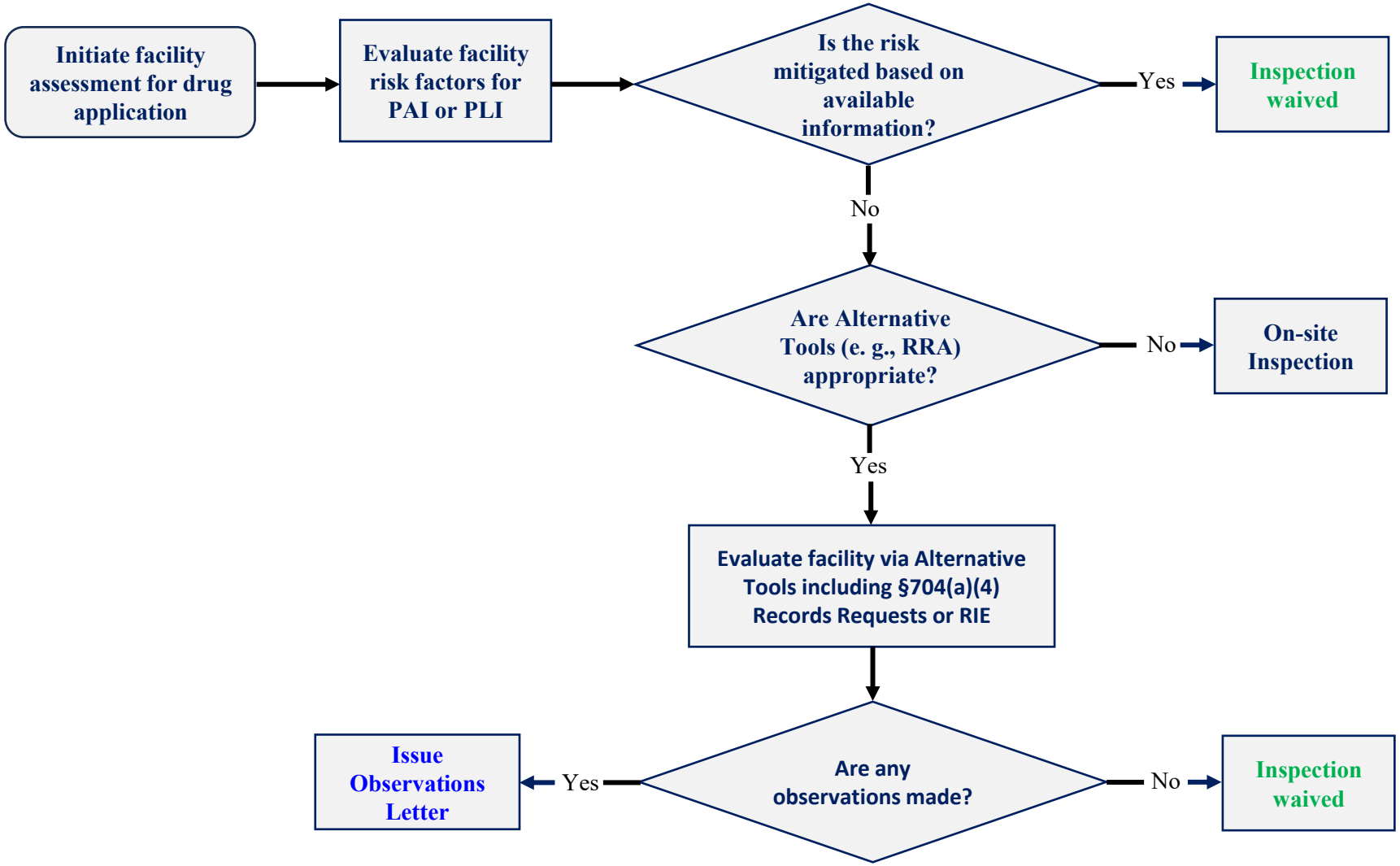



***Act as a central scientific resource and liaison for drug quality, facility standards, and current good manufacturing practice (CGMP).***

***Identify, monitor, and communicate manufacturing risks and post-approval changes across the FDA and the pharmaceutical industry.***

https://www.fda.gov/about-fda/cder-offices-and-divisions/office-pharmaceutical-manufacturing-assessment

# A High-Level Illustration of Facility Assessment at OPMA



# Facility Assessment: Risk Considerations

- OPMA considers the following areas during facility assessment:
  - Product attributes and associated manufacturing risks including scale-up, new technologies, or dosage forms
  - Manufacturing complexities: difficult to execute or monitor state of control
  - Commercial manufacturing experience and process understanding
  - Lack of FDA inspection history
  - Susceptibility of manufacturing process to contamination
  - Significant process changes for supplement applications
  - Quality surveillance intelligence

# 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.

# Using RRA to Assist Facility Evaluation For Drug Application

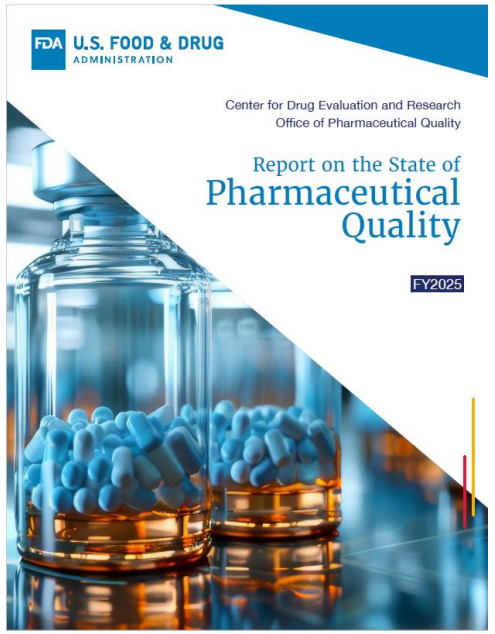
- Example #1 (from a supplement application)
  - DP manufacturing facility proposed for Tablets, >10x increase of batch size
  - Proposed manufacturing equipment not covered during previous inspections
  - No other compliance issues or facility related concerns
  - 704(a)(4) Records Request utilized to assess manufacturing capacity

- Example #2 (from an original application)
  - Proposed injectable product to be sterilized via terminal sterilization (TS)
  - DP manufacturer has inspection history of sterilized filtration but not TS
  - No other compliance issues or facility related concerns
  - 704(a)(4) Records Request utilized to assess autoclave qualification and process validation

- Example #3 (from an original application)
  - Proposed new drug/device combination for aerosol foam
  - Facility had recent and successful inspections on ointments and liquid products
  - No other compliance issues or facility related concerns
  - 704(a)(4) record review followed by RIE utilized to assess new dosage form and operation

***Note: FDA uses RRA for facility evaluation as appropriate and on a case-by-case basis. Each application (and the associated facilities) is assessed independently and the decision to request RRA is made individually. The above examples should not be generalized and considered applicable broadly.***

# Recent Trends In the Use of Alternative Tools



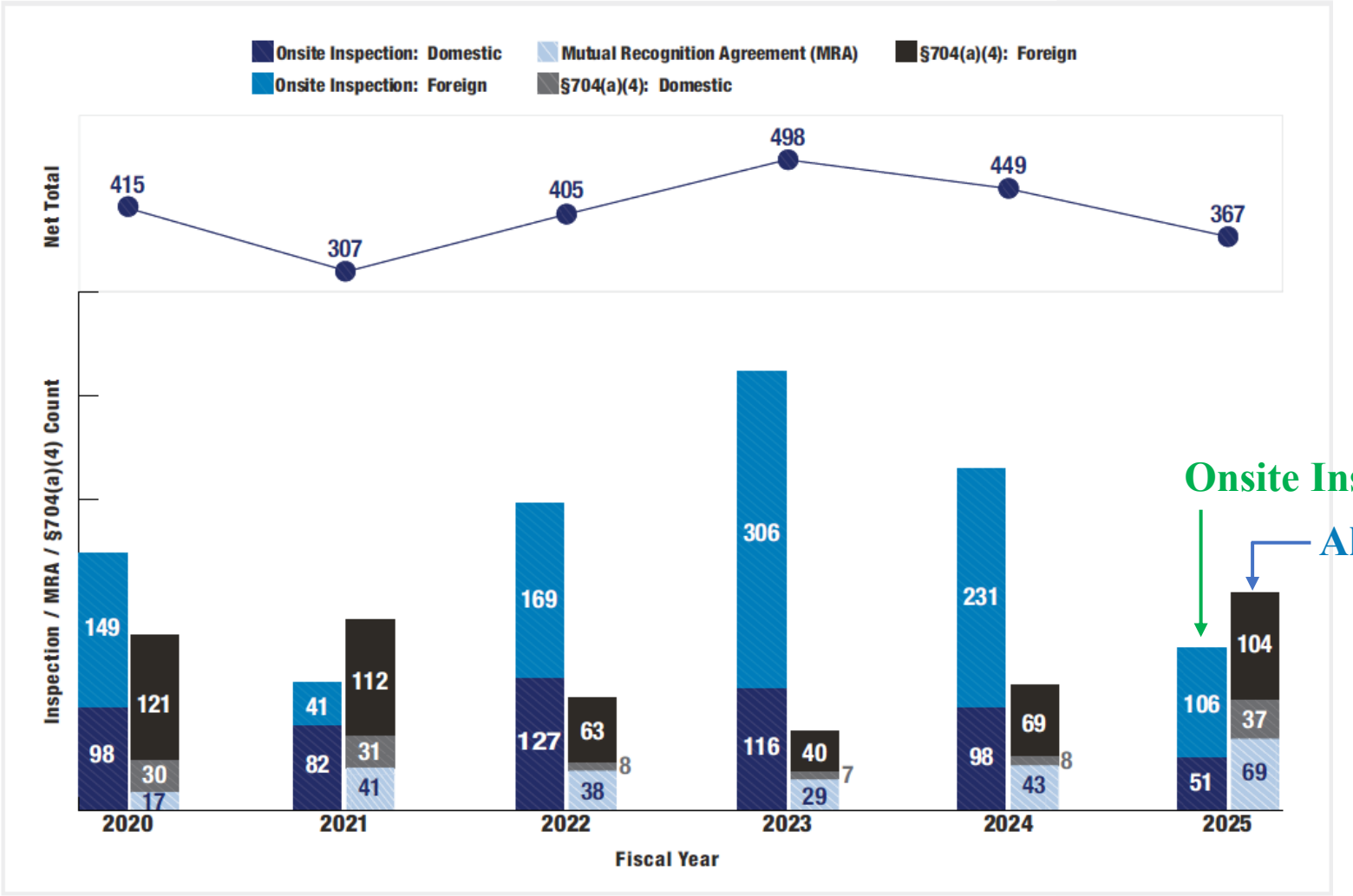




**Figure 6. Application Evaluation Tools for FY 2020-2025: FDA Pre-Approval Inspections, Pre-License Inspections, FD&C Act §704(a)(4) Records Request Reviews, and MRA Partner Inspections**

# Pre-approval/Pre-license Inspections – Tips

- Operate within state of control following regulations and policies
- Review events, understand trends, investigate, and take CAPA when needed
- Ensure documented scientific evidence supporting investigation conclusions
- Ensure product/process understanding and conformance to application commitments
- Implement adequate measures to detect, control, and prevent data integrity issues
- Manage product lifecycle by looking at key post marketing information
- Have a robust Pharmaceutical Quality System (PQS)

# Remote Regulatory Assessment (RRA) – Tips

- Treat §704(a)(4) Records Requests like responding to requests during on-site inspections – commit same level of importance and attention as you would for an inspection.
- Provide complete, clear, and accurate records within the requested timeframe. Organize documents in an easy-to-understand format.
- Ask for clarity as necessary to ensure response will address the record request.
- Respond to Observation Letter within the requested response time.
- Ensure to implement CAPAs and provide updates as appropriate.
- Applicant: ensure your CMOs are prepared for application-specific pre-approval records requests.

# 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