INTEGRATION OF FDA FACILITY EVALUATION AND INSPECTION PROGRAM FOR HUMAN DRUGS: A CONCEPT OF OPERATIONS

CENTER FOR DRUG EVALUATION AND RESEARCH
OFFICE OF INSPECTIONS AND INVESTIGATIONS

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1. INTRODUCTION

This updated Concept of Operations (ConOps) document outlines how the Center for Drug Evaluation and Research (CDER) and the Office of Inspections and Investigations (OII), formerly the Office of Regulatory Affairs, collaborate in a coordinated, programmatically-aligned environment regarding marketing application (hereinafter, application) assessment, inspections, and related compliance activities. It covers Preapproval, Postapproval, Surveillance, and For-Cause Inspection processes, presenting an operating model for establishment[1] evaluation and inspection for human drugs,[2] which has further evolved since the previous ConOps published in 2017.

Included in this revision are establishment and drug evaluation processes using Remote Regulatory Assessments (RRA).[3] This type of evaluation is conducted remotely through an assessment of records or other information submitted by an establishment upon request from FDA under section 704(a)(4) of the Federal Food, Drug, and Cosmetic Act (hereinafter, the Act) or through a Remote Interactive Evaluation (such as remote livestreaming of video of operations, teleconferences, and screen sharing).[4] FDA intends to use a risk-based approach to determine whether to initiate or request an RRA. While RRAs conducted using 704(a)(4) authority **do not satisfy inspection requirements as outlined under section 704(a)(1) of the Act** due to the lack of physical entry into the establishment, RRAs can help the Agency to fulfill its regulatory responsibilities.

This revision also incorporates establishment evaluation processes using inspection information from regulatory partners with which FDA has entered into Mutual Recognition Agreements (MRAs).[5] These MRAs enable regulators to utilize each other's inspection information and findings. FDA may use recent inspection reports from MRA partners to assess manufacturers' compliance with U.S. Current Good Manufacturing Practice (CGMP) requirements, support establishment recommendations for application actions, and ensure that facilities manufacture quality drugs for the U.S. market. Unlike 704(a)(4) assessments, these MRA inspection reports can fulfill the inspection requirements[6] outlined under section 510(h) of the Act.

This revised operating model enables FDA to better handle the growing complexity of the pharmaceutical drug manufacturing landscape and to meet new challenges by:

- Ensuring consistency, efficiency, and transparency in establishment evaluations, inspections, and regulatory decision-making for human drugs across FDA,
- Advancing strategic alignment across CDER and OII functional units by updating and clarifying roles and responsibilities,

[1] This document uses the term "establishment" throughout, understanding it may be used interchangeably with "facility," "manufacturer," or "site."
[2] Other than Pharmacy Compounding and Bioresearch Monitoring (BIMO).
[3] Both OII and CDER may lead RRAs as necessary. See FDA Guidance for Industry: Conducting remote regulatory assessments, questions and answers (June 2025), available at: https://www.fda.gov/media/160173/download.
[4] See FDA Draft Guidance for Industry: Remote Interactive Evaluations of Drug Manufacturing and Bioresearch Monitoring Facilities (October 2023), available at: https://www.fda.gov/media/173286/download. When final, this guidance will represent FDA's current thinking on this topic.
[5] Such as those between the US and EU, US and Switzerland, and US and UK.
[6] FDA's Mutual Recognition Agreements with the European Union, Switzerland, and the United Kingdom provide for the recognition of official inspection reports issued by a regulatory partner for manufacturing establishments located inside and outside of the partner's territory. For more information, see https://www.fda.gov/international-programs/international-arrangements/mutual-recognition-agreements-mra and https://www.fda.gov/media/103391/download.

- Improving FDA's operational capacity and efficiency by enhancing collaboration and reducing redundancy between various CDER and OII offices after the October 2024 reorganization,[7]
- Enhancing the quality of, and increasing access to, establishment and regulatory decisional information across FDA, and
- Meeting User Fee commitments and improving the timelines for regulatory actions to protect public health and promote drug quality, safety, and effectiveness.

The following offices played a significant role in the development of this ConOps:

- Center for Drug Evaluation and Research
  - Office of Pharmaceutical Quality (OPQ)
    - Office of Quality Surveillance (OQS)
    - Office of Pharmaceutical Manufacturing Assessment (OPMA)
  - Office of Compliance (OC)
    - Office of Manufacturing Quality (OMQ)
- Office of Inspections and Investigations[8]
  - Office of Human and Animal Drug Inspectorate (OHADI)

2. PREAPPROVAL EVALUATIONS AND INSPECTIONS: AN OPERATING MODEL

Preapproval Evaluations and Inspections directly support the assessment of applications by assuring that any manufacturing[9] establishment named in an application is capable of manufacturing the corresponding drug in conformance to CGMP requirements and application commitments and that the data submitted in the application are accurate and complete.

- **Preapproval Evaluations are conducted by CDER**. This type of evaluation considers available information about each establishment named in an application, the drug being manufactured, and other information in the application to determine whether a Preapproval Inspection (PAI) or RRA is needed to support decision-making regarding the approvability of an application from a quality perspective.

[7] See: https://www.fda.gov/about-fda/fda-organization/fda-modernization-efforts-establishing-unified-human-foods-program-new-model-field-operations-and and https://www.fda.gov/media/172385/download.
[8] Inspections led by OII may be carried out or led by investigators assigned to the foreign offices under the auspices of the Office of Global Policy and Strategy (OGPS).
[9] Including processing, testing, packaging, and labeling.

- **Preapproval Inspections are generally led by OII[10,11] with CDER participation when appropriate.** This type of inspection directly supports the assessment of applications by evaluating the adequacy of the manufacturing processes and control strategy to ensure drug quality and conformance to application and CGMP requirements. The inspection information is used in conjunction with other information to determine the overall approvability of an application.

- **Remote Regulatory Assessments to support Preapproval Evaluations are generally led by CDER**.[12] The RRA is an evaluation of an FDA-regulated establishment and/or its records, conducted entirely remotely, to evaluate compliance with applicable FDA requirements. The RRA outcome is used to support the overall approvability of an application.

2.1 PLANNING THE STRATEGY FOR THE INSPECTION AND RRA

A Preapproval Evaluation is initiated in conjunction with the submission of an application. At the time of submission, an Integrated Quality Assessment (IQA) Team, composed of assessors and if needed, subject matter experts (SMEs) from different disciplines in OPQ, is assembled to perform a quality assessment of the application. If an inspection is requested, the inspection team[13] is fully apprised of any issue uncovered by the IQA Team, and vice versa. The IQA Team is responsible for providing the final quality recommendation for applications, which considers the Preapproval Evaluation and the outcome of the PAI (if conducted), in advance of Generic Drug User Fee Amendments (GDUFA) or Prescription Drug User Fee Act (PDUFA) goal dates.

OPMA performs an initial establishment risk assessment based on information in the application, the establishment's inspection history (including MRA inspections, if available), quality intelligence information provided by OQS, and other relevant information from OHADI and OMQ. Once the initial establishment risk assessment is completed, the OPMA assessor, with input from other IQA Team members, determines whether an inspection will be needed. This determination is based on the risk assessment findings, along with an evaluation of the quality and manufacturing information provided in the application.

If a PAI is deemed necessary, the IQA Team identifies areas of concern found during assessment of the application for inspectional coverage and conveys them to the OHADI Preapproval Manager (PAM) associated with the PAI request, who subsequently communicates this information to an inspection lead. If OPMA determines that a PAI is not necessary based on its risk assessment of the available quality and manufacturing information including those from the application, OPMA may

[10] PAIs requested by CDER are led by OII but may be carried out by investigators assigned to the foreign offices under the auspices of the Office of Global Policy and Strategy (OGPS), or under certain circumstances by CDER staff, provided that all team members conducting PAIs have appropriate training and experience.
[11] The process for Preapproval Inspections for biological product applications, where CDER generally leads, remains unchanged as part of this ConOps.
[12] RRAs to support Preapproval Evaluations may be led by OII under certain circumstances, provided that there is discussion with the IQA Team.
[13] For the purposes of this document, "inspection team" refers to one or more investigators or appropriately trained individual(s) conducting an inspection and includes inspections performed by a single investigator or appropriately trained individual.

conduct an RRA to address outstanding concerns identified by the IQA Team and continues to monitor the establishment's CGMP status as related to the pending application.

2.2 CONDUCTING THE INSPECTION AND RRA

PAIs cover the areas of concern outlined by the IQA Team and are conducted in accordance with the PAI Compliance Program.[14] The inspection lead[15] documents observations and issues a Form FDA 483 when significant objectionable conditions[16] are identified. If the PAI is conducted by an inspection team, all team members are responsible for preparing for, executing, and documenting the inspection, including contributing to the Establishment Inspection Report (EIR) and its corresponding inspection documents (i.e., exhibits, attachments, etc.). Collectively, the EIR and inspection documents constitute the "complete EIR package," which documents all items covered during the inspection. The inspection team is responsible for ensuring the complete EIR package is endorsed within 45 days of the inspection close. If this 45-day timeline exceeds application-related deadlines, the necessary information should be communicated promptly from the inspection lead to the IQA Team to inform timely decision making ahead of any application-related deadlines.

For RRAs, all staff follow FDA Remote Regulatory Assessment Standard Practices.[17] An RRA Report is completed at the end of the assessment.

2.3 COMMUNICATING THE FINDINGS OF THE INSPECTION AND RRA

Upon completion of the inspection, the inspection lead generates the Initial Field Recommendation (IFR) and the EIR, which are then assessed and endorsed by their appropriate management. For inspections with an IFR of No Action Indicated (NAI), OHADI makes the final classification. For inspections with an IFR of Voluntary Action Indicated (VAI) or Official Action Indicated (OAI), the inspection team refers the matter with the complete EIR package to OPMA. OPMA makes a final classification by conducting a risk-based assessment of the complete EIR package and the establishment's written response to observations in the Form FDA 483. OPMA's final classification determines the adequacy of an establishment to support application approval. OPMA may address any outstanding issues or obtain needed clarifications through additional Information Requests, if needed. OPMA completes the final classification within 45 days of receiving both the complete EIR package and the establishment's response, or by the applicable application-related due date, whichever is sooner.

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[14] Preapproval Inspections Compliance Program 7346.832, available at: https://www.fda.gov/media/193382/download.
[15] The PAI lead seeks input from inspection team members when the inspection is conducted by an inspection team as opposed to only by the PAI lead.
[16] As defined in Investigations Operations Manual (2026), available at: https://www.fda.gov/media/166525/download, the term "significant objectionable conditions" is synonymous with "significant inspection findings" in Drug Manufacturing Inspections Compliance Program 7356.002 and "significant issues" in Preapproval Inspections Compliance Program 7346.832.
[17] Staff Manual Guide 6001.1, available at: https://www.fda.gov/media/186992/download.

In situations where the inspection included both Surveillance and PAI coverage, OMQ and OPQ coordinate as needed to ensure alignment on inspection findings, regulatory considerations, and follow-up actions. If the establishment is considered inadequate to support the application approval, OPMA will issue a letter to the establishment, outlining the outstanding application-specific concerns. Significant objectionable conditions that impact marketed products are managed as described in the Surveillance Inspection Model in Section (4) below. The lead office performing the RRA communicates the assessment outcome and RRA report to the establishment.

When the scope of an inspection or RRA includes an assessment of a new Profile Class Code (PCC), the inspection or RRA lead adds the PCC to the appropriate establishment database only if the establishment is found acceptable. The addition of the PCC ensures that the stakeholders that access FDA information systems have the information that they require about the establishment.

3. POSTAPPROVAL EVALUATIONS AND INSPECTIONS: AN OPERATING MODEL

Postapproval Inspections (PoAIs) are similar to PAIs in that they are drug-specific but are conducted after applications have been approved within the timeframes specified in the Postapproval Inspections Compliance Program.[18] This type of inspection focuses largely on the process validation lifecycle and any manufacturing changes that may have occurred following approval. Changes in perceived risk may also initiate such an inspection, even in cases where a PAI was not deemed necessary.

- **Postapproval Inspections are led by OII with CDER participation when appropriate**. This type of inspection ensures commercial-scale processes for an approved drug are executed per application commitments and CGMP requirements. The inspection information is used to update lifecycle risk for a specific drug and/or to determine any regulatory actions.

- **Remote Regulatory Assessments are generally led by CDER**.[19] The information is used to support Postapproval Evaluations and update lifecycle risk for a specific drug and/or to determine further agency actions.

3.1 PLANNING THE STRATEGY FOR THE INSPECTION AND RRA

The IQA Team summarizes potential risks identified during application assessment and approval to inform OPMA's decision to generate an assignment for a Postapproval Evaluation conducted either through inspection or RRA. To the extent feasible, prior to issuing an inspection assignment or conducting an RRA, OPMA confirms that the drug has reached the market after approval through either regulatory submission information or quality surveillance intelligence from OQS. If a PoAI is deemed necessary, OPMA prepares an assignment to provide recommendations on areas of concern for PoAI coverage. After the assignment is prepared, OHADI schedules the PoAI. If a PoAI

[18] Postapproval Inspections Compliance Program 7356.843, available at: https://www.fda.gov/media/164791/download.
[19] See footnote 12.

is not deemed necessary, OPMA conducts,[20] when needed, an RRA to address outstanding concerns identified by the IQA team during the application assessment.

3.2 CONDUCTING THE INSPECTION AND RRA

PoAIs are conducted following the Postapproval Inspections Compliance Program, and they cover the areas of concern identified by the IQA team. If the PoAI lead or inspection team observes significant objectionable conditions that warrant input from OPMA, OC, and/or OQS, a discussion should be held among these groups before the inspection closes. At this point, if deemed necessary, the inspection may expand to include Surveillance Inspection coverage based on the Drug Manufacturing Inspections Compliance Program,[21] following the Surveillance Inspection Model in Section 4 below. The PoAI lead documents observations and issues a Form FDA 483 when significant objectionable conditions are identified.

RRAs focus on the residual risks identified by the IQA team during application assessment. If significant findings are identified, OPMA will share and discuss these findings with OC and/or OQS, who may subsequently initiate For-Cause or Surveillance Inspections.

3.3 COMMUNICATING THE FINDINGS OF THE INSPECTION AND RRA

When significant objectionable conditions are observed, the PoAI lead discusses the findings with the establishment and documents them on the Form FDA 483 in accordance with operational policy. The inspection team is responsible for ensuring the complete EIR package is endorsed within 45 days of the inspection close. OPMA completes the final assessment and recommendation in the following 45 days. OPMA, in coordination with other relevant OPQ sub-offices, initiates follow-up action according to the Postapproval Compliance Program with the applicant, establishment, and as needed, related programs (e.g., OHADI, OC, and/or Office of the Chief Counsel (OCC)) in the following 10 days. If a CGMP surveillance coverage is added, initial VAIs and OAIs are referred to OMQ, per the surveillance process (see section 4).

4. SURVEILLANCE INSPECTIONS: AN OPERATING MODEL

Surveillance Inspections focus on establishments that manufacture[22] prescription and over-the-counter monograph drug products, as well as in-process materials and drug substances used in the drug products. This type of inspection is meant to monitor conformance to CGMP requirements and is not necessarily an assessment of a specific drug. Instead, it is a system-based inspection. The purpose of this type of inspection is to identify systemic issues and/or adverse trends at establishments so that FDA can develop strategies to mitigate them.

[20] See footnote 12.
[21] Drug Manufacturing Inspections Compliance Program 7356.002, available at: https://www.fda.gov/media/75167/download.
[22] Including processing, testing, packaging, and labeling.

- **Surveillance Inspections are led by OII with CDER participation when requested by OII.** OII conducts Surveillance Inspections at establishments prioritized by CDER's risk-based site selection model.

4.1 PLANNING THE STRATEGY FOR THE INSPECTION

OQS developed and maintains the CDER Facilities Catalog. OQS maintains, updates, and uses a risk-based Site Selection Model to assess the relative quality risks for establishments in the CDER Facilities Catalog. This model generates a risk-based ranking of establishments to annually prioritize the highest-risk establishments for surveillance inspection. After OQS generates and assigns a list of prioritized establishments for inspection, OHADI schedules Surveillance Inspections based on their drug inspectional capacity. By request and in advance of a scheduled Surveillance Inspection, OQS prepares an up-to-date Site Dossier[23] to streamline inspection coverage. The Site Dossier includes, but is not limited to, information on establishment inspection history, recalls, shortages, customer complaints, foreign regulatory inspection outcomes, information on submitted Field Alert Reports (FARs) or Biological Product Defect Reports (BPDRs), and a listing of all drug products manufactured at the establishment. The inspection team then conducts an on-site inspection based on the relevant portions of the Drug Manufacturing Inspections Compliance Program and quality information summarized in the Site Dossier.

Quality System Assessments through Remote Regulatory Assessments:[24] A quality systems assessment may be considered for establishments that are in Travel Warning Areas (Level 3 or higher, based on the Department of State Travel Advisories) or other areas identified by FDA in which an establishment inspection mandated by section 510(h) of the Act is not feasible within the fiscal year of assignments.

Mutual Recognition Agreement: Through established procedures, OII and CDER generally request, assess, and classify MRA inspection reports for relevant establishments identified for Surveillance Inspection. These classifications satisfy inspection requirements under section 510(h) of the Act. Classification outcomes follow the same process as detailed below.

4.2 CONDUCTING THE INSPECTION

The inspection team conducts the on-site inspection, with the CDER SME when requested by OII. If the inspection team observes conditions that, for example, may result in an imminent health hazard and warrant input from OMQ, a discussion should be held among these groups before the inspection closes. OHADI and OMQ collaboratively decide whether to continue the inspection to gather additional information or to close the inspection to initiate a prompt regulatory action. The inspection team documents observations, discusses them with the establishment, and issues a Form FDA 483 when significant objectionable conditions are identified, in accordance with operational policy.

[23] Site Dossiers are provided commensurate with Surveillance Inspection schedule and resource capacity.
[24] Although not an inspection, 704(a)(4) quality systems assessment can be used in preparation of, and influence the scheduling and priority of, inspections.

If the inspection team becomes aware during the inspection of any activities that may impact a drug's ongoing production or distribution, the inspection team should follow notification processes to ensure CDER's Drug Shortage Staff (DSS) is promptly alerted (DRUGSHORTAGES@fda.hhs.gov). The inspection team should also request that the establishment notify the DSS of any potential decisions that could impact a drug's production or distribution.

4.3 COMMUNICATING THE FINDINGS OF THE INSPECTION

Within 45 days of the close of a Surveillance Inspection, OHADI completes the complete EIR package, and issues an initial classification from the following:

- No Action Indicated (NAI)
- Voluntary Action Indicated (VAI)
- Official Action Indicated (OAI)

NAI Classification

If the inspection indicates an NAI classification and no further action is recommended, OHADI will issue a Field Management Directive (FMD)-145/decisional letter within 90 days following the close of the inspection.

VAI/OAI Classification

When significant objectionable conditions are observed, OHADI discusses the findings with the establishment, documents them on the Form FDA 483 in accordance with operational policy, and informs CDER as soon as practical, but at most within two days of the close of the inspection, that an establishment is potentially OAI (pOAI) by entering such information into the appropriate systems and issuing an IFR.

For **initial** VAI or OAI classifications, OHADI refers the matter and complete EIR package to OMQ within 45 days of the close of the inspection. OMQ makes a final classification and, subject to input from the OCC, issues a decisional letter in the following 45 days (90 days following the close of the inspection).[25] Classification letters may be withheld in instances where multiple FDA Centers or Programs are involved, as the content and regulatory implications may not be uniformly applicable or appropriate across the various regulatory programs. In instances where the inspection includes both surveillance and preapproval coverage, OMQ and OPQ coordinate as appropriate to ensure alignment on inspection findings, regulatory considerations, and follow-up actions.

For **final** VAI classifications, OMQ issues an FMD-145/decisional letter and includes the EIR, finalizes the inspection classification, and updates PCCs no later than 45 days following the receipt of the complete EIR package.

[25] Establishments classified as OAI do not receive the EIR concurrently with their classification letter.

For **final** OAI classifications, OMQ updates any potential OAI Alerts (if needed) and takes an appropriate action within three months of the FMD-145/decisional letter. Unlike VAI classifications, OMQ may hold release of the EIR until the appropriate action is determined. OMQ and OHADI collaborate on interactions with establishments following enforcement actions.

For reclassification of an inspection,[26] OHADI is notified of the change in classification and is provided with a written description of the reason(s) for the classification change within 10 days of the final classification decision.

If an inspection results in an FDA Regulatory Meeting,[27] OII representative(s) will be invited. Additionally, CDER-issued regulatory letters and correspondence (e.g., Warning Letters) will include a courtesy copy provided to OII.

4.4 SURVEILLANCE ANALYSIS

As part of its general remit, OQS conducts post-classification analysis of relevant quality information available to examine trends in quality issues observed across establishments, drug products, regions, etc., using routine processes. OQS uses this analysis to identify key areas of coverage on the next inspection of an establishment. OQS intelligence is summarized in multiple dashboards, reports, and dossiers.

5. FOR-CAUSE INSPECTIONS: AN OPERATING MODEL

For-Cause Inspections are initiated in response to a specific event or information that brings into question the compliance and quality of a manufacturing practice, establishment, process, or drug product. This type of inspection is meant to gather additional information to determine the quality of a drug and to determine whether enforcement actions are warranted. These inspections can also be used to investigate compliance with applicant obligations and to follow up to verify corrective actions following enforcement actions.

- **For-Cause Inspections are led by OII with CDER participation when appropriate**. OII conducts For-Cause Inspections on establishments identified by OII, CDER, or other sources. For-Cause Inspections can focus on specific issues and evaluate an establishment's conformance to CGMP.

5.1 PLANNING THE STRATEGY FOR THE INSPECTION

Requests for For-Cause Inspections are generally[28] initiated by OC or OPQ. For-Cause Inspection assignments intended to cover other program areas (e.g., unapproved drug product and bioresearch

[26] Applies to both initial OAI reclassified to final NAI/VAI or initial NAI/VAI reclassified to final OAI.
[27] Regulatory Procedures Manual, Chapter 10, available at: https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-manuals/regulatory-procedures-manual.
[28] Other offices can request For-Cause assignments in the event of an urgent public health emergency.

monitoring) are not covered by this operating model. If OC or OPQ determines a For-Cause Inspection is warranted, this CDER office prepares an assignment that identifies the areas of required coverage and/or refers to the Drug Manufacturing Inspections Compliance Program.

Assignments are issued per OHADI assignment clearance processes. OHADI schedules the inspection, dependent on risk and priorities in consultation with CDER. An inspection team conducts the on-site inspection, though a SME from CDER may participate when appropriate. The inspection team develops an on-site inspection strategy based on the coverage requirements described in the assignment and conducts a pre-inspection briefing, if necessary.

For Cause Remote Regulatory Assessments:[29] Information requests, targeted coverage, and full quality systems assessment may be considered for establishments and generally follow the For-Cause process for inspection. Various offices may issue the RRA.

Mutual Recognition Agreement: OC and OPQ, in discussion with OHADI, determine on a case-by-case basis whether to request an inspection from an MRA partner. Through established procedures, OHADI requests, assesses, and initially classifies MRA inspection reports or MRA inspections for For-Cause assignments. Final classification for For-Cause MRA inspections follows the For-Cause inspection process, as illustrated in Attachment 2.

5.2 CONDUCTING THE INSPECTION

If significant objectionable conditions are identified, the inspection team discusses these observations with the initiating office and involves other offices (e.g., OPMA, OQS, and/or OC), as appropriate, to discuss whether to continue the inspection to gather additional information or to close the inspection and initiate a prompt regulatory action. For observations which could impact multiple commodities (devices, biologics, etc.), impacted OII programs and respective Centers should be consulted. The inspection team documents observations, discusses them with the establishment, and issues a Form FDA 483 when significant objectionable conditions are identified, in accordance with operational policy.

If, during the inspection, the inspection team becomes aware of any activities that may impact a drug's ongoing production or distribution, the inspection team should follow notification processes to ensure CDER's Drug Shortage Staff (DSS) is promptly alerted (DRUGSHORTAGES@fda.hhs.gov). The inspection team should also request that the establishment notify DSS of any potential decisions that could impact a drug's production or distribution.

5.3 COMMUNICATING THE FINDINGS OF THE INSPECTION

Within 45 days of the close of a For-Cause Inspection, OHADI completes the complete EIR package, and issues an initial classification from the following:

- No Action Indicated (NAI)
- Voluntary Action Indicated (VAI)
- Official Action Indicated (OAI)

[29] Although not an inspection, 704(a)(4) quality systems assessment can be used in preparation for, and influence the scheduling and priority of, inspections.

NAI Classification

If the initial establishment inspection indicates an NAI classification and no further action is recommended, OHADI completes, and makes available for assessment by the initiating office, a complete EIR package within 45 days of the close of the inspection. The initiating office then issues an FMD-145/decisional letter, finalizes the inspection classification, and updates PCCs (if necessary) in the appropriate systems no later than 90 days, following the close of the inspection.

VAI/OAI Classification

See Section 4.3, Communicating the Findings of the Inspection, VAI/OAI Classification.

6. APPROVALS

The signatures of the people below indicate an understanding of the purpose and content of this document by those signing it. By signing this document, you indicate that you approve of the proposed project outlined in this business case. The Working Group will move to an implementation phase, if needed, to fully develop the new processes and policies necessary to fully operationalize this operating model.

Approver Name	Title	Signature	Date
Michael Kopcha	Director, Office of Pharmaceutical Quality, Center for Drug Evaluation and Research		
Jill Furman	Director, Office of Compliance, Center for Drug Evaluation and Research		
Ivy Sweeney	Director (Acting), Office of Human and Animal Drug Inspectorate, Office of Inspections and Investigations		
Rebecca Dowd	Deputy Director (Acting), Office of Human and Animal Drug Inspectorate, Office of Inspections and Investigations		

7. ATTACHMENTS

Attachment 1: Integrated Quality Assessment: Roles and Responsibilities
Attachment 2: Flow diagram for Drug Manufacturing Inspections
Attachment 3: RACI charts for Preapproval, Surveillance, Postapproval, and For-Cause Establishment Evaluations/Inspections

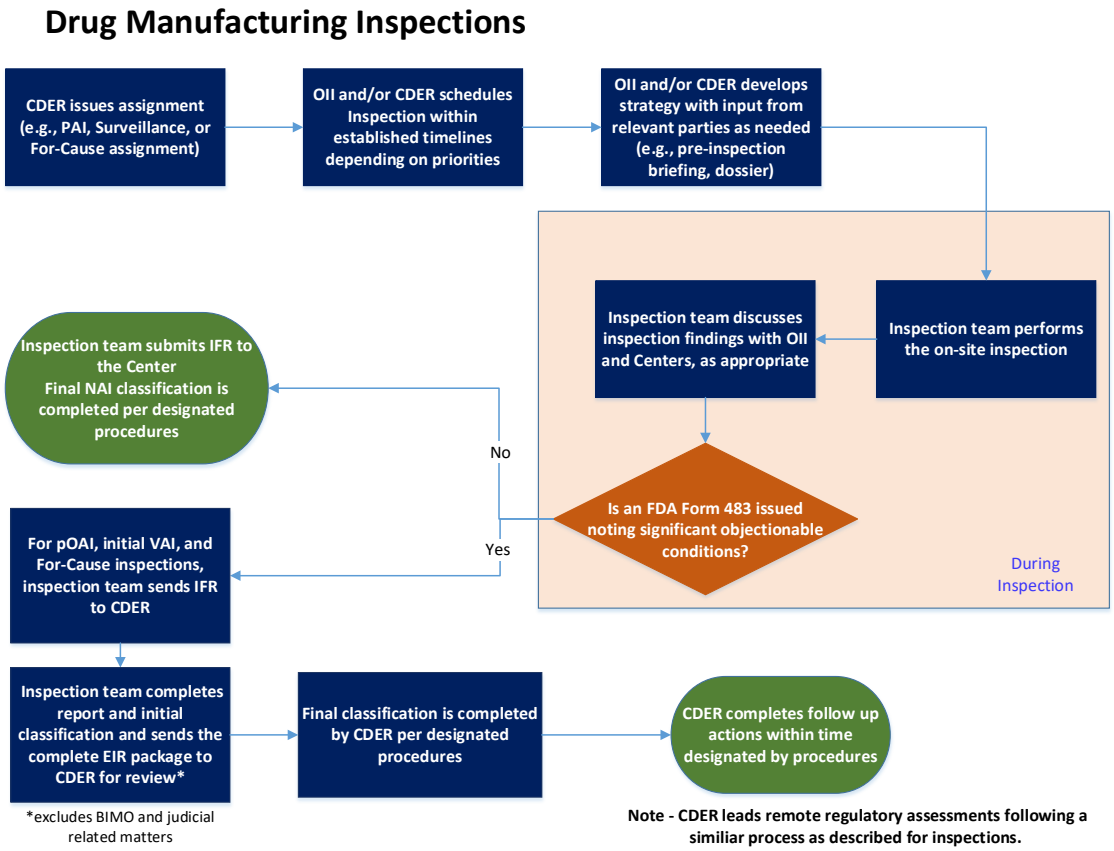
Attachment 1: Integrated Quality Assessment: Roles and Responsibilities

The Integrated Quality Assessment (IQA) Team provides aligned, patient-focused, and risk-based drug product quality recommendations inclusive of drug substance, drug product, biopharmaceutics, manufacturing, and facilities disciplines. The IQA Team integrates the preapproval inspection into the application assessment process. OHADI investigators are fully apprised of any issue uncovered by CDER assessors that may impact the inspection coverage and/or the approvability of an application, and vice versa. The roles and responsibilities of IQA team members are listed in Table 1. The IQA Team is responsible for the assessment and overall quality recommendation for applications, including the preapproval establishment evaluation, determination of PAI necessity, identification of inspection coverage areas related to the product and application, and determination of application approvability from a quality perspective. The quality assessment and recommendation is provided in advance of the GDUFA or PDUFA goal dates, as applicable.

TABLE 1. Integrated Quality Assessment (IQA) Team Roles and Responsibilities

Role / Task	Responsibility in IQA Team
Scientific Content/Initial Risk Assessment	Application Technical Lead (ATL) / IQA Team
Process and Timeline	Regulatory Business Project Manager (RBPM)
Assessment of Drug Substance/Drug Master File	Drug Substance Assessor
Assessment of Drug Product, Labeling, and Package Insert	Drug Product Assessor
Assessment of Manufacturing Process/Sterility Assurance/Facilities	Manufacturing Assessor
Assessment of Biopharmaceutics When Needed	Biopharmaceutics Assessor
Preapproval Inspections When Needed	OHADI PAI Leads/OPQ Assessor(s)

Attachment 2: Flow Diagram



Attachment 3: RACI charts for Preapproval, Surveillance, Postapproval, and For-Cause Establishment Evaluations/Inspections

RACI Chart for Preapproval Inspection

R: Responsibility; A: Accountability; C: Consulted; I: Informed

Tasks	OPQ/OPMA	OPQ (IQA)	OII/OHADI	CDER	OII
Conduct establishment evaluation	R	C	I	A	-
Assess accuracy and integrity of the application	C	R	I	A	-
Risk-based inspection determination	R	C	I	A	-
Provide input for inspection coverage	R	C	I	A	-
Develop inspection strategy	C	C	R	-	A
Schedule inspection	I	I	R	-	A
Conduct inspection*	C	C	R	-	A
Issue Form FDA 483, as necessary	C	C	R	-	A
Complete inspection report and make NAI final classification	C	C	R	-	A
Review the inspection report and make VAI/OAI final classification	R	C	C	A	-
Monitor establishment status	R	I	I	A	-
Provide establishment recommendation	R	I	I	A	-
Issue IR/CR, as appropriate	C	R	I	A	-

* See Footnote 10

RACI Chart for Postapproval Inspection Process

R: Responsibility; A: Accountability; C: Consulted; I: Informed

Tasks	OPQ/OPMA	OII/OHADI	CDER	OII
Identify high risk products / establishments for post-approval coverage	R	I	A	-
Prepare and issue assignment	R	C	A	-
Schedule Postapproval Inspection	I	R	-	A
Develop inspection coverage	C	R	-	A
Conduct inspection	C	R	-	A
Discuss inspection findings	C	R	-	A
Issue Form FDA 483, as needed	C	R	-	A
Complete report and initial recommendation in 45 days post- inspection	I	R	-	A
Complete final recommendation in 45 days	R	C	A	-
Complete follow up actions in 10 days	R	C	A	-

RACI Chart for Surveillance Inspection

R: Responsibility; A: Accountability; C: Consulted; I: Informed

Tasks	OPQ/OQS	OII/OHADI	OC/OMQ	CDER	OII
Maintain CDER Facilities Catalog	R	C	I	A	-
Develop Site Selection Model	R	C	I	A	-
Select establishments for Surveillance Inspection	R	C	I	A	-
Schedule inspection	I	R	I	-	A
Prepare Site Dossier	R	C	I	A	-
Develop on-site inspection strategy	C	R	I	-	A
Conduct inspection	I	R	I	-	A
Convene discussion, as appropriate, if significant objectionable conditions identified	C	R	C	-	A
Issue Form FDA 483, as necessary	I	R	I	-	A
Complete report and initial classification in 45 days post-inspection	I	R	I	-	A
Complete final classification for NAIs in 45 days and issue decisional letter 90 days post-inspection	I	R	I	-	A
Complete VAI/OAI final classification and issue VAI/OAI decisional letter within 90 days post-inspection	C	C	R	A	-
If OAI is reclassified, issue NAI or VAI decisional letter in 10 days post final classification	I	I	R	A	-
Implement appropriate action for OAIs within 3 months of decisional letter	C	C	R	A	-
Conduct trend analysis	R	I	I	A	-

RACI Chart for For-Cause Inspection

R: Responsibility; A: Accountability; C: Consulted; I: Informed

Tasks	CDER (OC, OQS, or OPMA)	OII/OHADI	CDER	OII
Initiate For-Cause Inspection assignment	R	I	A	-
Prepare assignment	R	C	A	-
Schedule For-Cause Inspection	C	R	-	A
Form inspection team	C	R	-	A
Develop inspection strategy	C	R	-	A
Conduct inspection	C	R	-	A
Discuss inspection findings	C	R	-	A
Issue Form FDA 483, as needed	C	R	-	A
Complete initial classification and inspection report in 45 days post-inspection	I	R	-	A
Complete final assessment and/or final classification in 45 days	R*	C	A	-
Complete follow-up actions within 6 months post-inspection	R*	C	A	-

* If significant objectionable conditions are identified, the inspection is generally transferred to OMQ and may involve the other initiating CDER offices.