PRACTICAL INDUSTRY PERSPECTIVE

Leveraging Facility Quality History, Digital Readiness & Risk-Based Inspection Decision Making to Reduce Approval Delays

Enhancing Inspection and Remote Assessment Efficiencies to Reduce Approval Delays

Piyush Modi
Director, Regulatory Affairs | Amneal Pharmaceuticals

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THE OPPORTUNITY: MAKE THE FACILITY EASIER TO ASSESS

Three evidence streams can reduce avoidable uncertainty before it becomes a late-cycle delay.

POLL • How many organizations here could retrieve all critical inspection records within 24 hours today?

1 FACILITY QUALITY HISTORY

Present a complete facility story: capability, compliance history, major changes, and current quality signals, not just the last inspection classification.

2 DIGITAL READINESS

Make records reviewable, traceable, and consistent across applications and facility systems while protecting confidential information.

3 RISK-BASED ALIGNMENT

Focus the evidence package on what is new, complex, different or uncertain for the proposed product and manufacturing operations.

Earlier, more confident facility decision

Goal: reduce avoidable uncertainty–not "avoid inspection."

WHAT DRIVES A RISK-BASED PREAPPROVAL FACILITY DECISION?

FDA's 2026 PAI compliance program reinforces a holistic assessment of product, process, facility and information risk.

Product and Process risk

Complexity, criticality, CQAs and how well the process is understood/ controlled

Facility Capability

Proposed operations vs. what the facility has demonstrated it can do

Compliance & inspection history

Prior findings, status, EIRs, regulatory actions and relevance to the proposed operations

Need for a preapproval inspection?

Industry implication: Organize evidence around the unresolved risk, not around the org chart.

Application Accuracy & Reliability

Does the facility operation match what the application says? Is the submitted data trustworthy?

Quality / Risk signals

Recalls, complaints, FARs, defect reports and other signals that change the risk picture

Available alternative evidence

Prior FDA/MRA information, records requests and other tools that may answer the question.

Source: FDA Compliance Program 7346.832, Preapproval Inspections (issued June 29, 2026), Part II.2.A.

TURN “QUALITY HISTORY” INTO A DECISION-USEFUL FACILITY NARRATIVE

A mature facility should be able to explain what is unchanged, what changed, and what evidence closes the remaining risk.

1 RECENT REGULATORY HISTORY

- Scope and relevance of recent FDA / MRA inspections
- Classification and significant observations
- CAPA effectiveness and recurrence
- Open commitments or unresolved issues

2 DEMONSTRATED CAPABILITY

- Similar technologies / unit operations
- Sterile vs. non-sterile complexity
- Scale and commercial experience
- Testing capability and data integrity controls

3 CHANGES SINCE LAST ASSESSMENT

- Major equipment / process changes
- New data systems or laboratories
- Facility expansion / new lines
- PQS or leadership changes affecting execution

4 CURRENT QUALITY SIGNALS

- Deviations and recurring trends
- Complaints / recalls / FARs
- OOS / OOT patterns
- Supplier / raw material risks relevant to product

A practical one-page facility risk summary

What is unchanged → What changed → Evidence available → Remaining risk → Accountable owner

A “strong compliance history” alone is not enough; relevance to the proposed manufacturing responsibility is what makes history useful.

DIGITAL READINESS: MAKE EVIDENCE FAST TO RETRIEVE, EASY TO TRACE, HARD TO CONTRADICT

Remote and records-based assessments are most effective when evidence is organized and the narrative is consistent.

A	**Data organization**	Indexed records, clear metadata, version control, translations, and direct links to underlying raw data.
B	**Application-to-floor traceability**	Map CMC statements to SOPs, batch records, validation packages, equipment and current site practice.
C	**Remote review capability**	Secure exchange, tested connectivity, document display, virtual walkthrough capability and available SMEs.
D	**Response governance**	One command center, one issue log, one QA review path, and consistent answers from applicant + facility.

DIGITAL INSPECTION-READINESS PACK

Pre-indexed | **Traceable**

Current | **Consistent**

- ❑ Facility / system overview and change map
- ❑ Executed batch + validation evidence
- ❑ Data-integrity / audit-trail support
- ❑ Deviation / CAPA packages
- ❑ SME matrix and escalation route
- ❑ Secure sharing + remote dry run

Transparency > "perfect-looking" data

ILLUSTRATIVE INDUSTRY EXAMPLE: A mature oral solid dosage facility inspected within the last 2 years, with no significant recurring quality signals, validated digital-record access, and demonstrated experience with comparable products, may be better positioned for a focused records-based assessment than a full PAI. Illustrative scenario— not an FDA criterion for determining need for PAI.

Sources: FDA final guidance, Conducting Remote Regulatory Assessments, Q&A (June 2025); Alternative Tools for Pending Applications (Sept. 2025).

PRACTICAL PLAYBOOK ACROSS THE APPLICATION LIFECYCLE

Inspection readiness should start before submission and remain active until the facility assessment is complete.

PRE-SUBMISSION

- Gap-assess proposed operations vs. current capability
- Close repeat / overdue high-risk CAPAs
- Confirm commercial process + validation readiness
- Build the one-page facility risk summary

Delay trap: readiness begins after FDA asks.

AT SUBMISSION

- Submit accurate, complete facility information
- Confirm readiness dates and ownership
- Identify significant changes since prior inspection
- Reconcile exhibit / validation / commercial practice

Delay trap: Outdated establishment information or mismatched site details.

DURING FACILITY EVALUATION

- Anticipate targeted records requests
- Deliver complete, indexed responses
- Keep applicant + facility narratives aligned
- Escalate any material readiness change immediately

Delay trap: partial responses, late translations, conflicting explanations.

IF ASSESSMENT / PAI OCCURS

- Put the highest-risk SMEs first
- Rapidly fact-check observations / questions
- Define containment + remediation ownership
- Communicate issues affecting approvability early

Delay trap: discovering CMC-to-floor mismatches during inspection.

Operating principle: keep the "facility evidence package" alive until the approval decision, not just until submission.

MEASURE READINESS BY DECISION QUALITY, NOT BY "INSPECTION AVOIDANCE"

The useful metrics include those that reduce uncertainty, rework and response friction.

Records readiness

Priority evidence is pre-indexed, current and retrievable

Traceability

Application ↔ process ↔ validation ↔ executed records are reconciled

Quality risk

High-risk CAPAs and repeat trends have clear status and effectiveness evidence

Response control

Single owner / issue log / QA review route is tested

Change visibility

Material changes since prior inspection are captured and assessed

THE INDUSTRY "ASK"

Create the conditions for an earlier, evidence-based facility decision:

- More usable facility history
- Faster access to reliable records
- Clearer visibility to what changed
- Earlier communication when facility risk may affect review

The goal is not fewer inspections.
The goal is smarter use of inspections, remote assessments and quality data, so FDA can focus resources where risk is highest and patients gain timely access to medicines.

FY2025 evidence of increased use of alternative assessment tools

FDA reported 141 §704(a)(4) records-request reviews and 69 MRA partner inspections used to support risk-based application facility evaluations in FY2025.

Source: FDA FY2025 Report on the State of Pharmaceutical Quality, pp. 14–15.

SELECTED REGULATORY REFERENCES

FDA Compliance Program 7346.832 — Preapproval Inspections

Issued June 29, 2026. Risk-based preapproval facility evaluation and inspection strategy; includes product/process risk, facility capability/history, data reliability, hazard signals and alternative tools.

FDA — Alternative Tools: Assessing Drug Manufacturing Facilities Identified in Pending Applications

Final guidance, September 2025. Describes FDA use of alternative tools to support facility assessment for NDAs, ANDAs, BLAs and supplements.

FDA — Conducting Remote Regulatory Assessments: Questions and Answers

Final guidance, June 2025. Describes FDA's use of voluntary and mandatory RRAs, including §704(a)(4) records requests.

FDA FY2025 Report on the State of Pharmaceutical Quality

Describes use of PAIs/PLIs, MRA partner inspection information and §704(a)(4) records-request reviews in risk-based application facility evaluation.

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THANK
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