**cGMP CONSULTING INC.**
**WHITE PAPER**

# Inspection Readiness as a Steady State: Building the Quality Organization That Is Ready on an Ordinary Tuesday

*A cGMP Consulting White Paper on Continuous Inspection Readiness, Response Architecture, and the Post-QSIT Model*

**Inspection Readiness | Quality Operations | Regulatory Compliance | Enforcement**

*An educational resource for executive and technical leaders in FDA-regulated life sciences.*

## Executive Summary

Inspection readiness built as a pre-audit sprint no longer matches the environment it is meant to address. Inspections arrive unannounced, enforcement escalates quickly when responses are weak, and the records investigators may examine have expanded. An organization that mobilizes before an expected inspection and relaxes afterward is preparing for a predictability that no longer exists.

The consequences of that mismatch land in the response. Firms that answer inspection observations with vague commitments, generic promises of retraining, and closure targets rather than evidence increasingly

receive follow-on correspondence finding the response inadequate, which stretches the enforcement cycle and invites broader scrutiny. The observation itself is frequently manageable. The response is what decides whether it stays that way.

The environment has shifted in ways that specifically reward continuous readiness. For device manufacturers, the Quality Management System Regulation took effect on February 2, 2026, the Quality System Inspection Technique was retired the same day in favor of an updated compliance program, and the exception that previously shielded management review, internal audit, and supplier audit reports from routine inspection was not carried forward. For drug manufacturers, data integrity scrutiny has intensified, with investigators examining audit trails, metadata, and the timing of record creation rather than taking documentation at face value. In both cases, you cannot assemble the evidence of a functioning quality system during the inspection. Either it exists or it does not.

This paper examines what inspection readiness requires when inspections are unannounced and responses are scrutinized, why episodic preparation fails, and how to build readiness as a property of ordinary operations. It addresses the architecture of a response that avoids escalation, the front room and back room discipline inspection management requires, and the metrics that tell leadership whether the organization is actually ready today rather than whether it was ready at the last mock audit.

## Introduction

Most organizations know how to prepare for an inspection they expect. Documents get assembled, mock audits get run, subject matter experts get briefed, and the site presents well. That model works when inspections are predictable and the preparation window is long enough to close whatever gaps the mock audit turns up. It fails when the inspection arrives without notice, because the gaps preparation would have closed are still open when the investigator walks in.

The deeper problem is what the sprint model reveals about the organization. If you need weeks of preparation to be ready, then in the ordinary course of business you are not ready, which means the quality system is not producing the evidence of control it is supposed to produce. Preparation, in that model, is not readiness. It is the assembly of an appearance of readiness, and investigators are good at telling the two apart.

A more useful framing is that inspection readiness is not a project the quality organization runs but a property the quality system either has or lacks. A system whose records are current, whose investigations are rigorous, whose audit trails are reviewed, and whose findings are closed with evidence is ready on any ordinary day, because readiness is the natural byproduct of the system working. A system that lacks those properties cannot be made ready by preparation. It can only be made presentable.

This paper is for the quality, site, and executive leaders responsible for inspection outcomes. It focuses on the operational design that makes readiness continuous and on the response architecture that determines whether an observation becomes a footnote or a warning letter.

## Industry Background

The FDA's authority to inspect is established in the Federal Food, Drug, and Cosmetic Act, and the agency conducts pre-approval, surveillance, for-cause, and compliance follow-up inspections. The Form 483 documents observations of conditions that in the investigator's judgment may constitute violations, and the establishment inspection report provides the agency's fuller account. Where observations are significant and the response is inadequate, the agency may issue a warning letter, and where problems persist, may pursue import alerts, injunctions, or consent decrees.

The response to a Form 483 is not a courtesy response. The agency's practice is to review responses received within a defined period after the inspection closes, and the adequacy of that response influences whether the matter escalates or if further action is required immediately. That creates a decision point many organizations underestimate. A response demonstrating that the firm understood the problem, determined its scope, addressed its cause, and verified the fix can close a matter. A response promising corrective action without evidence frequently does not meet the inspectors’ expectations.

The inspection landscape for device manufacturers changed structurally in 2026. The Quality Management System Regulation took effect on February 2, 2026, and on the same date the agency stopped using the Quality System Inspection Technique, moving to the process described in the updated

Inspection of Medical Device Manufacturers Compliance Program 7382.850. Two prior compliance program documents were retired. The agency has indicated there is no successor document functioning as a replacement QSIT, so organizations that structured readiness around the QSIT subsystem model have to adapt to the new regulations.

A less discussed but consequential change came with the transition. The legacy Part 820 contained an exception at 21 CFR 820.180(c) limiting FDA access to management review, internal quality audit, and supplier audit reports during routine inspection. The QMSR does not maintain it. The agency reasoned in the final rule preamble that because manufacturers already provide such records to other regulators, making them available to FDA investigators imposes no additional burden. The practical effect is that an organization's own assessment of its quality system, including what it found and how it responded, is now inspectable, which changes what readiness means.

## Regulatory Landscape

The framework governing inspection readiness spans the inspectional authority itself, the expectations for the records investigators examine, and the practices that determine how findings escalate.

### Inspection Authority and Practice

The Federal Food, Drug, and Cosmetic Act establishes the agency's authority to inspect facilities, and the current good manufacturing practice requirements in 21 CFR Parts 210 and 211 for drugs, and 21 CFR Part 820 as amended by the QMSR for devices, establish the requirements against which facilities are assessed. Inspections may be announced or unannounced, and for foreign facilities announcement practice has varied. Assume an inspection may begin on any business day, because the alternative assumption has no basis in the agency's practice.

### The Device Inspection Model After February 2026

With the QMSR effective on February 2, 2026, device inspections proceed under the updated Inspection of Medical Device Manufacturers Compliance Program 7382.850, and the Quality System Inspection Technique is retired. Investigators may review records that are part of the quality management system, including those created before the effective date, and the agency has noted that a comparative analysis demonstrating that pre-transition records satisfy QMSR requirements may be useful to manufacturers. Because the 820.180(c) exception was not maintained, management review, internal audit, and supplier audit reports are subject to inspection.

### Records, Data Integrity, and What Investigators Examine

Inspection practice has become more data-driven across both drug and device sectors. Investigators examine audit trails, metadata, and the timing of record creation rather than accepting documentation at face value, consistent with the expectations in the FDA's data integrity guidance and the equivalent guidance from MHRA, PIC/S, and WHO. For drug manufacturers, the requirement that audit trail review occur at a frequency aligned with the review of the underlying data means records supporting batch release should have been reviewed before release, and an inspection tests whether that actually happened.

### The Response and Escalation Pathway

How an organization responds to observations materially affects the outcome. Responses that identify root cause with evidence, determine the scope of the problem across products and time, implement corrective action addressing the cause, and provide a plan for verifying effectiveness are treated differently from responses that commit to activity without demonstrating understanding. Where a response is found inadequate, the agency may escalate, and the resulting warning letter frequently characterizes the quality system as systemically deficient rather than citing isolated observations, which expands the remediation the firm has to demonstrate.

> *Investigators do not assess whether a site prepared well. They assess whether a quality system functions. Preparation can organize evidence of a functioning system, but it cannot create evidence the system did not generate in the ordinary course of operating.*

## Current Industry Challenges

The obstacles to continuous readiness are structural, and they persist in organizations with capable quality functions and genuine commitment.

### The Episodic Preparation Model

Organizations mobilize before expected inspections and relax afterward, producing a readiness curve that peaks on a schedule the agency does not follow. Between peaks, records fall behind, findings age, and the gap between the system's actual state and its presentable state widens. Because the model has usually worked, it rarely gets questioned until an unannounced inspection arrives during a trough.

### The Backlog Problem

Nothing undermines readiness more reliably than open items: investigations past due, CAPAs not closed, internal audit findings unresolved, change controls pending, training incomplete. Each is individually explicable and collectively damning, because a backlog is direct evidence that the quality system is not keeping pace with the operation it governs. Organizations frequently try to close backlogs during preparation, which produces closure without rigor and creates a second problem where the first one was.

### Records That Cannot Be Found

An inspection tests retrieval as much as content. A record that exists but cannot be produced within a reasonable time is functionally absent, and repeated retrieval failures suggest a system that is not in control regardless of the underlying quality. Organizations that have migrated systems, changed formats, or spread records across sites and platforms frequently discover during inspection that retrieval is far harder than they assumed.

### Newly Inspectable Internal Records

For device manufacturers, removing the 820.180(c) exception creates a challenge many transition plans did not address. Internal audit and management review records were candid partly because they were protected. Organizations now have to reckon with those records being inspectable, and the right response is not to soften internal audits, which would remove the control that finds problems, but to make sure

findings are closed rigorously. Organizations that have not adjusted may find their own records describing weaknesses they never resolved.

### Response Under Pressure

Responses get drafted in a compressed window under pressure, which favors commitment over evidence. The response a stressed organization produces quickly tends to promise retraining and rapid closure, which is exactly the pattern that draws escalation and attention. Organizations without a defined response architecture, pre-identified resources, and the investigative capability to determine scope quickly will produce weak responses reliably, because the conditions demand it.

### Inspection Management Capability

Front room and back room discipline, escalation protocols, and the ability to interact with investigators effectively get treated in many organizations as skills that appear when needed. They do not. Subject matter experts who have never been questioned by an investigator answer poorly, volunteer information beyond the question, or speculate. These are learnable behaviors, but they are learned through practice, not through a briefing the morning the inspection starts.

## Risks of Poor Implementation

The risks of episodic readiness compound, because a weak inspection outcome shapes the regulatory posture toward the organization for years.

| Risk Category | Potential Consequence |
|---|---|
| Escalation to warning letter | Observations that could have been closed by an adequate response instead escalating, with the resulting letter frequently characterizing the quality system as systemically deficient. |
| Expanded scope | Investigators broadening the inspection when initial findings suggest systemic weakness, converting a targeted inspection into a comprehensive one. |
| Exposed internal records | For device manufacturers, internal audit and management review records revealing identified deficiencies that were not adequately addressed. |
| Approval delay | Pre-approval inspection findings postponing licensure, with direct revenue and patient access consequences. |
| Prolonged enforcement cycle | Inadequate response correspondence extending the matter, consuming leadership attention and resources over quarters rather than weeks. |
| Damaged regulatory credibility | A record of weak responses shaping how the agency approaches the organization thereafter, which is slow and difficult to reverse. |

The credibility dimension deserves emphasis because it is durable. An organization that responds to findings with rigor establishes a record that affects how subsequent findings are received. One whose responses are consistently thin establishes the opposite, and the agency's posture shifts in ways that outlast the specific matter. This is why the response is worth more attention than most organizations give it: it is the moment at which the organization's regulatory reputation is actually made.

There is also a straightforward operational cost. Episodic readiness consumes substantial effort in each preparation cycle, and much of that effort goes to assembling and closing items that continuous operation would have handled as routine. The sprint model is not cheaper than continuous readiness. It is more expensive, and it delivers a worse result.

## Best Practices

Continuous readiness comes from making the quality system produce evidence of its own functioning as a byproduct of ordinary operation, and from building response capability before it is needed.

### Manage Backlogs as a Readiness Metric

Because open items are the most direct evidence of a system not keeping pace, manage overdue investigations, open CAPAs, unresolved audit findings, pending change controls, and incomplete training as continuous readiness indicators reported to leadership. The objective is not zero open items, which is unrealistic, but an aging profile that shows the system closing items at the rate they arise. A backlog that grows is a readiness failure regardless of what a mock audit concludes.

### Ensure Records Are Current and Retrievable

Records should be complete, contemporaneous, and retrievable within a reasonable time, and retrieval should be tested rather than assumed. Request records at random and measure how long production takes, particularly for records spanning system migrations, format changes, or multiple sites. Retrieval capability is invisible until it fails, and it fails in front of an investigator.

### Build Response Architecture Before It Is Needed

Define in advance how a response will be produced: who leads, who investigates scope, who drafts, who approves, and what standard the response has to meet. The architecture should require evidence-based root cause, an assessment of scope across products and time, corrective action addressing the cause rather than the symptom, and a plan for verifying effectiveness. Having this defined converts a compressed, high-pressure drafting exercise into the execution of a prepared process.

### Develop Inspection Management as a Standing Capability

Front room and back room discipline should be practiced rather than briefed. Subject matter experts should experience being questioned, learning to answer the question asked, to avoid speculation, and to say they will find out rather than guessing. Runners, scribes, and back room reviewers should know their roles. These capabilities decay without practice, so exercises should recur rather than cluster before expected inspections.

### Close Internal Findings With Evidence

For device manufacturers in particular, where internal audit and management review records are now inspectable, close findings with evidence of effectiveness rather than with completion of an action. The internal record should tell the story of an organization that finds its own problems and fixes them, because

that is the story an investigator will read. Review open internal findings specifically with this exposure in mind.

### Measure Readiness Continuously, Not Episodically

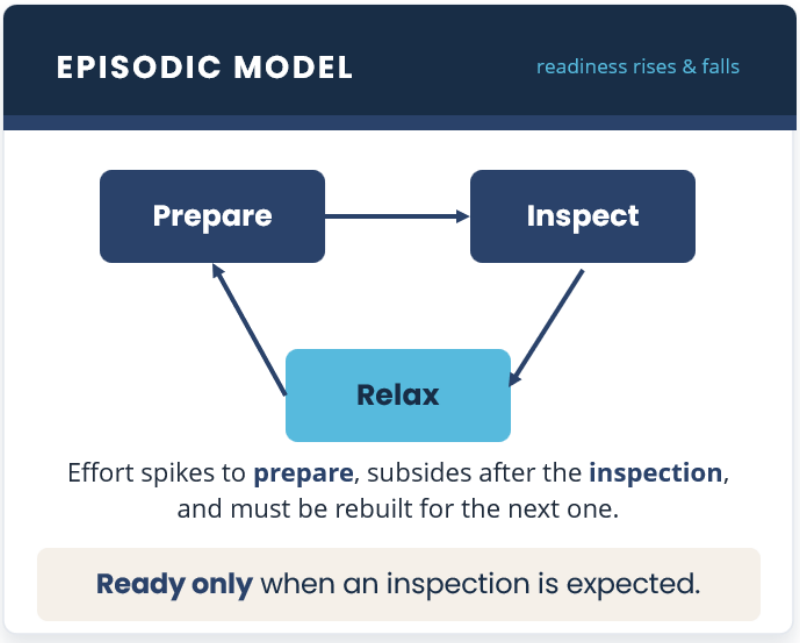
Leadership should receive metrics that answer whether the organization is ready today: backlog aging, record retrieval performance, audit trail review completion, internal finding closure with verified effectiveness, and training currency. A mock audit reports readiness at a moment; these metrics report it continuously. Where a mock audit is used, it should test the system as it actually operates rather than a prepared version of it.

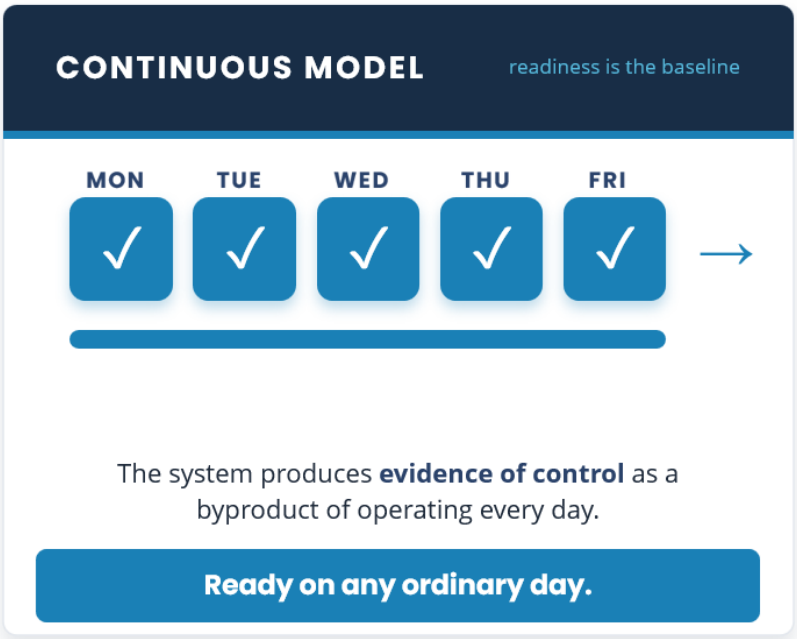
## Implementation Roadmap

The roadmap below moves an organization from episodic preparation to readiness as an operating property.

FIGURE 1

**Two Models of Inspection Readiness**






### Step 1: Assess Current Readiness Honestly

Assess the state of the system as it stands today, without preparation. Examine backlogs, record retrieval, audit trail review status, and open internal findings. The value of the assessment depends on its candor, and a prepared assessment measures preparation rather than readiness.

### Step 2: Perform a Gap Assessment

Compare current state against the requirements applicable to the operation and against the inspection model that will apply, which for device manufacturers means the updated compliance program rather than the retired QSIT framework. Identify where readiness depends on preparation rather than on the system functioning.

### Step 3: Address Backlogs Rigorously

Close open items with rigor rather than speed, recognizing that a backlog closed carelessly creates investigation quality problems worse than the backlog. Where the backlog exceeds capacity, address the capacity, since a system that cannot keep pace will regenerate the backlog no matter how often it is cleared.

### Step 4: Establish Record Currency and Retrieval

Ensure records are contemporaneous and retrievable, and test retrieval by request rather than by assumption. Address the systems, migrations, and distributions that make retrieval slow, since these are structural problems preparation cannot solve.

### Step 5: Build Response Architecture

Define the response process, the roles, and the standard a response has to meet, and ensure the investigative capability exists to determine scope quickly. Rehearse the process, because a response architecture that has never been executed is a document rather than a capability.

### Step 6: Develop Inspection Management Capability

Train and practice front room and back room roles, investigator interaction, and escalation. Recur the practice so capability persists rather than peaking before expected inspections.

### Step 7: Implement Continuous Metrics

Report readiness indicators to leadership continuously, so a readiness decline is visible as it develops rather than at the next mock audit. Metrics should reflect the system's current state, not its last prepared state.

### Step 8: Sustain and Improve

Use inspection experience, internal findings, and industry enforcement patterns to refine readiness. Treat each inspection, whether at the organization or elsewhere in the industry, as information about what readiness now requires.

## Technology Considerations

Technology supports continuous readiness principally by making the system's current state visible and by making records retrievable.

Electronic quality management systems hold the record of investigations, CAPAs, change controls, audit findings, and training, and they make backlog aging visible in real time rather than through periodic reporting. A system that surfaces overdue items to their owners and to leadership converts backlog management from a preparation activity into an operating discipline. Where these systems enforce required elements before closure, they also raise the quality of the record an investigator will examine.

Document and record management systems determine retrieval performance, which is a readiness property that only becomes visible under inspection. Evaluate retrieval across the full record retention period, including records created in superseded systems, since a migration that preserved data without preserving retrievability has created a readiness gap no preparation can close in an inspection window.

Automated audit trail review tooling addresses one of the most resource-intensive readiness requirements, particularly for drug manufacturers where audit trail review before batch release is expected. Tooling that surfaces the events warranting human attention makes the expectation sustainable at scale, converting an obligation that is frequently deferred into one that is met continuously. Any such system supporting quality decisions falls within the risk-based assurance expectations applicable to software in the quality system.

## Future Outlook

The direction of inspection practice favors organizations whose readiness is continuous. Data-driven inspection will keep deepening, with investigators making increasing use of metadata and audit trails to reconstruct what actually happened rather than what records assert. That favors systems producing reliable evidence as a byproduct of operating and disadvantages those that assemble evidence for presentation.

For device manufacturers, the practical character of inspection under the updated compliance program will clarify as experience accumulates, and the expanded record access will shape what investigators examine. Expect internal audit and management review records to receive attention, since they offer a direct view into the organization's self-assessment that was previously unavailable.

The organizations that fare best will stop treating readiness as something the quality organization achieves before an inspection and start treating it as something the quality system exhibits because it works. That reframing is not rhetorical. It changes what gets measured, what gets funded, and what leadership asks about, and those changes are what produce a site that is ready on an ordinary Tuesday.

## How cGMP Consulting Can Help

Building readiness as a steady state takes knowing what investigators actually examine, assessing a system without the flattery of preparation, and developing capabilities that persist between inspections. cGMP Consulting works with pharmaceutical, biologics, and device organizations to build readiness that does not depend on advance notice.

Our consultants assess readiness as it stands rather than as it can be prepared, examining backlogs, record retrieval, audit trail review, and open internal findings against what an inspection would test. We conduct mock inspections designed to test the system as it operates, and for device manufacturers we assess readiness against the updated compliance program rather than the retired QSIT framework, including the implications of newly inspectable internal audit and management review records. We help organizations build response architecture before it is needed, develop the investigative capability to determine scope quickly, and train front room and back room teams in the disciplines inspection management requires. For organizations facing an active inspection or responding to observations, we help develop evidence-based responses that address root cause, scope, and effectiveness rather than promising activity.

Our approach is consultative and grounded in how inspections actually unfold and how responses are actually evaluated. We aim to leave organizations with readiness they retain, not with a binder they refresh.

## Conclusion

Inspection readiness built as a sprint prepares for a world that no longer exists. Inspections arrive unannounced, responses are scrutinized, and for device manufacturers the records available to investigators now include the organization's own assessment of its quality system. An organization that requires weeks of preparation to be ready is telling itself something important about its quality system, and an investigator arriving without notice will hear it.

The alternative is to make readiness a property rather than a project. Manage backlogs as a continuous indicator rather than a preparation task. Ensure records are current and test whether they can actually be retrieved. Build response architecture before the observation arrives, so the response reflects a prepared process rather than a pressured drafting exercise. Develop inspection management as a standing capability practiced rather than briefed. Close internal findings with evidence, particularly where those findings are now inspectable. Measure readiness continuously so leadership knows the answer today.

These practices cost less than the sprint model they replace, because they distribute across ordinary operations the effort the sprint concentrates into a preparation window. More important, they produce a different result. A system that generates evidence of its own control as a byproduct of working is ready on any ordinary day, and it is the only kind of system that survives an inspection nobody scheduled.

> *If your organization is strengthening its inspection readiness, adapting to the updated device inspection model, or responding to observations, the experienced consultants at cGMP Consulting can help assess your current state, identify gaps, and develop practical solutions tailored to your business objectives. To start a confidential conversation, complete the Contact Us form at* cgmpconsulting.com/contact-us*.*

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