Your System's Annual Health Check-up

A Guide to Periodic Evaluation for Continued Computerized System Validation

Just like an annual physical, a periodic review ensures your critical systems remain healthy, compliant, and in a validated state throughout their operational life.

The Goals of a Good Check-up

1. Provide Independent Assurance

Confirm to process owners and management that system controls are in place, functioning correctly, and maintaining the system's validation status.

2. Identify and Improve

Pinpoint controls that are not working effectively and help eliminate weaknesses, improving the health of not just one system, but potentially all systems in a facility.

Who is Your System's Doctor?

The Anatomy of an Effective Reviewer

Independent & Competent:
Must be impartial and knowledgeable to ensure an objective review.

Regulatory Fluency:
Deep knowledge of current GMP regulations and guidance documents.

Technical Experience:
Hands-on experience with computerized systems to know "where bad practices could occur."

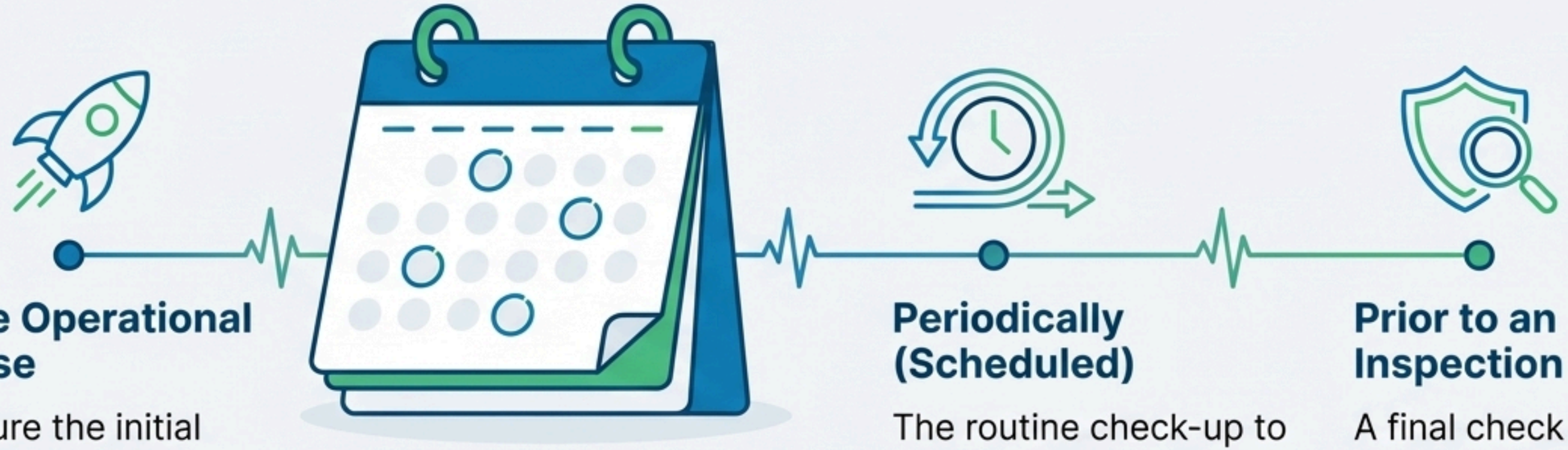
Procedural Understanding:
Firm grasp of the company's own procedures for validation and operation.

Open & Flexible Approach:
Understands there are many ways to be in control and remain compliant.

Strong Interpersonal Skills:
Able to ask pertinent questions and persuade others to improve.

Scheduling the Appointment: When to Perform a Review

The frequency of the periodic review is based upon the criticality of the computerized system. Critical systems require more frequent reviews than lower-risk systems.



Before Operational Release

To ensure the initial validation was flawless before the system goes live.

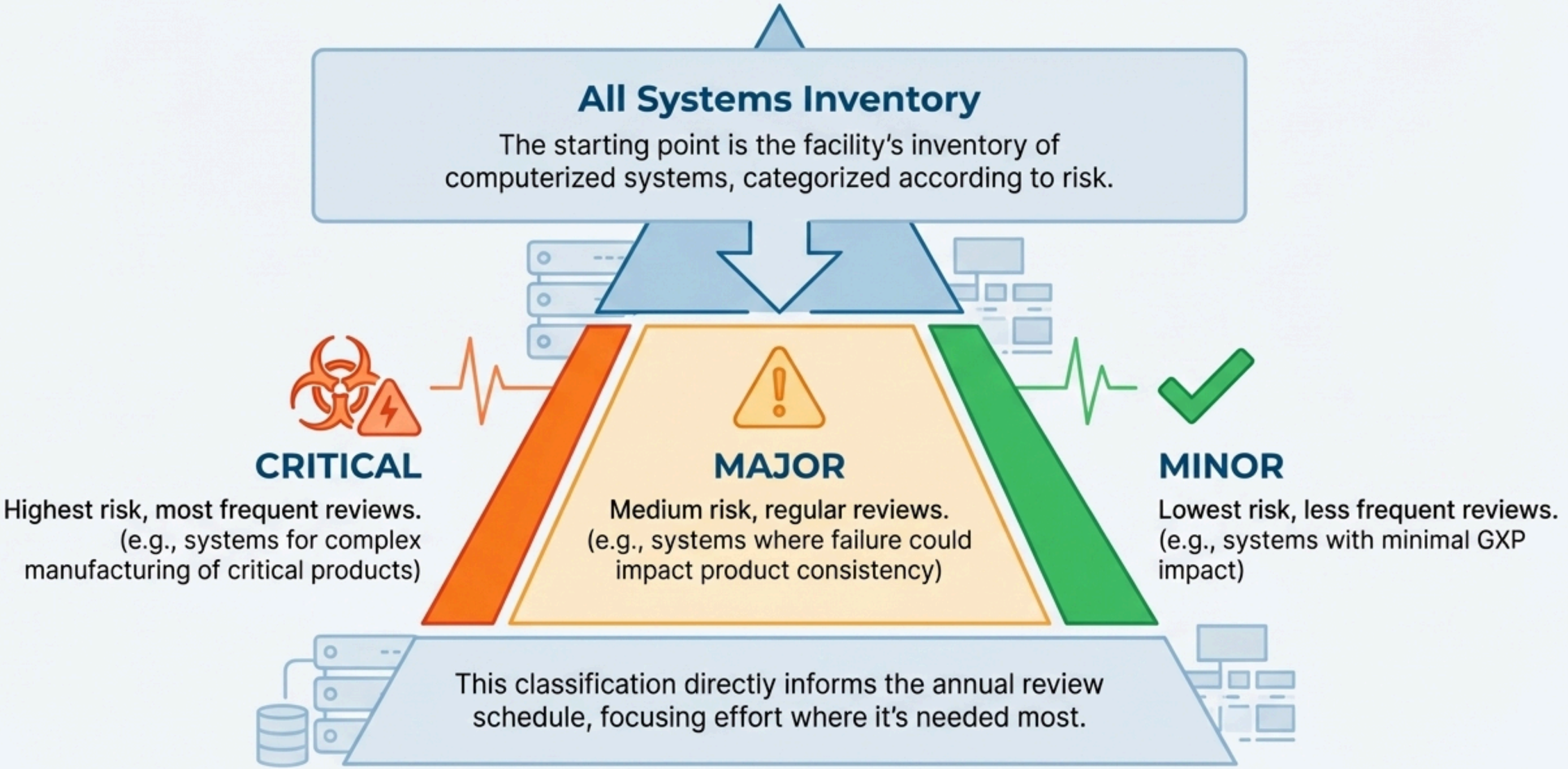
Periodically (Scheduled)

The routine check-up to ensure the operational system remains validated.

Prior to an Inspection

A final check to ensure there are no major compliance issues before before an external audit.

Patient Triage: How Critical Is Your System?



The Health Check-up Process Map

Phase 1: Planning (Annual)

Link System Inventory & Risk classification to the SOP.

Create the annual **Self-Inspection Schedule**.

Leads to

Phase 2: Execution (Per System)

Plan Review: Read key documents.

Conduct Review: The "examination."

Closing Meeting: Discuss findings.

Opening Meeting: Set objectives.

Reviewer's Closed Meeting: Analyze observations.

Report & Action Plan: The "diagnosis and prescription."

Choosing the Right Examination

Horizontal Review
(The General Wellness Check)

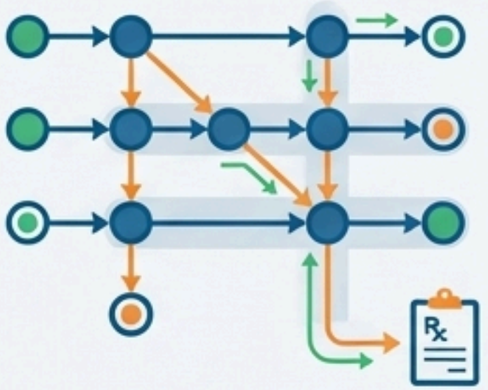
Scope: Covers all areas of the system, but at a low depth.

Best For: First-time reviews or when time is limited. Gives confidence that major requisites are in place.

Vertical Review
(The Specialist Consultation)

Scope: A narrow perspective on one or more areas, but in great detail.

Example: A deep-dive into the change control procedure and every change request for the system.



Diagonal Review
(The Full Diagnostic)

Scope: A mix of horizontal and vertical. Confirms major elements are in place AND that they operate and integrate correctly.

Example: Tracing a user requirement all the way through the life cycle to a specific test script and back again.

Reviewing the Patient's History

Preparatory Reading Before a Periodic Review

To understand the system's history and intended state, the reviewer must read these key documents before the on-site review begins:

Validation Plan

To understand what was intended to be performed and written.

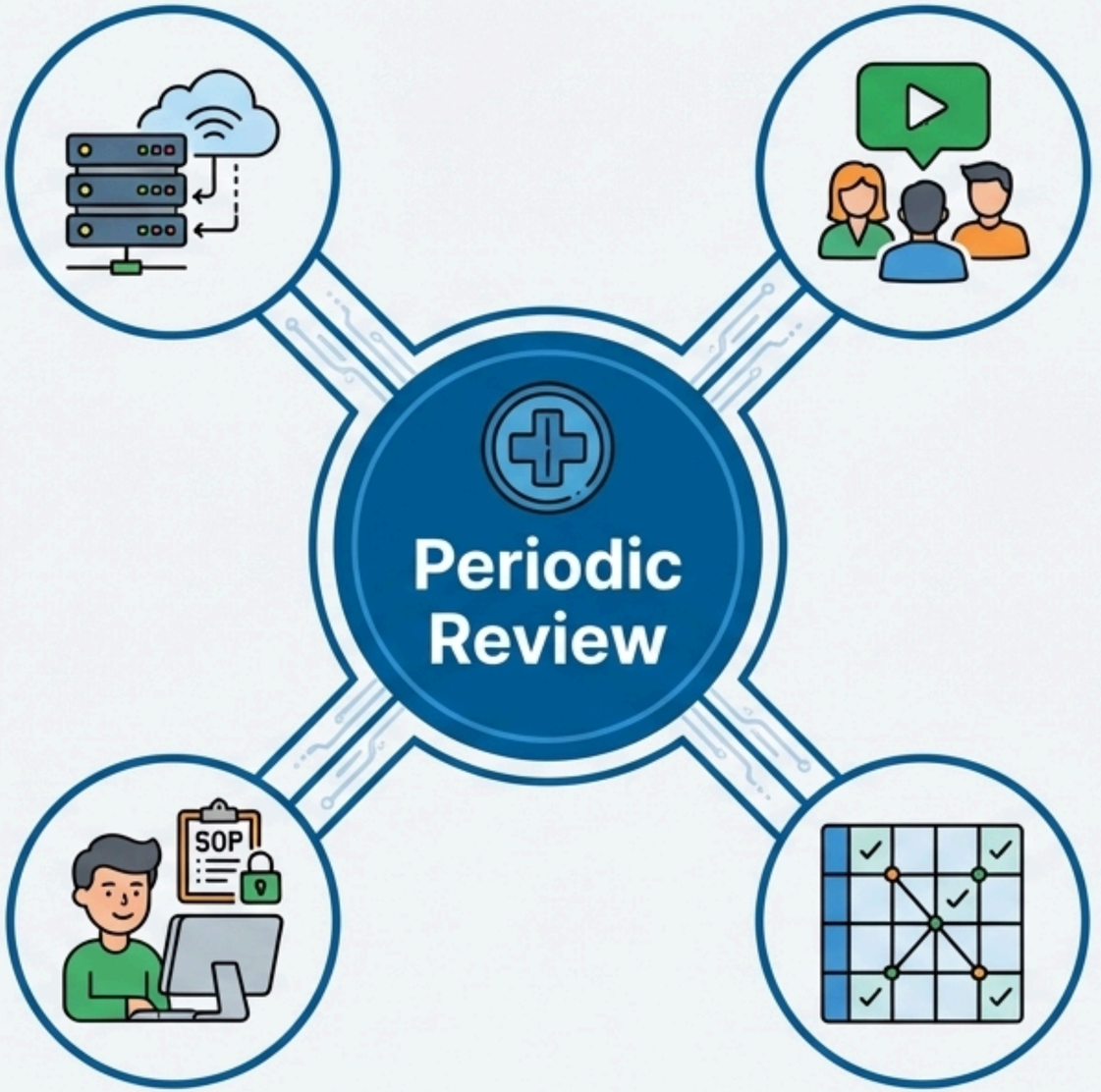
User Requirements Specification (URS)

To define the intended use of the system and assess if requirements are testable.

Key Insight: This checks the quality of the validation by comparing what was promised versus what was delivered.

The Examination in Detail

IT Department Involvement: For networked systems, review IT procedures like backup, recovery, and change control. Verify that practice matches the procedures.



Opening Meeting: Introductions and a clear statement of the review's aims. Department head attendance is critical.

Operational Review: Go to the operational area. Talk to to users. Review training records, SOPs, and system security in practice.

Review of Last Validation: Assess the quality of the most recent validation effort, using the traceability matrix as a key tool.

From Examination to Diagnosis

1 The Reviewer's Closed Meeting (The Consultation)

- A private session for the reviewer to analyze all notes and documents.
- This is where observations are classified into formal findings or non-compliances.
- All major issues are prepared for the closing discussion.

2 The Closing Meeting (Presenting the Diagnosis)

- Initial findings are presented and discussed with the full team.
- **No Surprises Rule**: All major findings must be covered face-to-face so nothing in the final report is unexpected.
- Findings are based on objective evidence (e.g., non-compliance with a specific procedure or regulation).

Understanding the Diagnosis: A Severity Scale for Findings

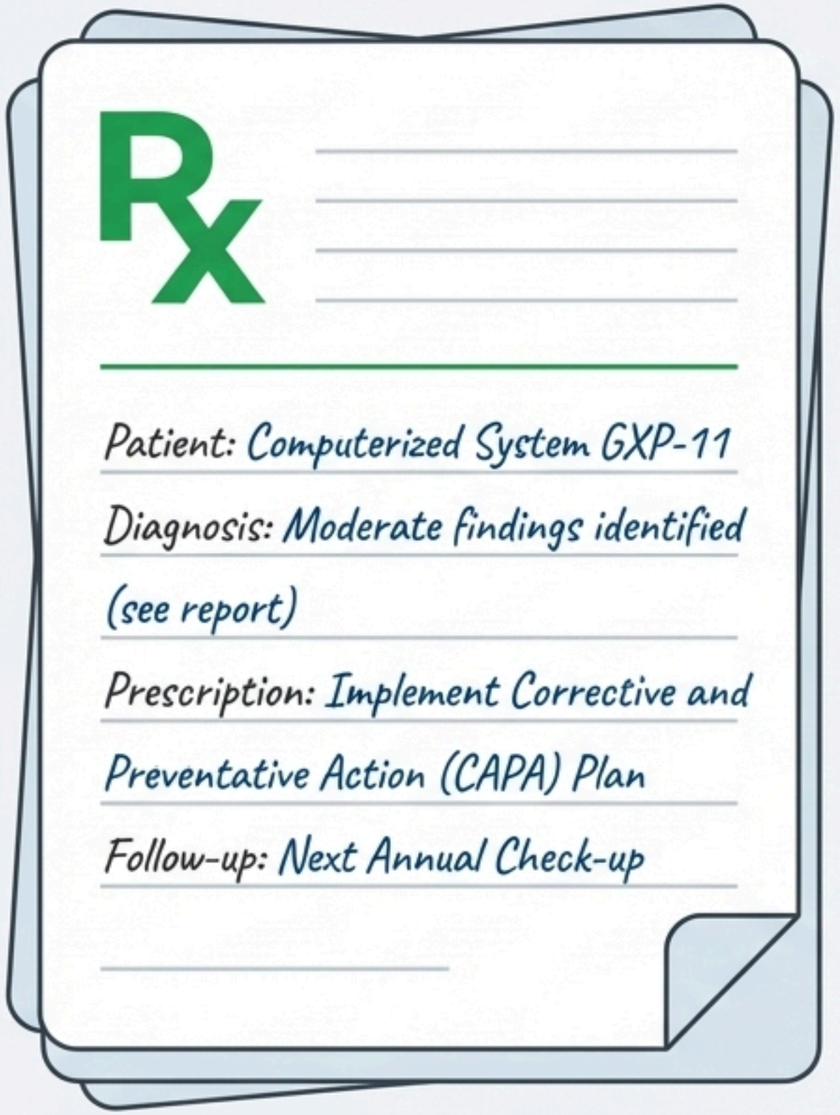
CRITICAL (Rank 4) A deficiency with a significant risk of producing a harmful product or that could result in regulatory action.

MAJOR (Rank 3) A system-based deviation that could produce a non-compliant product or indicates a major deviation from GXP.

MODERATE (Rank 2) A small impact on data or product quality. A single GXP deviation that is not system-based. A procedure is not followed.

MINOR (Rank 1) Does not impact data quality, product quality, or patient safety.

The Prescription: Your Action Plan for System Health



The formal outcome of the review is a two-part deliverable:

1. The Periodic Review Report

- A draft is issued for comments.
- The final report contains all observations and classified findings.

2. The Corrective and Preventative Action (CAPA) Plan

- The process owner completes the plan to address all moderate, major, and critical findings.
- These actions are implemented and monitored, ready for the next scheduled check-up.

The goal is not just to find problems, but to create a clear, actionable path to a healthier, more robust system.