Mock Inspections conducted by Horizon Phoenix expert auditors under realistic and entirely professional circumstances is the best test of your processes, procedures, records and people. Identify and remedy weaknesses before they become expensive and time consuming embarrassments. If any of these common problems sound familiar to you, you really need a Mock Inspection.

1. The quality management or regulatory compliance system is missing or misinterprets a requirement. Nearly every FDA Warning Letter or Notified Body major non-conformance cites the absence of a process.

2. Internal audit process does not provide a robust examination. You never saw the problems coming.

3. Key process linkages are weak or absent (e. g. customer complaints to CAPA) resulting in the same issues coming up and being unresolved frequently.

4. The documentation so complex your staff take short cuts or ignore requirements altogether.

5. There is a wide variance in completing, handling and storage of quality records.

6. Objective evidence cannot be produced in a timely fashion. No evidence, no compliance.

7. Standards used to establish product compliance are not current or worse not used correctly.

8. Core documents such as design outputs, bill of materials, inspection and test plans are not the same documents used in the day to day operation of the company.

9. The competency of key decision-makers cannot be verified.

10. The documentation available in the public domain such as your website, marketing literature or presentations at trade shows, do not align with your market access approvals.

11. Staff training is not sufficient – usually taking the form of a simple question asked of several employees yielding more than one answer.

12. Root cause of a non-conformance is either shallow or worse not established.

13. Staff simply does not know how to interact with a regulatory inspector usually resulting in panic stricken answers.

14. Documentation such as STED Files, Design History Records and market access approvals do not reflect all device options, accessories or variants that are available.

15. AND ALL TO OFTEN departments successfully hide poor performance from internal auditors but cannot hide it from experienced ones.

Find the problems before the regulatory inspectors do! The only thing worse than explaining why you do not have a key market approval is explaining how you lost one.

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