

What to expect during a Horizon Phoenix Mock Inspection using FDA QSIT; Health Canada CMDR or EU Directives and harmonized standards

I. Preparation is the key, prior to arrival your mentor will complete a...

- a) Comprehensive review of your quality and regulatory documentation including quality manual, procedures, STED Files, risk assessments, post market surveillance, vigilance reports, instructions for use, labeling and other key objective evidence of compliance to requirements.
- b) Detailed assessment of all previous inspections/audits, non-conformances, observations and warning letters (if any)
- c) Exhaustive examination of regulatory databases for market access approvals; MAUDE reports, warning letters, recalls and field corrections, and a
- d) Thorough review of your website, catalogue and other information that may be found in the public domain

Mentor - a trusted counselor or guide; one who freely imparts knowledge and wisdom

Your mentor will be prepared to hit the ground running!

II. Open communication and employee buy in makes this work, on the first day of the Mock FDA Inspection your mentor will...

- a) Meet with executives, management staff, internal auditors and other employees to explain what is happening and what we going to learn from the Mock FDA Inspection.
- b) Review the inspection plan, start of day discussions, end of day reviews and final reports and the written inspection report
- c) Describe inspection techniques, sample collection and how to interact with the inspector.
- d) Explain the “two hat” method – that of being the mean spirited inspector and then as the helpful mentor, and
- e) Take questions and provide valuable answers

III. The learning begins the moment we start interacting with your staff as first and foremost a Mock FDA Inspection is a learning experience with a variety of valuable goals:

- a) Determine precisely where you stand versus your regulatory compliance
- b) Identify weaknesses or shortcomings
- c) Pinpoint bottlenecks and other inefficiencies
- d) Distinguish robust processes from onerous burdens
- e) Cultivate confidence and can do attitude in your staff, and
- f) Learn how to resolve issues in a cost effective and orderly process.

IV. What does a Horizon Phoenix Mock Inspection cover...

Every part of your operation from design to shipping product out the door! A cradle to the grave examination of your processes, procedures, records and organizational structure using USFDA QSR, cGMP, cGLP and QSIT; EU Directive and harmonized standards and/or Health Canada CMDR as our guide that will carefully examine:

- a) Management commitment
- b) Design Control
- c) Product Realization
- d) Calibration
- e) Validation, verification and testing
- f) Corrective/Preventive Actions (CAPA)
- g) Training
- h) Quality Assurance
- i) Regulatory Affairs
- j) Critical supplier control, monitoring and oversight
- k) Device History or Batch Records
- l) Traceability and Recall
- m) Sterilization or other special processes
- n) Internal Audits
- o) Change control
- p) Post Market Surveillance/Vigilance
- q) Post Market Clinical Follow Up
- r) STED Files
- s) Risk Management Plan
- t) Labeling and Instructions for Use
- u) Nonconforming Product
- v) Quality Records, retention, safeguard and disposition
- w) Raw Materials, receiving, assessment and inventory control
- x) Product returns, repairs and reworks
- y) Customer complaints
- z) Regulatory Notifications (routine)
- aa) Mandatory Device Reporting

A typical regulatory inspection will take at least three days and give you lots of time to discuss even the most thorny of issues (wash your dirty laundry so to speak)!

Using knowledgeable Horizon Phoenix expert auditors will make the Mock Inspection process a fun and interesting learning experience, not the Spanish Inquisition or a boring square-filling exercise!

V. What will a typical Mock Inspection day look like...

Your Horizon Phoenix mentor carefully assesses each procedure and process obtaining sufficient objective evidence of compliance. We will also teach, explain and answer questions along the way as your mentor. Being skilled diplomats as well as experienced auditors when we find a non-conformance we will take that opportunity to outline expectations and help you sort out options and alternatives.

VI. The best defense is a good offense and a comprehensive Mock Regulatory Inspection from Horizon Phoenix is a smart play that will:

- a) Provide you with objective evidence of your strengths
- b) Describe common sense solutions to address shortcomings
- c) Outline sound and cost effective options to streamline your quality system
- d) See immediate and valuable results with more innovative and flexible processes
- e) Augment your own team's competency and confidence
- f) Begin doing things that cultivate intense customer loyalty
- g) Give you peace of mind

Each day of the Mock Inspection your team will receive a briefing on strengths and weaknesses so that you can immediately begin considering corrective or preventive actions while your mentor is still on site.

We encourage members of your quality and regulatory staff as well as your internal auditors to shadow your mentor during their visit and to freely ask questions.

At the conclusion of the on-site time together you will receive a concise summary of key findings and options for cost effective solutions.

Within five business days you will receive a comprehensive (confidential) written report.

Regulatory compliance is a journey - not a destination. When you stop, the inspectors will run you over. With Horizon Phoenix as your internal audit provider your competition will be doing the chasing!