



INSPECTION READINESS FOR SME’S & INDIVIDUAL CONTRIBUTORS

A two-day, live FDA and health authority inspection simulation that builds the participant’s composure, accuracy, and credibility

“Walk me through this investigation.” *You did not write it. The author left last year. The inspector is waiting.*

In an inspection, your SMEs speak for the company. An unclear, speculative, or overextended answer can expand the conversation beyond the original question and create avoidable inspection concerns. This course gives your people realistic, high-pressure practice before it counts, using mock documents modeled on recent 483 observations.

WHEN	WHERE	INVESTMENT	CLASS SIZE
February 2–3, 2027 9:00 a.m.–5:00 p.m., both days In person	Four Points by Sheraton Norwood, Massachusetts Free parking; hotel rooms on site	\$2,800 per participant Lunch and refreshments included Save 10% with EARLYBIRD10 by Dec. 31	12 per instructor Laptop required Certificate of completion

THE RETURN ON YOUR INVESTMENT

FOR YOUR ORGANIZATION	FOR YOUR PARTICIPANTS	FOR YOU AS THEIR MANAGER
- Lower the risk of avoidable inspection concerns & associated investigations, CAPAs, response letters /resource demands created - Consistent, evidence-based answers across QA, operations, and the lab - SMEs who can defend legacy work when the original author is gone - Stronger front-room and back-room performance on inspection day	- Composure and clear thinking under direct inspector questioning - Practiced skill defending records they did not write - Practical stress tools that hold up as pressure rises - A personal inspection-readiness playbook to keep using	- Pre/post-training confidence and stress measurement - Hands-on simulation, not lecture: skills show up on the job - Small cohort w/individual facilitator coaching - No internal prep required; two days, fully facilitated - More confident, composed, and effective staff during high-pressure moments

Put \$2,800 in context: a single 483 observation typically pulls several functions into investigation, CAPA, a written response, and follow-up. Preventing even one avoidable observation, or one answer that expands scope, can outweigh the cost of preparing a team.

WHO SHOULD ATTEND

- QA and QC professionals; manufacturing and laboratory staff
- Validation, engineering, and process or system owners
- Documentation and supply chain personnel
- New staff wanting to be ready for their first inspection
- Experienced SMEs who want more experience

WHAT PARTICIPANTS PRACTICE

- Explaining and supporting work they did or did not author
- Separating verified facts from assumptions
- Answering clearly and concisely without oversharing
- Leading focused document and investigation walkthroughs
- Handling missing information and unavailable authors
- Recovering professionally from unexpected questions or data issues

TWO DAY COURSE OVERVIEW/GOALS

DAY 1 | INSPECTION OPENS & INITIAL REQUESTS

- Understanding the audit logistics, goals & participant roles
- Initial requests, document verification and preparing requests
- SME briefings/strategizing plans
- Live questioning, walkthroughs, follow-ups, and then goals for tomorrow

DAY 2 | FINAL AUDIT DAY & CLOSEOUT

- Follow-up requests, find “errors” and inspector pivots
- Legacy records and decisions made by others
- Cross-functional alignment and final presentations
- Closeout meeting, discuss near misses & prepare for any 483s

HOW IT WORKS

Every module follows **PQS See → Do → Refine™**: concise instruction, realistic practice, and structured coaching. Pressure is also applied gradually, using stress exposure / stress inoculation training principles and strategies to handle it.

BUILT ON PUBLISHED RESEARCH FOR EVIDENCE-BASED PERFORMANCE PSYCHOLOGY AND NEUROSCIENCE:

- 3 in 4** A meta-analysis of 37 studies (1,800+ participants) found stress inoculation training reduced anxiety and improved performance under stress; the typical trained participant outperformed about three out of four untrained peers. *(Saunders et al., 1996)*
- 2x** A 2024 meta-analysis of 35 studies (5,600+ participants) found combining stress reappraisal with mindset training roughly doubled the performance effect, with larger gains on public, high-stakes tasks. *(Bosshard & Gomez, 2024)*

READY TO ENROLL YOUR TEAM?

Reserve seats now; 12 participants per instructor. Sending several people, or want this delivered in-house? Book a free 30-minute call with Paul Hefner to discuss company cohort options.

Register at

www.positivequalitysolutions.com

We don’t just teach inspection readiness. We simulate it, so confidence holds when the pressure is real.



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