

Inspection Ready: Fixing the GMP Gaps That Lead to 483s

Wednesday, December 2, 2026

12:00 to 3:30 PM EST

Live online

Recording included

12:00 to 12:05 PM EST

Welcome, orientation, and how to get the most from the session

12:05 to 12:55 PM EST**MODULE ONE**

Investigations That Hold Up

Why "root cause not identified" keeps showing up in 483s

Scoping an investigation so it reaches a defensible root cause

Linking root cause to CAPA so the fix actually holds

Writing an investigation that closes and survives inspector review

12:55 to 1:05 PM EST

Break

1:05 to 1:55 PM EST**MODULE TWO**

Surviving an Audit of Your Validated Computerized Systems

What inspectors look at first in a validated system

Audit trails, access controls, and data integrity expectations

Keeping validation evidence inspection ready between audits

Lessons from real audits on the front line

1:55 to 2:05 PM EST

Break

2:05 to 2:55 PM EST**MODULE THREE**

Inspection-Proof Change Control

Why well-intended changes still end up on 483s

The change control failure modes inspectors find most often

What "risk-based" really means to a reviewer

Impact assessments and effectiveness checks that hold up

2:55 to 3:30 PM EST

Open Q&A

Bring the finding your site is worried about. Submit questions in advance at registration and we will work through as many as time allows.

\$325 per seat early bird through November 20

\$395 after November 20. Team rate: \$1,495 for up to 8 seats. Seats are limited. Registration closes as soon as capacity is reached.

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Reserve your seat