FULL AGENDA

KENX
KNOWLEDGE EXCHANGE NETWORK

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

SPEAKER
Cindy Duhigg
Senior Principal, Global Manufacturing Science & Technology Engineering
Alcon

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

SPEAKER
Raul Soto
MedTech Senior Manager
Johnson & Johnson

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

SPEAKER
Tim Roy Kirkelie
Co-Founder & COO
Genari AI

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.

kenx.org/webinar/inspection-ready-fixing-the-gmp-gaps-that-lead-to-483s

Reserve your seat