Wrap-Up and Final Questions

"Mr. Wong, may I be excused?
My brain is full."

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FDANEWS

Reminder:
Helpful Reference Materials

- Slide handouts (3 slides per page)
- Checklists, templates and sample SOP
  - Checklist: Site Inspection Proof Binder
  - Checklist: FDA Inspection Handling
  - Checklist: Pre-Inspection Activities
  - Checklist: Post-Inspection Response
  - Template: Inspection Observation-Closure Matrix
  - Sample SOP: Handling Regulatory Agency Inspections
- FDA and internationally harmonized inspectional policies and guidance documents
  - 6 different FDA forms (463a, 482, 483, etc.)
  - FDA IOM Chapter 5 – Establishment Inspections
  - FDA Inspection Manual for Devices, 2011-2015
  - FDA QSIT, 1999
  - 2 FDA Inspection Compliance Program Guides (pre-approval and routine post-approval inspections)
  - ORA FDASIA § 707 Inspection Guidance (circumstances that constitute delay, deny, etc.)
  - 2 GHTF/IMDRF regulatory inspection guidelines
  - 4 PIC/S inspection guidelines
- Bonus: "Rapid Deployment Tips to Prepare for a Sudden FDA Inspection" *PDA Letter*, September 2010

Key Point Review

- FDA investigators spend at least 1-2 days preparing for an inspection
- Since 2010, every FDA investigator is aware of data integrity issues
- FDA inspections begin before investigator arrival
- Firms have several opportunities to close gaps during the inspection
- Nearly all inspection questions require evidence to answer
- Form FDA-483 is used to document significant, serious deviations
- Other deviations may only be orally communicated
- FDA Center or ORA makes final determination on enforcement
- Brief Form FDA-483s are not representative of total deviations
- FDA's revamp of inspectional policies is "slaying" some sacred cows
- Failed inspections and public enforcement have real bottom line impacts that last for years

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Key Point Review

- Create and keep current a Site Inspection Response Team (SIRT)
- Compile – and update annually – an Inspection Proof Binder
- Craft a Regulatory Inspection Handling SOP and other policies/SOPs
- Conduct annual regulatory training in a variety methods
- Consider preparing any critical suppliers for an FDA inspection
- Keep calm and walk through the pre-inspection steps upon notification
- Turn the site tour to your advantage by showcasing physical controls
- Use an inspection observation-closure matrix to track progress
- Remember to fill out a CAPA for any observations and fixes
- Make sure senior management is present for the closeout meeting
- Use the closeout meeting to obtain clarity and resolution expectations
- Only orally commit to those actions you have control over

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Key Point Review

- Respond to FDA within 15 business days with objective proof
- FDA will generally know within 60-seconds if you "get it"
- FDA expects a mix of short-term and long-term remediation activities
- Use the inspection observation-closure matrix to speed response
- Make sure your response is professional and reasonable
- The response needs to come from top management
- If you get a warning letter, you have even less time to respond (10 days), so make sure you get your 483 response right

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Exercise – Action Plan to Consider

What's ONE (1) thing that you can commit to do over the next 30 days to improve your FDA inspection handling and response?

Examples:

- Incorporate Cerulean's checklists into our SOP
- Summarize my learnings & recommendations from this workshop into a short memo for my management
- Call you when FDA shows up

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About Your Presenter
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Trainer for FDA and Health Canada inspectors and district officers on advanced data integrity inspection techniques and detecting data fraud

Served on behalf of the US Department of Justice as the independent overseer for the five-year, multi-million dollar Dr. Comfort Corporate Integrity Agreement

Industry reviewer for the international standard, BSI 10008 *Evidential Weight and Legal Admissibility of Electronic Information* (2015)

Former lead expert for the ISPE GAMP Data Integrity Working Group

Author of Get to Market Now! Turn FDA Compliance into a Competitive Edge in the Era of Personalized Medicine (2010); co-author of Pharmaceutical Regulatory Inspections (2014)

Prior to founding Cerulean, John spent more than 15 years designing, implementing, and being accountable for quality systems and data compliance programs for FDA, DEA, BIS, ICH, IMDRF, and ISO

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Final Questions?

thank you

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