Flawless FDA Inspection
Handling and Response

Practical Approaches to Success

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cerulean associates LLC
lean compliance + FDA consulting

FDANEWS

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Handout of Exercises

- List of all the workshop reference materials, checklists, sample SOP, guidelines, etc.
- Structured exercises
- Executive bio

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> “ As a general rule, a Warning Letter should not be issued if the agency concludes that a **firm’s corrective actions are adequate and that the violations** that would have supported the letter **have been corrected**.”

FDA, *Regulatory Procedures Manual, § 4-1-3 #3*
http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm176870.htm

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In every Warning Letter, FDA tells the firm HOW they failed in their response to the inspection

"We acknowledge your commitment to update your procedure for laboratory records. However, **you did not address how you will assure that procedures are appropriate, properly implemented, and followed**. You also **did not adequately address the impact of your insufficient data on decisions** made by your firm regarding manufacturing and product quality."

Warning Letter to Degasa S.A. De C.V., April 2018
https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm605390.htm

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Session Goal

This is NOT "how to prepare for an inspection"

Avoiding a Warning Letter (or worse) through…

1. Properly handling an FDA inspection **to FDA's expectations**
2. Expertly **balancing your and FDA needs** during the inspection closeout meeting
3. Crafting an **inspection response that meets FDA's expectations and requirements**.

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Agenda

1. FDA inspectional tactics and ***how to take advantage*** of these
2. Handling the actual inspection and closeout meeting with an ***eye toward your response***
3. Writing a successful response to FDA

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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 (October 2017 revision)
  - 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

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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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Disclaimer

This is not legal advice.

Information in this presentation draws upon a variety of sources, including published FDA warning letters and Form FDA-483s, FDA regulations and statutes, FDA presentations, policies, and other regulatory guidance documents, personal experiences, interviews and research, all or any of which may or may not have been prepared or conducted by the presenter. Presenter does not provide a warranty concerning the accuracy of the information contained in this presentation. The contents of this presentation are intended for general information only and should not be construed as legal advice. Presenter assumes no liability for actions taken or not taken as a result of the information in this presentation.

Approach

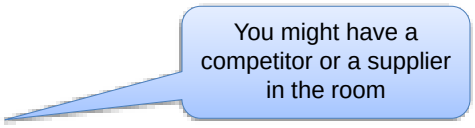
- Learning can come studying the mistakes of others!
  - Use of FDA Warning Letters and Form FDA-483s is to illustrate some issues – not to denigrate firms or individuals involved in any way
- Employ simple questions to help check understanding
- Structured interactive exercises throughout

Ground Rules

- Business casual approach
- Turn off (or silence) your cell phones for the workshop
- Ask lots of questions – *this is for you!*
- Bring examples from your experience
- Participate – don't be afraid to disagree based your experiences … *there are exceptions to every rule*
- Have fun!

Participant Introduction

- Your Name
- Your company
- Your job title
- What's ONE reason you decided to attend this pre-conference workshop?



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