

Health Authority Inspection Facilitation and Management

Janet Rose Christensen, M.S.P.H.

Vice President, Regulatory Affairs and Quality

AVI BioPharma, Inc.

Portland, OR 97258

503.227.0554

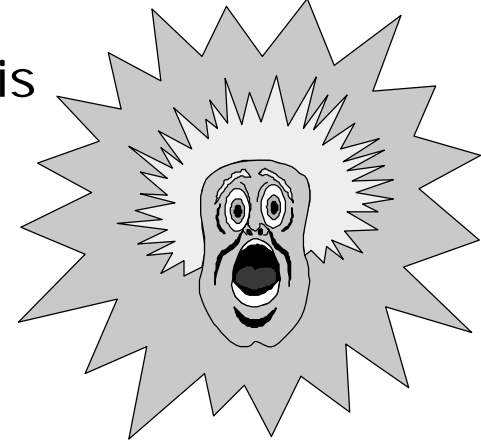
jrc@avibio.com

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"The FDA is
here to
see you!"



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OK, so NOW what????



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*Inspection preparation requires
time, but can minimize inspection
problems (which is why you are
here...)*

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AGENDA

- Types of Inspections
- What's our Strategy?
- How Inspections Work
- Rules
- Tips for Interacting with Inspectors
- When It's Over...
- Questions?

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■ Types of Inspections

- General Compliance (*most often Unannounced*)
- Treatment IND
- For Cause
- Pre-Approval ("PAI")

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Our organization and execution of the inspection will be assessed by the inspectors, and reflects on the company as a whole.

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- Expectations for interactions with FDA:

Collegial
Professional
Respectful
Honest



Health Authority Inspection Facilitation and Management: *Team Rules*

Inspections are a TEAM SPORT-work together:

No indirect back stabbing, innuendoes, etc.

1. Do not lie or misrepresent information
2. Do not antagonize the inspectors; respect the job they are doing.
3. Listen carefully and request clarification to ensure the issue is understood before responding.
4. Demonstrate respect to other members of your team.

Health Authority Inspection Facilitation and Management: *Team Rules*

5. Correct any errors or miscommunication as soon as it comes to light.
6. Identify potentially contentious issues to the Inspection Coordinator out of the inspection team's presence.
7. Avoid responding with qualifiers, such as "typically", "normally", "generally", "we usually", etc., unless it is clear that an error was made, and the deviation can be documented.

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Inspection Team

INSPECTION COORDINATOR

AREA HOST

SCRIBE *[Use pink ink for taking notes.]*

RUNNERS

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Space planning

- ✓ Primary meeting room is Small Conference Room
Your meeting will be canceled in this room during inspections
- ✓ Document Staging Area is Document Control for both documents and people

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“Inspection Books” for the inspection team:

- organizational charts
- inspection team “rules”
- company’s Annual Report
- a list of the products
- a copy of the last 483 and responses
- floor plans
- list of the key individuals with cards
- those that will attend the Exit Interview.

Health Authority Inspection Facilitation and Management: *Inspection Rules*

1. The inspector(s) will be accompanied throughout the inspection.
2. The inspectors will gown appropriately.
3. No cameras and recording devices.
4. Copies provided upon request (make duplicates for the diary).

Health Authority Inspection Facilitation and Management: *Inspection Rules*

5. The inspection can occur during normal business hours, unless otherwise arranged.
6. Policy on samples: we provide them.
7. Policy on signing legal documents (affidavits, receipts, etc.): do not sign anything.

Health Authority Inspection Facilitation and Management: *Inspection Rules*

8. Provide the Inspectors refreshments (e.g., coffee). Ask the Team Leader if they can accept other items such as snacks or lunch.

Health Authority Inspection Facilitation and Management: *Inspection Execution*

- The designated (or back-up) individual greets the inspectors, and escorts them to the conference room.
- Receive the FDA 482 and inspect credentials.
- Review the "List of Rules" for the Inspection Team (IT).
- Jointly develop agenda and issue copies

Health Authority Inspection Facilitation and Management: *Inspection Execution*

- IT may request preliminary list of records for review.
- The inspection may start with tour, or review of complaints and AE's or a combination of both.
- There usually is a daily wrap with IT, to review issues and plan for next day.
 - identify erroneous answers or problems.

Health Authority Inspection Facilitation and Management: *Inspection Execution*

After Inspection Team leaves, hold internal Daily Wrap Meeting.

- *areas of concern*
- *review discussions to prep others*
- *identify potential miscommunication*
- *are there potential issues that were uncovered that can be corrected in other areas?*

Health Authority Inspection Facilitation and Management: *Inspection Completion*

- The Exit Interview is the Inspector Team's meeting, not yours; let them talk.
- Listen carefully to all comments and observations.
 - We will request clarification of observations, if needed.
 - We will identify erroneous statements.
 - We will inquire if there were any interactions with which they were not pleased.

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Health Authority Inspection Facilitation and Management: *Inspection Completion*

- If a FDA Form 483 is issued, and immediately after Inspectors leave, we will determine who is responsible for each item and assign due date for responses.



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Post-Inspection

- Respond to 483 in the stated time-frame
 - If you cannot provide complete responses, do indicate what you can and when you will be providing a complete response.
- Evaluate the appropriateness of implementing corrective action Apply throughout the organization, even if the observations pertained to a specific area
- Prepare a record documenting the implementation of all corrective action and monitor progress.
 - Use this to prepare for audits, future inspections and regulatory filings.
- Obtain a complete and redacted EIR

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Health Authority Inspection Facilitation and Management: *After its Over...*

- Regardless of the outcome



- *Celebrate!!!*

The completion of an FDA inspection is an accomplishment.

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Health Authority Inspection Facilitation and Management: *Personal Reflections*

- FDA inspectors were very well prepared, professional and knowledgeable.
- Inspections are learning experiences
- Keeping everything on track is a challenge when all inspectors split up.
- It is important to send a message of cooperation, sincere desire to produce quality material and comply with regulations.

