LEGAL ASPECTS OF FDA REGULATORY COMPLIANCE: PREPARING FOR AN FDA FACILITY INSPECTION AND RESPONDING TO A 483 LETTER

KRISTY KIMBALL | BRENT JOHNSON | LEE GRAY

HOLLAND&HART LLP

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AGENDA

- **Preparing for an FDA Inspection – Brent Johnson**
- **What to do During an FDA Inspection – Lee Gray**
- **Responding to a 483 Letter – Kristy Kimball**

PREPARING FOR AN FDA INSPECTION

Brent E. Johnson, Partner
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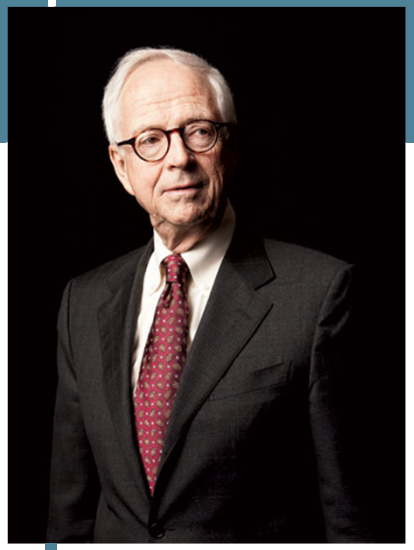

“I am not a potted plant.”

Brendan Sullivan
— attorney for Lieutenant Colonel Oliver North, Iran Contra Hearings. 7/10/87.

“I have always relied on the kindness of strangers.”

Blanche DuBois
— *A Streetcar Named Desire*

“Even a fool, when he holdeth his peace, is counted wise: and he that shutteth his lips is esteemed a man of understanding.”
—Proverbs 17:28

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FDA'S LEGAL AUTHORITY TO CONDUCT A FACILITY INSPECTION

- **Designated representatives of FDA**
- upon presenting **appropriate credentials** and a **written notice** to the owner or operator
- are **authorized to enter** and
- inspect **at a reasonable time**, **in a reasonable manner**
- any factory, warehouse, or establishment in which food, drugs, devices, tobacco products, or cosmetics are manufactured, processed, packed or held for introduction into interstate commerce
  - Food includes dietary supplements

  21 USC § 374 (a)

TYPES OF INSPECTIONS

- CGMP/QS inspections
- Pre-Approval Inspections (PAIS) typically result when you have sought Pre-Market Approval for a device
- For Cause Inspections – Recalls, complaints

REFUSAL TO PERMIT INSPECTION IS A PROHIBITED ACT

- Denying FDA entry to the establishment is a prohibited act.
- Responsible Persons may be held personally liable
  - Up to one year in prison
  - $100,000 penalty to individual/ $200,000 penalty to corporation

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DELAY IN INSPECTIONS

- **Delay Scheduling Pre-announced Inspections**
- **Delay During an Inspection**
  - Facility does not allow the FDA investigator access to an area of the facility
    - until a specific future date or time even though the area is operational.
  - Facility leaves the FDA investigator in a conference room without access
    - to necessary documentation or responsible individuals for
    - an unreasonable period.
  - Facility does not provide the FDA investigator access to aseptic processing areas
    - until the investigator accommodates the facility's documented gowning procedures.
- **Delay Producing Records** — Failing to timely produce records in response to an investigator request
  - that is specific and timely.

CONSEQUENCES OF A DELAY IN INSPECTION

- FDA may deem products from the establishment adulterated.

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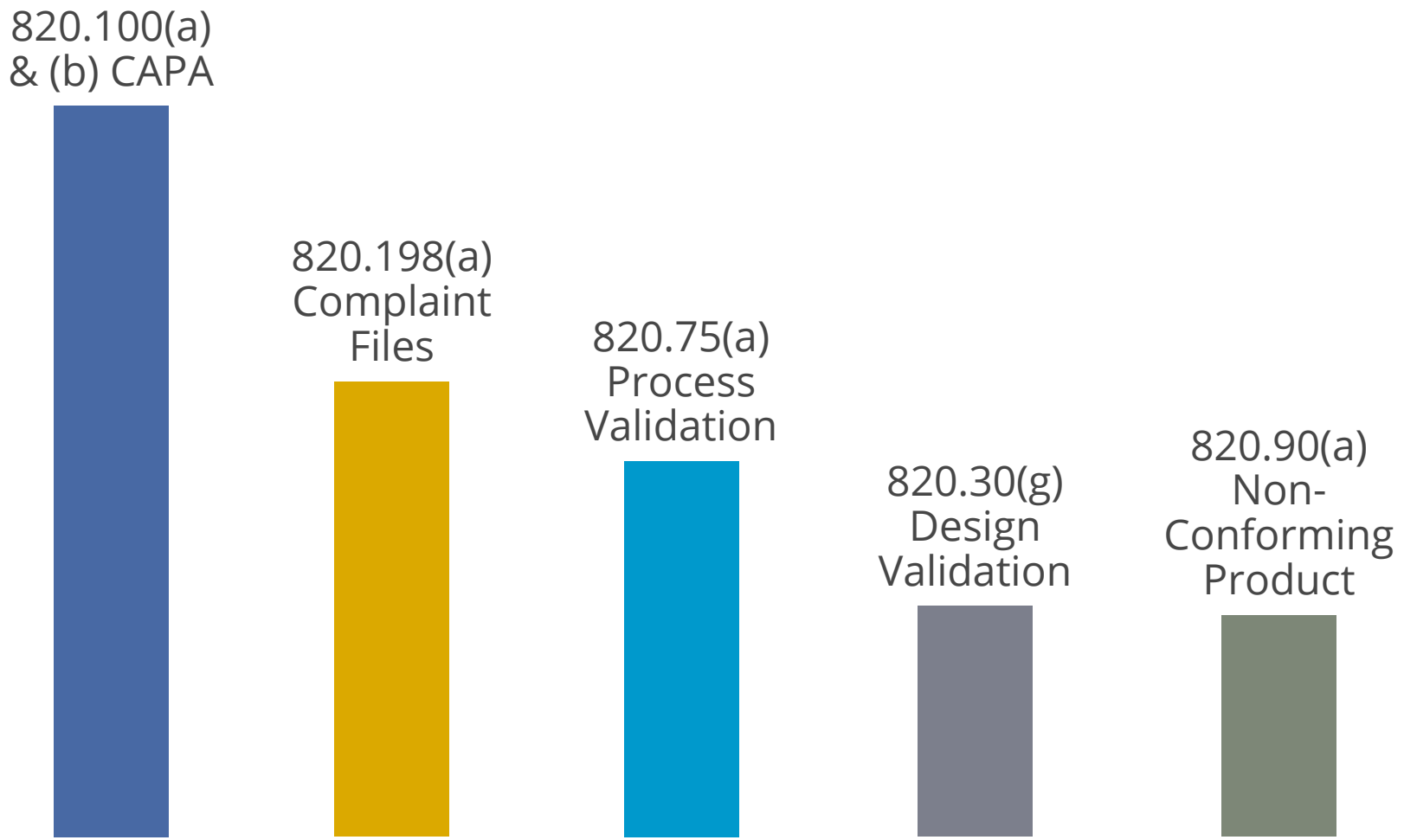
MOST COMMON FDA 483 OBSERVATIONS FOR MEDICAL DEVICE COMPANIES IN 2017



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MOST IMPORTANT ITEM…

Make sure

- Prior observations in Establishment Inspection Report (“EIR”)
- 483 Observations
- Corrective Action Plan items

and the resolutions are documented!!

COMPANY GOALS

Demonstrate that:

- You understand your legal obligations.
- You are committed to producing safe product.

Protect the Company's confidential business information.

- Photographs
- Records

Both are subject to the Freedom of Information Act (FOIA),

- meaning that anyone can request that the FDA release any documents related to inspection of the company.
- ***CAN BE RAISED IN LITIGATION***

HOW TO MEET THESE GOALS

- Have a core team of individuals that understand their roles and responsibilities within the inspection team
- Have your important records collected in a place that is easily accessible, but not in the room where you meet with the FDA inspector
- Be prepared to answer anticipated questions
- Be able to demonstrate a robust and consistent approach to confidentiality
  - Cannot be made up on the spot – and must be followed all the time
- Be able to present differences of opinion and preserve objections through the conduct of the inspection

DESIGNATE AN INSPECTION TEAM

- FDA Contact
- Note Taker
- Technical contact(s)

"Great is our admiration of the orator who speaks with fluency and discretion."

— Marcus Tullius Cicero

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THE INSPECTION POLICY AND MANUAL

- FDA Inspection Policy
  - If appropriately treated, contains privileged and confidential attorney-client communications
  - Provides the "why" of items in the inspection manual
- Inspection Manual
  - Designed to be used the day of the inspection so that you can provide FDA with written evidence of your policies for regulatory inspection.
  - Lists the actual written policies to be presented to the FDA

INSPECTION POLICIES

- The Inspector shall follow all health and safety rules
- The Inspector shall always be accompanied
- The Inspector will direct all questions to the FDA contact or designated personnel
- The Company does not permit FDA photography
- The Company does not permit recording equipment

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THE INSPECTOR SHALL FOLLOW ALL HEALTH AND SAFETY RULES

POLICY

The Inspector Will Abide by All Health and Safety Rules

- The Inspector is expected to comply with the Company's health and safety rules at the facility. This includes, but is not limited to:
  - Washing and sanitizing hands before entry into the facility or any work area.
  - Wearing protective clothing
  - Not touching or handling products without prior request
  - Following all safety instructions of the FDA Contact or Technical Contacts

REASONING

- Start here because this is clearly a reasonable limitation to the inspection
- Common ground with FDA – production of safe products
- Not covering this may be a red flag

ONLY DESIGNATED PERSONNEL MAY RESPOND TO QUESTIONS

POLICY

Only Designated Personnel May Respond to Questions or Requests

The Inspector will be instructed that all questions should be addressed to the Company Contacts or other designated company representatives. The Inspector is not permitted to conduct private employee interviews on company property. Employees are reminded that they are not permitted to respond to the Inspector's questions without express authorization from the Company Contact, as to specific questions. This will help to facilitate appropriate communication across linguistic and cultural barriers, and limit accidental exposure to confidential or proprietary information of the company.

REASONING

- That certain persons do not speak English is not enough
- The FDA inspector may request to interview employees about their specific duties
- Do not outright refuse, but FDA contact can insist on being present, and may also object to questions outside the scope of that person's job performance

USE OF PHOTOGRAPHIC EQUIPMENT

POLICY

Use of Photographic Equipment

To protect the confidential business information and trade secrets of Company, photography is not allowed in the facility. Specifically, Company has invested considerable time and effort in building its established network of suppliers that provide high quality inputs and the development of processes to effectively process and package inputs that offer Company a competitive advantage in the marketplace. The disclosure of such confidential information and trade secrets would therefore cause competitive harm to Company. Accordingly, Company has posted signs prohibiting photography within the facility, requires all visitors and Independent Contractors to sign a document acknowledging it has a 'no photography' policy, and prohibits visitors from bringing photographic equipment or cell phones with photographic capability into the facility. We have been advised that the Inspector does not have the statutory authority to take photographs at the facility.

REASONING

- Most contentious area
- Sometimes the FDA response is
  - "The facility declined photography."
  - Other times it is, **"Are you refusing inspection?"**
- When companies are successful in preventing FDA photography, it is when they have a uniform confidentiality policy. Be prepared to present the following in support:
  - Visitor Policy & Blank Questionnaire
  - Independent Contractor Policy & Blank Questionnaire
  - Written employee training curriculum
- Once finalized, each should be a part of the Inspection Manual
  - As changes are made though, policies must be kept up to date.

VISITOR POLICY – EMPHASIS ON FOLLOWING THE RULES

- Short introduction session to cover the rules listed on the form
- **How many people actually read forms on a visit?**
- Best practice is to actually cover these items and ask for questions before entering the facility.
- This could probably take 10-15 minutes
- **Company Rules**
  - All visitors shall present valid identification matching the name listed on the form.
  - No visitor shall be permitted entry with any of the above listed conditions, or other condition of concern that could risk contaminating the product. The Plant representative shall make the final determination as to whether any other ailment reported is a condition of concern.
  - All visitors must be accompanied at all times during their visit to the plant. This is to ensure that no visitor places him or herself in an unsafe position, and that the risk of product contamination and risk of incidental exposure to confidential information is minimized.
  - **Follow all safety instructions as given to you by the Plant representative or posted on placards and signs within the plant.**
  - **Before entering the plant, remove watches and any loose jewelry.**
  - **Before entering the plant, please check any cell phone, camera, or recording device in with the plant staff. It will be held in a secure area for you and returned to you upon the completion of your visit.**
  - Wear the protective clothing provided at all times while in the plant (apron, mask, shoe covers, gloves).
  - Do not handle or touch any products.
  - Do not touch any equipment, walls, or instruments.
  - Do not eat, smoke, chew tobacco, or drink anywhere in the plant.
  - Spitting is totally forbidden.
  - Wash & sanitize hands each time you enter the work areas.

FACILITY AND PROCESS MODIFICATIONS

- FDA compliance is writing down what you do, and then doing what you have written down
  - Must be a procedure for collecting and securely holding visitor cell phones, jewelry, etc.
  - Signs in the facility prohibiting:
    - Photography
    - Recording
    - Eating
    - Smoking
    - Spitting
  - Image checklist before entering the process area
    - Hands washed?
    - Protective apparel?
  - Keeping these questionnaires on file?
    - Each questionnaire gets scanned into the DMS every time.

Example Sign

Images work best

THE HEALTH QUESTIONNAIRE (FROM VISITOR POLICY)

Disease	Yes	No
Diarrhea		
Typhoid		
Fever		
Yellowing of the eyes		
Throat infection		
Sneezing		
Open sores		
Skin infections / Eczema		
Any other communicable disease?		

VERIFICATION PORTIONS OF THE VISITOR

- **Photo and Recording Equipment Surrender for Visitors**

  The following is agreed to by signature on this form:

  I have truthfully reported my health history and have no conditions that would prevent me from entering the plant.

  I have read, understood, and will comply with all Company Rules.

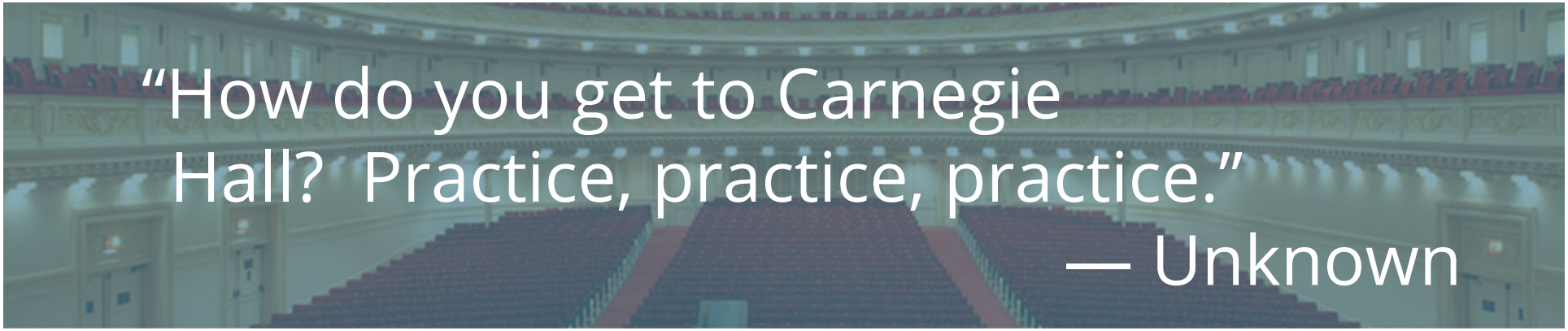
  I will not carry a cell phone, camera, recording device into the plant. Nor will I otherwise record or commit to memory my observations. I will not disclose or share what I have observed with persons outside Company.

  Visitor's Signature:..... Date:.....

  Plant Representative Signature:..... Date:.....
  (Production Manager/Asst. Manager–Production/Sr. Executive-Production)

SAFETY AND CONFIDENTIALITY MUST BE VIGILANTLY ENFORCED

- **No exceptions.**
  - Visitor,
  - Independent Contractor,
  - Employee, or
  - Officer of the Corporation.
- **Safety**: It can be uncomfortable to ask someone if they are feeling okay today, but you need to do that.
- Why: Diagnosed illness in one person, visitor or worker, can trigger a major recall if product gets shipped
  - It does not matter if the product is contaminated or not
  - FDA has the authority to suspend a facility registration, or mandate a recall when it believes there is a **reasonable probability of a serious risk to human health**
- **Confidentiality**: Photos inside the plant are not permitted by anyone.
- Why: Photos on the internet will undermine and likely waive an FDA photography argument rooted in confidentiality
  - It is not "reasonable" to limit FDA photography if the facility does not limit photography by others



Conduct mock FDA inspections

- Include security, receptionists, and Inspection Team
- Make sure you can access important records easily
- Make sure you can explain company inspection policies
- Develop inspection routes

WHAT TO DO DURING AN FDA INSPECTION

Lee Gray, Partner
Holland & Hart LLP

WHAT TO DO DURING AN FDA INSPECTION

- FDA's Purpose for the Inspection

  A careful, critical, official examination of a facility to determine its compliance with the laws and regulations administered by the FDA. Inspections may be used to collect evidence to document violations and to support regulatory action, when appropriate, or they may be directed to obtaining specific information on new technologies, good commercial practices, or data for establishing other regulations.

WHAT TO DO DURING AN FDA INSPECTION

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SO, HOW LONG IS THIS GOING TO TAKE?

- **It depends on many factors.**
  - Type/scope of inspection
    - Full/Comprehensive (not targeted)
      - But inspectors will still have a good idea of your "compliance culture" very quickly
    - Abbreviated/Directed (targeted to specific areas)
  - Size of establishment
    - Smaller establishments may properly have less documentation (e.g., protocols or procedures) where there is a shorter line of communication and fewer employees involved in each production step.
      - Detailed written assembly, process, and other instructional procedures required for larger firms may not be needed. In many cases, blueprints or engineering drawings could be adequate procedures.
      - The QS regulation requires that certain activities be defined, documented and implemented, not separate procedures for each requirement.
    - Evidence of non-conforming products and knowledge/training are significant for such smaller establishments.
  - Complexity of establishment/device being produced
    - The complexity/extent of the procedures should be proportional to the complexity of the manufacturer's quality system, the complexity of the organizational structure and the complexity/risk of the finished device being produced
  - Conditions of establishment
  - What is found during the inspection

SO, HOW LONG IS THIS GOING TO TAKE?

- **Factors (con't.)**
  - Firm history and FDA records
    - Information from different FDA locations is pulled into Total Product Life Cycle (TPLC) Reports and Establishment History Reports (EHR2).
      - TPLC Reports combine registration and listing, premarket, adverse event (MDR), CDRH complaint details, and high level recall and inspection information.
      - EHR2 Reports combine detailed recall and inspection history information.
  - Your "FDA permanent record" is another sign of your culture of compliance—or non-compliance
    - Correspondence with FDA, MDR/consumer complaints, recalls
  - Not just these, but also inspector notes from prior inspections (e.g., confrontational situations)

MAIN CONSIDERATIONS

- **Personnel**
  - Should appear (and be) professional, trained, and knowledgeable
- **Facilities**
  - Should be clean and organized
- **Documentation**
  - Organized and detailed enough for your size of establishment
  - Inspector will often use a sampling technique to reduce time reviewing records and use statistically-based inferences on what other records look like. This sampling may turn to more robust document review if an objectionable condition is found.
- **Product Samples**
  - Although not routinely collected, products, packaging, and labeling will be examined and must comply with your written specifications and FDA clearance/approval

SCOPE OF INSPECTION

- **Medical Device Establishments**
  - Quality Systems (21 CFR § 820)
  - Generally grouped into seven subsystems
    1. **Management Control**
    2. **Design Controls**
    3. **Production and Process Controls (P&PC)**
    4. **Corrective and Preventive Actions (CAPA)**
    5. Facilities and Equipment Controls,
    6. Materials Controls and
    7. Document/Records/Change Controls

QUALITY SUBSYSTEMS

- **Management Controls (21 CFR § 820.20-25)**
  - Those with executive responsibility must establish sufficient quality system and assure that the policy is understood, implemented, and maintained throughout the organization.
  - Adequate organizational structure/personnel
  - Adequate responsibility, authority and independence of personnel that manage, perform, and assess work
  - Documentation
  - Review/Audit

QUALITY SUBSYSTEMS

- **Design Controls (21 CFR § 820.30)**
  - Class II and III devices (and 5 Class I devices)
  - Design History File (DHF) for each type of device
    - Planning – describes design and development activities and implementation responsibility (approvals)
    - Input
    - Output
    - Review
    - Verification
    - Validation
    - Product Specifications

QUALITY SUBSYSTEMS

- **Production and Process Controls (P&PC) (21 CFR § 820.70-75)**
  - Documented instructions, SOPs and methods that define and control the manner of production
    - Process changes
      - Validation of process parameters
    - Facilities
      - Environmental controls, contamination, equipment, buildings
    - Personnel
    - Maintenance/inspection/adjustments
      - Inspection, measuring, testing equipment
    - Automation/software

QUALITY SUBSYSTEMS

- **CAPA (21 CFR § 820.100)**
  - Critical in most Product Liability litigation
  - Reporting requirements, corrective actions and removals, and tracking requirements (where applicable), are covered in inspections of this subsystem.
    - Analyze all processes, operations, records
    - Tracking and analyzing reported issues/complaints, returned/failed products
    - Statistical methodology to detect quality problems
    - Investigate causes (product, processes, quality system)
    - Actions to correct/prevent issues
    - Verify/validate corrective/preventative actions
    - Implementing/recording changes
    - Communicate to responsible parties
    - Management review

QUALITY SUBSYSTEMS

- **Facilities and Equipment Controls**
- **Materials Controls, and**
- **Document/Records/Change Controls**
  - These three subsystems are generally found across a firm's entire quality management system and are evaluated during inspection the four major subsystems described above.

SCOPE OF INSPECTION

- **Medical Device Establishments**
  - **Level 1 – Abbreviated**
    - Routine surveillance and initial inspections of all firms, other than firms that manufacture Class III devices
    - Covers two subsystems:
      - Corrective and Preventive Actions (CAPA) plus
      - Production and Process Controls (P&PC) or Design Controls
    - If post-market information and/or objectionable conditions found, may be converted to Level 2
  - **Level 2 – Comprehensive**
    - Initial inspections of Class III device manufacturers, foreign establishments, training purposes, and Class II device manufacturers (based on risk assessment and where possible)
    - Covers the four major subsystems
      - Management Controls,
      - Design Controls,
      - CAPA and
      - P&PC
  - **Level 3 – Special/For Cause**

SCOPE OF INSPECTION

- Pharmaceutical Establishment
  - Risk-based approach for frequency
    - Types of products
    - Types of processes
    - Type of facility

    } Site risk potential
  - In this context, the risk is the probability or severity that a drug will fail to meet the needs or expectations of the patients and their surrogates.

TYPICAL PROCEDURE

- Pre-Inspection Notice (If applicable)
- Present credentials/482 Notice
- Walk Through
- Interviews
- Record review
- Samples

INSPECTION NOTICE (FDA 482)

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION	1. DISTRICT OFFICE ADDRESS & PHONE NO. 1431 Harbor Bay Parkway Alameda, CA 94502 (510)337-8700

TO			
	2. NAME AND TITLE OF INDIVIDUAL Helen E. Castro, President	3. DATE 07/28/13	
	4. FIRM NAME ABC Bread Company	5. HOUR	7:30 a.m.
	6. NUMBER AND STREET 579 Main Street		p.m.
	7. CITY AND STATE & ZIP CODE Richmond, CA 94805	8. PHONE NO. & AREA CODE (510)123-4567	

Notice of Inspection is hereby given pursuant to Section 704(a)(1) of the Federal Food, Drug, and Cosmetics Act [21 U.S.C. 374(a)][1] and/or Part F or G, Title III of the Public Health Service Act [42 U.S.C. 262-264][2]

As a small business that is subject to FDA regulation, you have the right to seek assistance from the U.S. Small Business Administration (SBA). This assistance includes a mechanism to address the enforcement actions of Federal agencies. SBA has a National Ombudsman's Office that receives comments from small businesses about Federal agency enforcement actions. If you wish to comment on the enforcement actions of FDA, CALL (888) 734-3247. The website address is www.sba.gov/ombudsman.

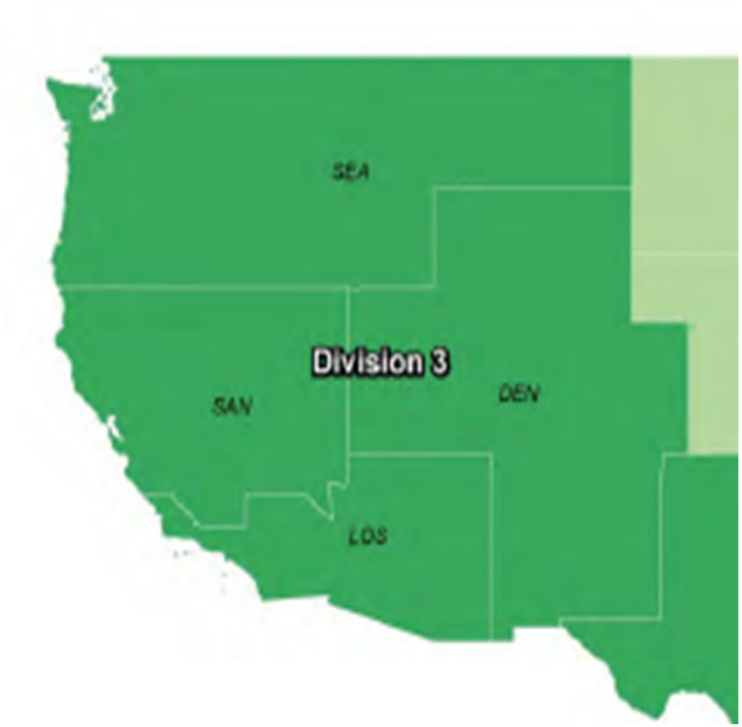
FDA has an Office of the Ombudsman that can directly assist small business with complaints or disputes about actions of the FDA. That office can be reached by calling (301) 796-8530 or by email at ombuds@oc.fda.gov.

For industry information, go to www.fda.gov/oc/industry.

9. SIGNATURE(S) *(Food and Drug Administration Employee(s))*	10. TYPE OR PRINT NAME(S) AND TITLE(S) *(FDA Employee(s))*
Sidney H. Rogers	Sidney H. Rogers, Investigator

WHO AM I DEALING WITH?

- Pharma



- Medical Devices

HOW TO RESPOND TO A 483 NOTICE

Kristy Kimball, Partner
Holland & Hart LLP

HOLLAND&HART LLP

483 OBSERVATIONS BY INDUSTRY IN 2019

Cite Program Area Name	483s Issued
Biologics	116
Bioresearch Monitoring	190
Devices	822
Drugs	779
Foods	2540
Human Tissue for Transplantation	109
Parts 1240 and 1250	47
Radiological Health	17
Veterinary Medicine	229
Sum Product Area 483s from System*	**4849**
Actual Total in System 483s**	**4770**

YOU RECEIVE A FORM 483 NOTICE: NOW WHAT?

APPENDIX B

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER
6th & Kipling St. (P.O. Box 25087)
Denver, CO 80225-0087
(303)236-3000 Fax:(303)236-3100

DATE(S) OF INSPECTION [redacted]

FEI NUMBER [redacted]

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
[redacted] General Manager

FIRM NAME [redacted]

STREET ADDRESS [redacted]

CITY, STATE, ZIP CODE, COUNTRY [redacted]

TYPE ESTABLISHMENT INSPECTED
Device Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

Procedures for design control have not been established.

Specifically, you have not adequately maintained a design history file for the [redacted]
For example, your firm does not maintain the following design control elements:

a) Design and development plan, design inputs, and design outputs;

b) Design review;

c) Verification and validation of the design; and

d) Design transfer for the product.

OBSERVATION 2

Procedures for corrective and preventive action have not been established.

Specifically, your firm has not established procedures for corrective and preventive action, which must include requirements for the following:

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE [redacted]

X [redacted]

DATE ISSUED [redacted]

FORM FDA 483 (09/08) PREVIOUS EDITION OBSOLETE INSPECTIONAL OBSERVATIONS PAGE 1 OF 8 PAGES

HOW TO RESPOND TO A 483 NOTICE

- Treat any 483 Observation with the utmost seriousness.
- Review the related section of the CFR (21 CFR 820) to understand the standard.
- If you don't have adequate, sophisticated in-house resources to respond, DO NOT TRY.
- Get the necessary resources you need to respond, which sometimes includes legal counsel, a consultant, or both.

HOW TO RESPOND TO A 483 NOTICE

- Use the FDA contacts as a resource. Open up lines of communications to mitigate misunderstanding
  - In most cases, FDA officials are willing to answer questions, and if they can see you are exerting sincere efforts to address concerns, they will be less punitive.
- Avoid becoming defensive or hostile. Ensure professionalism at all times. If there is an argument to be had over FDA findings, let an attorney do it for you.
- Generally, need to give an initial written response within 15 days but can supplement; sometimes, it takes time to implement all of the needed changes. FDA understands this and if making progress, normally this is acceptable.

HOW TO RESPOND TO A 483 NOTICE

- Each of the asserted deficiencies needs to be addressed with specificity. Often, SOPs need to be re-written in a manner to strictly comport.
  - This often requires outside consultants. Don't try and do this "in-house" if you don't have sophisticated and experienced personnel.
- The response needs to be highly professional and follow a format of a "call and response" for each deficiency, with the included documentation to show how your actions bring you back into compliance.

483 RESPONSE EXAMPLE

- Include a cover letter that creates some sympathy, but shows the company is taking the 483 seriously and implementing needed changes.

Example:

OBSERVATION 1

Observation 1:

Procedures for design control have not been established.

Specifically, you have not adequately maintained a design history file for the [redacted]. For example, your firm does not maintain the following design control elements:

a. Design and development plan, design inputs, and design outputs;
b. Design review;
c. Verification and validation of design; and
d. Design transfer for the product.

Response to Observation 1:

We present document *QA14-Product Design and Development Process* (Appendix G). This document comprises:

a. Design and development plan (Sections 1-3),
b. Design inputs (Section 4),
c. Design outputs (Sections 5-7);
d. Design review (Sections 8-10);
e. Verification (Sections 11-15) and validation of design (Sections16-17) ; and
f. Design transfer for the product (Section 18-20); and
g. Design changes (Section 21).

These Sections are in accordance with 21 CFR 820.30(b)-(i). The document also includes tables to provide proper revision control of the document. Section 3(e) of the document also states that a Design History File (DHF) will be created and implemented according to 21 CFR 820.30(j).

In addition, we provide document *QC4-Software Verification/Validation SOP* (Appendix H) This process will be implemented to verify and validate the firmware used in the [redacted] device.

483 RESPONSE

- May be a back and forth with FDA until they are fully assuaged. If they aren't or if a company ignores or doesn't seem to take the matter seriously, it can escalate:
  - Public Warning Letter
  - Forcing an in-person meeting at FDA offices
  - Suspending ability to distribute
  - Fines/penalties

OTHER CONSIDERATIONS

- If company is a contract manufacturer, may have underlying contracts that require a customer be notified of any FDA audits and/or 483 Observations.
  - If don't abide, can cause breach of contract claims.
- If company is a contract manufacturer, often, the customer is also contacted by FDA; this can lead to customer concern, disputes and litigation.
- Bottom line: Quickly identify what third parties should be quickly notified for contractual or practical reasons in order to mitigate "fall out."

RESOURCES

- FDA Inspection Observations
- FDA Form 483 FAQ
- FDA Quality System(QS) Regulation/Medical Device Good Manufacturing Practices
- FDA ORI FOIA Electronic Reading Room

Q&A

THANK YOU

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