FDA Drug Manufacturing Inspections and Current Good Manufacturing Practice

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“This presentation reflects the views of the authors and should not be construed to represent FDA’s views or policies.”
The presentation will summarize what to expect from an FDA inspection of a manufacturing facility. You will learn about the different kinds of inspections FDA performs, the standards by which your facility will be assessed (e.g., the Current Good Manufacturing Practice (CGMP) regulations), and what happens when deviations are observed.
Agenda

• CGMP
• Types of Inspections
  – Pre-Approval Inspection
  – Post-Approval Inspection
  – Surveillance
• Preparing for an Inspection
• Post-inspection
• Questions
Marketing Categories

• IND (clinical trial materials)
• NDA (new drug) or BLA (biologic) or ANDA (generic)
  – Rx and OTC
• OTC Monograph (e.g., toothpaste w/ fluoride, antiperspirant, aspirin)
• Unapproved drug
• Homeopathic product
• Medical gas (certificate or A/NDA)
What is a drug?

The term “drug” means¹ ...

A) An article *recognized* in the US Pharmacopeia (USP) or Homeopathic Pharmacopeia of the US (HPUS) or National Formulary (NF).

B) Articles *intended* for use in the *diagnosis, cure, mitigation, treatment, or prevention* of disease in man or other animal.

C) Articles *(other than food)* *intended* to affect the structure or function of the body of man or other animal.

D) Articles *intended* for use as *a component* of any article specified in A, B, or C.

¹ As defined in section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act
Section 501(a)(2)(B):

“A drug... shall be deemed to be adulterated if the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this Act as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess.”
Legal Bases for CGMP

FDASIA 2012 amendment to section 501:

CGMP “includes the implementation of oversight and controls over the manufacture of drugs to ensure quality, including managing the risk of and establishing the safety of raw materials, materials used in the manufacturing of drugs, and finished drug products.”
“Current” in CGMP means...

Dynamic and evolves over time

Based on what?

- risk; cost/benefit; response to problems

Practice need not be prevalent

both “feasible and valuable” in assuring quality

flexible enough to accommodate innovation
Regulations – the CGMP History

1962: Authorizing legislation passed
1963: Initial version; several minor changes followed
1978: Major revision; most remains in current version
1979 – 2008: Many revisions, incl. tamper-evident packaging, label control, and reserve samples
3-phased major revision underway:
   2009 – Finalized Phase 1 (‘easier’) revisions;
   2015 – ?
21 CFR 210: CGMPs in manufacturing, processing, packing, or holding of drugs; General

210.1 — **Minimum standard** for **methods** used in, and **facilities or controls** to be used for the manufacture, processing, packing or holding of a drug to ensure that such drug meets **requirements of the act** as to safety, and has the identity and strength and meets the quality and purity it purports.

210.2

INDs – Phase II and III; guidance for Phase I

210.3

Definitions
CGMP for *Finished Pharmaceuticals*  
21 Part 211

**Subpart A** - General Provisions  
**Subpart B** - Organization and Personnel  
**Subpart C** - Buildings and Facilities  
**Subpart D** - Equipment  
**Subpart E** - Control of Components and  
  drug product Containers and Closures  
**Subpart F** - Production and Process  
  Controls  
**Subpart G** - Packaging and Labeling  
  Controls  

**Subpart H** - Holding and  
  Distribution  
**Subpart I** - Laboratory Controls  
**Subpart J** - Records and Reports  
**Subpart K** - Returned and  
  Salvaged Drug Products
Subpart A - General Provisions

- Minimum standards for human and animal finished pharmaceuticals

- Biologics – applicable; also 21 CFR Part 600+
Subpart B - Organization and Personnel

- Quality unit: Responsible for... almost everything
- Operators are to be trained and in sufficient number for the work
- Operators must not contaminate the process/product: wear appropriate clothing, refrain from manufacturing activities when ill, maintain personal hygiene
Subpart C - Buildings and Facilities

- Designed to facilitate cleaning and maintenance
- Be big enough and have separation to prevent mix-ups and cross contamination
- For aseptic processes: have smooth walls and ceiling, temperature and humidity controls, HEPA filtration and under positive pressure air, environmental monitoring, cleaning and disinfection processes
- **PENICILLIN** will be in a separate facility with separate HVAC
Subpart C - Buildings and Facilities

- Adequate controls for air pressure, microbial, dust, humidity and temperature for manufacture, processing, packing or holding
- Recirculation – beware of risk for cross contamination
- Lights, potable water supply, drains have air break or mechanism to prevent back-siphonage
- Keep the place clean and keep it maintained
Subpart D - Equipment

- Appropriate equipment for intended use that isn't reactive, additive, or absorptive so as to alter safety identity strength quality or purity

- Keep it clean and sanitized appropriate to prevent contamination of the product

- Keep it maintained and identified
Subpart D - Equipment

• Electronic equipment: calibrated, inspected to ensure proper performance.
  – Changes made by authorized person
  – See electronic signatures in 21 CFR 11

  • Guidance for Industry, Part 11, Electronic Records; Electronic Signatures - Scope and Application:

• Filters: for sterile drugs – not fiber releasing; no asbestos filters
Subpart E - Control of Components and Drug Product Containers and Closures

- Components, containers and closures are handled to prevent contamination, stored off the floor, appropriately identified as to status (quarantined, approved, rejected)
- Examined upon receipt, stored under quarantine until released
- Each lot of component is withheld from use until sampled (a representative sample), tested and released by quality
- Sampled and examined as described
Subpart E - Control of Components and Drug Product Containers and Closures

- At least one test to determine identity
- Tested (and retest as needed) to ensure meets specifications or accepted with a CoA from a manufacturer that has been established (historic use, testing, audits) as a reliable source
- Check them for contamination of filth and for micro if there is a potential
- First-in, first-out
- Containers and closures should be appropriate to not harm the product
Subpart F - Production and Process Controls

- Written procedures “designed to assure” that drug products meet established specifications – are followed and documented at the time of performance; deviations justified.

- Formulated to not less than 100% label claim

- Components identified, examined by a 2nd person before added
Subpart F - Production and Process Controls

- Yields checked
- Equipment status identified
- In-process checks
- Hold times
- Reprocessing – allowed, but controlled and quality approved
- Prevent objectionable microorganisms (sterile or non-sterile)
Subpart G - Packaging and Labeling Controls

- Examination of material
- Operations:
  - Strict control over labeling issuance
  - Physical separation of labeling operations
  - Examination of materials before use
  - Inspection of line immediately before use
  - Investigate discrepancies
Subpart G - Packaging and Labeling Controls

• Finished product examined and retains pulled
• Tamper-evident packaging (for OTC products)
• Expiration dating – label shall bear and be supported by stability studies
  – Exemption for homeopathic, allergenic extracts, INDs, and certain OTCs
Subpart H – Holding and Distribution

• Controls for
  – Proper storage (temperature and humidity) to protect: identity, strength, quality, and purity
  – Keep separated until released

• First-in, first-out

• System to facilitate recall
Subpart I - Laboratory Controls

- Establish “scientifically sound” specifications, standards, sampling plans, and test procedure
- Calibrate instruments
- Test each batch of drug product with validated test methods
- Stability program
  - Exceptions: homeopathic; allergenic extracts
Subpart I - Laboratory Controls

• Special tests
  • Sterility and pyrogen tested, if relevant
  • Ophthalmic ointments tested for foreign/abrasive particles
  • Controlled release products checked for rate of release (i.e., multipoint dissolution)

• Keep/check reserve samples

• Test non-penicillin products for penicillin when reasonable possibility of cross-contamination exists
Subpart J - Records and Reports

- Keep records for production, distribution and make available for inspection
- Conduct *at least annual* review of each drug product for changes (look at batch records, complaints, recalls and investigations)
- Tell management (in writing) if there is a problem (*e.g.*, complaints or returns)
- Keep a log for the use and cleaning of equipment
- Keep component, container, closure, and labeling records
Subpart J  -Records and Reports

• Keep and control master production records (*full signature* and secondary check)
• Master record has the name strength and description, the name and weight of the active, complete list of components... *the recipe*
• Batch production records for each batch is an accurate reproduction of the master record.
• Document significant steps in the manufacture, processing, packing, and holding
  – dates, people, equipment, weights, in-process results, inspections, yields, labeling, and investigations
  – include any changes, with appropriate justification
Subpart J - Records and Reports

- Production records to be reviewed/approved by quality control unit (before released or distributed) with all discrepancies investigated
- Laboratory data for how it was tested (all methods sampling, weights, calculations, and comparison to standards)
- Distribution records with lot numbers
- Complaint procedures and investigations when necessary
Subpart K - Returned and Salvaged Drug Products

- Returned goods are controlled. If in doubt, returned product shall be destroyed unless tests, examination, and investigation can prove identity, strength, quality, or purity.

- Salvage (product subject to storage extremes, humidity, fumes, pressure, age or radiation, fires, accidents) only if tests and inspection show it has identity, strength, quality, or purity.
Establishments Routinely Inspected

- manufacturers of drugs, including
  - dosage form
  - active pharmaceutical ingredient
  - excipient
  - clinical trial material
  - “biotech” (e.g., MaB; therapeutic proteins)
  - medical gas processors and transfillers
- independent packagers/labelers
- independent sterilizers
- independent laboratories
- ‘export-only’ involved in any of above checked establishments
OFFICE OF REGULATORY AFFAIRS
227 OFFICES IN FY 2014
FDA Foreign Posts
Types of Inspections
Four Major CGMP Inspection Types

1. Pre-approval
2. Post-approval
3. Surveillance (CGMP, routine)
4. For-cause or directed
The Pre-Approval Inspection Program
Objectives of Preapproval Inspection Program (7346.832*)

- Assure applications are not approved if the applicant has not demonstrated ability to operate with integrity and in compliance with CGMPs (assure readiness for manufacturing)

- Assure adherence to application commitments

- Assure the authenticity and accuracy of data submitted in applications

Pre-Approval Inspection Process

• While surveillance inspection of manufacturing sites cover:
  – Quality systems
  – Actual conditions and practices
  – Analytical methods

• Pre-Approval inspections cover more – such as an evaluation of:
  – Product development documentation
  – Bio/clinical batch manufacturing
  – Proposed manufacturing process, operational procedures, and batch records
  – Analytical method development
What is a “Facility Evaluation”? 

1° Drug Product Mfg

Chemistry Contract Lab

Crude API/Drug Substance Mfg

Drug Product 1° Labeler

Application

Distribution Center

2° Drug Product Mfg

API/Drug Substance Mfg

Micro Contract Lab
Roles and Responsibilities:

PAI CPGM (Attachment A)
Responsibilities of on-site inspection and CDER review by Specific Area of Assessment (3 pages)

Areas:
- Raw data review
- API manufacturing
- Novel excipient manufacturing
- Intermediates
- Manufacturing facility controls
- Control of components (raw materials)
- Manufacturing and controls of finished product
- Container/Closure Systems
- Packaging and labeling processes and controls
- Finished product test methods and acceptance criteria
- Stability, finished product
- Comparison of pilot-scale batches and proposed commercial scale batches
- Sterility assurance (if applicable)
- Parametric release for moist heat terminal sterilization
Post-Approval* 
Inspections

* Not surveillance
The Post-Approval Inspection Program

• Provide continuing inspection coverage of products marketed under a recently approved application

• Monitor for changes in the production and control practices that occur after approval (6-24 months)

• Assignments issued by CDER based on recommendations and risk

• Coverage is based on reason for inspection (pre-approval inspection, past history...
Surveillance (CGMP) Inspections
What is a Pharmaceutical Quality System?

- The Quality System is the foundation for each of the drug manufacturing systems.
- Quality system is the nucleus that integrates each of the manufacturing systems.
Surveillance (CGMP, routine)
Systems Based Inspections

- Quality
- Facility and equipment
- Production
- Laboratory Control
- Materials
- Packaging and Labeling
Surveillance (CGMP, routine)
Systems Based Inspections

• Observations made during inspections are organized by system

• Two options for systems approach:
  – The Full Inspection Option
  – The Abbreviated Inspection Option

Inspection Classifications
After the Inspection

- Inspections are generally classified into one of three categories
  - **NAI** - No Action Indicated
  - **VAI** - Voluntary Action Indicated
  - **OAI** - Official Action Indicated

- Initial outcome:
  - **PAI**: Investigator informs firm management at the conclusion of the inspection of his/her initial recommendation
  - **Post-Approval**: Investigator will not provide recommendation at the conclusion of inspection

- Expect a copy of FDA inspection report
But what about *inspections*...
Inspections...

- An FDA inspection is a careful, critical, official examination of a facility to determine its compliance with Certain laws and regulations administered by the FDA
- Are FACT finding
- Obtain EVIDENCE
- Are REGULATORY
  - What is said could end up in court
New Inspection Protocol Project (NIPP)

- New paradigm for inspections and reports that will advance pharmaceutical quality
- Standardized approach to inspection
- Data gathering to inform “quality intelligence” of sites and products: both positive and negative behaviors
- Risk-based and rule-based process using expert questions
- Semi-quantitative scoring to allow for comparisons within and between sites
- More common inspection report structure
Authority of Enter and Inspect

- **Section 704(a) of the FD&C Act** provides authority for FDA to conduct inspections.
  - “upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge.”

Be reasonable (Time, Limits, Manner) in order to achieve the objective of the inspection
Statutory Authority

- **Section 704(b) of the FD&C Act** requires FDA employees, prior to leaving the premises to give to the owner, operator, or agent in charge a report in writing of any objectionable conditions or practices they observed.

- **Section 702(a) of the FD&C Act** authorizes examinations and investigations for the purposes of this Act. This basic authority for FDA includes sampling activities.

- **Section 704(c) of the FD&C Act** requires FDA employees, prior to leaving the premises to give to the owner, operator, or agent in charge, a receipt describing samples obtained.
Common FDA Inspection Forms

- FDA-482 Notice of Inspection
- FDA-484 Receipt for Samples
- FDA-483 Inspectional Observations
Who may participate on an inspection team?

- Investigators
- Analysts
- Compliance Officers
- CMC Reviewers
- Other Specialists
Preparing for an Inspection

- Review application or Drug Master File (DMF)
- Review previous EIRs and other reports in establishment file
- Review reference materials
- Know the CGMPs and the FFDCA
- Know FDA inspection programs, guides

ESTABLISHMENT INSPECTIONS

http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/ucm252671.htm
Inspection References
Compliance Program Guidance Manuals: CGMP Inspection Program

Pre-approval:
• 7346.832/7352.832, Pre-Approval Inspections/Investigations

Post-Approval/Surveillance:
• 7346.843, Post-Approval Audit Inspections
• 7356.002, Drug Process Inspections (sub-programs follow…)
  – 7356.002A, Sterile Drug Process Inspections
  – 7356.002B, Drug Repackers and Relabelers
  – 7356.002C, Radioactive Drugs
  – 7356.002E, Compressed Medical Gases
  – 7356.002F, Active Pharmaceutical Ingredients Process Inspections
  – 7356.002M, Inspections of Licensed Biological Therapeutic Drug Products
  – 7356.002P, Positron Emission Tomography

For all CPGs:
http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/ucm252671.htm
“FDA Guide to Inspections of...”

- Topical Drug Products
- Pharmaceutical Quality Control Laboratories
- Validation of Cleaning Processes
- High Purity Water Systems
- Lyophilization of Parenterals
- Microbiological Pharmaceutical Quality Control Labs
- Dosage Form Drug Manufacturers – CGMPs
- Solid Oral Dosage Forms Pre/Post Appr. Issues
- Oral Solutions and Suspensions

http://www.fda.gov/ICECI/Inspections/default.htm
“FDA Guidance for Industry”

- Q7 Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients (August 2001)

- Sterile Drug Products Produced by Aseptic Processing – Current Good Manufacturing Practice (September 2004)

- Investigating Out-of-Specification (OOS) Test Results for Pharmaceutical Production (October 2006)

- Process Validation: General Principles and Practices (January 2011)

- Process Validation Requirements for Drug Products and APIs Subject to Pre-Market Approval (CPG 7132c.08, March 12, 2004)

http://www.fda.gov/ICECI/Inspections/default.htm
ICH: International Conference on Harmonization

- ICH Q7, Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients
- ICH Q8, Pharmaceutical Development
- ICH Q9, Quality Risk Management
- ICH Q10, Pharmaceutical Quality System
- ICH Q11, Development and Manufacture of Drug Substances
Investigations Operations Manual

• Published annually
• Available both as a hard copy manual and on-line at

http://www.fda.gov/ICECI/Inspections/IOM/default.htm
Investigations Operations Manual (IOM)

• Primary source regarding Agency inspectional policy and procedures

• Extends to *all individuals* who perform field investigational activities*

• Any significant departures from IOM’s procedures must have the concurrence of district management

*Melinda K. Plaisier, Associate Commissioner for Regulatory Affairs, in the Foreword to the 2014 IOM
Investigations Operations Manual (IOM)

Covers:

• Administrative Procedures
• Regulatory Issues
• Sampling Procedures and Policy
• Inspectional Procedures and Policy
• Import Procedures and Policy
• Recall Activities
• Investigational Procedures and Policy
• ORA Directory (incl. field program monitors)
Credentials

• Required by law to be shown upon starting an inspection

• Investigator displays credentials to the top management official (“owner, operator, or agent in charge”)

• Management may examine the investigator’s credentials and record the number and name

• Credentials are **not** to be photocopied
Delegated Authority

When investigators are issued *Credentials*, certain parts of the Commissioner's enforcement authority, as specified in Staff Manual Guide 1410.32, is re-delegated to them. (i.e. conduct examinations, inspections, and investigations; to collect and obtain samples; to have access to and to copy and verify records as authorized by law)

http://www.fda.gov/AboutFDA/ReportsManualsForms/StaffManualGuides/ucm049578.htm
Notice of Inspection

- Must be issued to start the inspection (except for international sites)
- All team members must sign
- Original given to firm and copy included in EIR
- Also known as the FDA-482
**Notice of Inspection**

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) 734-5247. 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) 796-8590 or by email at ombuds@oc.fda.gov.

**9. SIGNATURE(S) (Food and Drug Administration Employee(s))**

Sidney H. Rogers

**10. TYPE OR PRINT NAME(S), AND TITLE(S) (FDA Employee(s))**

Sidney H. Rogers, Investigator

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**1** Applicable portions of Section 704 and other Sections of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374) are quoted below:

Section 704(a)(1) For purposes of enforcement of this Act, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized (A) to enter, at reasonable times, 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 or after such introduction, or to enter any vehicle being used to transport or held such food, drugs, devices, tobacco products, or cosmetics in interstate commerce, and (B) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein. In the case of any person (excluding farms and restaurants) who manufactures, processes, packs, transports, distributes, holds, or imports foods, the inspection shall extend to all records and other information described in section 414, when the standard for records inspection under paragraph (1) or (2) of section 414(a) applies, subject to the limitations established in section 414(c). In the case of any factory, warehouse, establishment, or consulting laboratory in which prescription drugs, nonprescription drugs intended for human use, restricted devices, or tobacco products are manufactured, processed, packed, or held, inspection shall extend to all things therein (including records, files, papers, processes, controls, and facilities) bearing on whether prescription drugs, nonprescription drugs intended for human use, restricted devices, or tobacco products which are adulterated or misbranded within the meaning of any provision of this Act, or which may not be manufactured, introduced into interstate commerce, or sold, or offered for sale by reason of any provision of this Act, have been or are being manufactured, processed, packed, transported, or held in any such place, or otherwise bearing on violation of this Act. No inspection authorized by the preceding sentence or by paragraph (5) shall extend to financial data, sales data other than shipment data, pricing data, personnel data (other than data as to qualifications of technical and professional personnel performing functions subject to this Act) (Continued on Next Page)
The FDA Inspection Begins...

- Issue Notice of Inspection
- Display Credentials
- Lead investigator states purpose of inspection
- Lead investigator provides general agenda
- Tour facility
- Get into details
- Daily wrap up meetings
What are Investigators Looking For?

- Evidence that a violation exists
  - Adulteration
  - Misbranding

- CGMP violations
  - Poor Employee Practices
  - Poor Equipment and facilities
  - Lack of process control

- Application departures

- Data integrity issues
Investigators look at the facility and operations

- Equipment and Facility
- Production
- Packaging and Labeling
- Laboratory
- Warehouse...reject cage
FDA-483 Observation: Equipment and Facility

The class 100 area used for the manufacture of sterile drug product is not maintained in a clean and sanitary condition. We observed:

- The return vent and surrounding wall area had a build-up of a brown and black residue.
- The floor directly under the filling machine (approx. 3 feet by 3 feet) area had a brownish black crusty residue.
- The area beneath the turntable that carries the opened filled vials to the conveyor belt had a white powdery and thick beige dried on residue that in some areas was hanging in hard dried drippings.
- The conveyor belt that carries open filled vials to be stoppered was observed to contain a dried up bumpy greenish-yellow residue that in some areas contained a hairy looking substance.
Investigators also look at documentation

- Can the firm produce documented evidence of past events...such as equipment calibration, cleaning and maintenance...If it’s not documented it’s not done...

- Do they have scientific evidence to support conclusions made in reports?

- Do investigations or trending reports demonstrate performance issues that could effect the proposed commercial batch manufacture? Equipment maintenance issues, water system or environmental issues, process issues?
Key Post Market Information

- Recall [21CFR 7]
- Complaints → FDA, firm, MedWatch
- Field Alert Reports and Biological Product Deviation Reports — NDA and ANDA holders are responsible for filing FARs [21CFR314.81(b)(1)], BLA holders are responsible for filing BPDRs [21CFR601.12]
- Rejects
Investigators also look for data integrity issues...what they find

- Not recording activities contemporaneously
- Backdating
- Fabricating data—create acceptable test results without performing test
- Copying existing data as new data
- Re-running samples without appropriate documentation
- Discarding data
- Data looks too good to be true
- Failing stability studies not submitted in the filing
- No raw data (i.e. sample weights, standard prep, sample solution prep)
Investigators need to document evidence to build a case

Examples of Evidence:

- Direct observation of CGMP deviations
- Procedures
  -- Observe not following or lack of a written procedure
- Verbal communications
  -- Admission that a violation occurred
- Written records and documents
- Investigator’s regulatory notes
  -- Written record created during inspection
Investigators need to document evidence to build a case

- Document responsibility
- How investigators incorporate the exhibits, and quotes in the EIR can effect the usability of their work and the outcome
- What to collect and how much is enough is a judgment call
Regulatory Notes

• Are the contemporaneous, sequential record of daily investigatory efforts
• They record observations relevant to violations
• Should be accurate, objective, factual and free of personal feelings or conclusions
• Are the property of the government and are releasable under the Freedom Of Information Act
• Vital link between investigator’s findings and their subsequent testimony in court
Regulatory Notes

• Accurate regulatory notes are to refresh the investigator’s memory when reporting certain important details of the inspection and serves as the basis for reports.

• Supports the principle of “presumption of regularity” that means in the absence of clear evidence to the contrary, courts presume public officers properly discharge their official duties.
The FDA inspection ends...

- **Formal Close Out**
- **May include:**
  - Sample Collections
  - Affidavits (domestic)
  - Issuance of FDA 483, Inspectional Observations
Back at the office (for the investigator)...

- **Write the Establishment Inspection Report**
  - Must be done in a timely manner
  - Incorporate all inspectional findings from each team member

- **Communicate with District personnel**
  - Investigations Branch
  - Compliance Branch

- **Communicate with laboratory**
  - Prepare sample collection reports

- **Submit District recommendation**
GMP Findings

• FMD-86 Establishment Inspection report conclusions and decisions
  – Voluntary Action
  – Advisory Action (i.e. Warning Letter, Untitled Letter)
  – Legal Sanctions (i.e. seizure, injunction, prosecution)

• Positive behaviors recognized
Questions?