

FDA Field Inspections

**Linda S. Mattingly Investigator
Baltimore District**

FDA Organization

- **Headquarters**
 - Office of the Commissioner, Office of Regulatory Affairs, etc.
- **Centers**
 - CBER, CDER, CVM, CDRH, CFSAN
- **Field Offices**
 - Regional, District, Resident Posts
 - Investigations Branch, Compliance Branch, Laboratory Branch, Administrative Branch

Field Investigators

- **Consumer Safety Officers**
- **Requirements**
 - 30 credit hours in science
- **Training**
 - New Hire Training
 - Law and Evidence Development
 - Investigative Interviewing
 - On-the-job Training

Blood Bank Investigators

- **Required to attend the national training course in Blood Banking and Plasmapheresis**
 - **Regulations**
 - **Inspectional Techniques**
 - **FDA-483 Preparation**
 - **Case Development**
 - **Introduction to technical topics in blood banking**

Purpose of FDA Inspections

- **Statutory obligation**
 - FDA must inspect each registered facility at least once every two years
- **Inspect for compliance with FD&C Act and PHS Act**
- **Inspect for compliance with applicable sections of 21 CFR Parts 600 and 211**

Types of FDA Inspections

- **Directed, limited or for cause inspections**
 - Complaint follow up
- **Routine cGMP inspections**
 - Level 1 – covers critical areas of each system
 - Quality Assurance, Donor Eligibility, Product Testing, Quarantine/Inventory Management and Product Processing Systems
 - Level 2 – covers critical areas of the Quality Assurance and Donor Eligibility systems and one other additional system
- **Compliance follow up cGMP inspections**

Anatomy of an FDA Inspection

- **Credentials and Notice of Inspection**
- **Grand Tour of Facility**
- **Gather General Information**
- **Written Procedures**
- ***Visual Observation of Practices***
- ***Record and Document Review***
- **Exit Meeting**

Scope of FDA Inspections

- **Visual Inspection of Practices**
 - Donor Screening
 - Blood Collection
 - Blood Processing
 - Component Preparation
 - Testing (ABO/Rh and infectious disease)
 - Distribution
 - Data Entry

Scope of FDA Inspections

- **Record and Document Review**
 - **Donation record**
 - **Donor history records**
 - **Deferral records**
 - **Test records**
 - **Quarantine records/reports**

Scope of FDA Inspections

- **Storage and distribution records**
- **Complaints**
- **Reports of adverse reactions (donor and recipient, including investigations of possible disease transmission)**
- **Training records**
- **Proficiency test results**

Scope of FDA Inspections

- **Lookback records**
- **Re-entry records**
- **Deviations and investigations into deviations**
- **Blood Product Deviation Reports**
- **Corrective actions**
- **Retrieval of unsuitable blood components**

Scope of FDA Inspections

- **Documentation for computer system**
 - **System description**
 - **User validation**
 - **Documentation for user-defined tables**
 - **Change control**
- **Written Procedures for regulated activities**

Scope of FDA Inspections

- **Timeframe for record review**
 - Time period since last inspection
 - **Exceptions—previous deferrals, lookback, re-entry**
- **Selection of records to thoroughly review**

Common Deficiencies

- **Failure to perform adequate investigations regarding deviations**
- **Failure to address/correct the cause of deviations**
 - **Unclear procedures?**
 - **Physical layout or ergonomic factors?**

Common Deficiencies

- **Failure to document comments for answers to donor questions that require further explanation**
- **Errors in malarial deferrals**
 - **SOP and/or references unclear**
 - **Follow-up questions not asked or answers not documented**
- **Donor deferrals not updated appropriately**

Common Deficiencies

- **Creation of duplicate donor records**
- **Blood unit/donor card/sample tube mix-ups**
- **Discrepant information on related records**
- **Improper arm preparation**

Common Deficiencies

- **Inadequate documentation for computer system**
 - Initial installation and changes
- **Inadequate user validation of computer system**
- **Failure to document user-defined tables**
- **Lack of documentation for access to computer functions**
- **Improper assignment of access per user role**

Common Deficiencies

- **Failure to perform calibration/maintenance per SOP and/or manufacturer's instructions**
- **Incorrect incubation time**
- **Inappropriate interpretation of test results**

Common Deficiencies

- **Failure to follow algorithm for donor re-entry**
- **Failure to appropriately handle donor call-backs**
- **Distribution errors—loss of traceability**

FDA-483 – Inspection Observations

- **Formal list of observations**
- **Issued at the end of the inspection**
- **Discussion—do not hesitate to ask for clarification if unsure of inspectional issues**
- **Respond to FDA-483 in writing**

Dealing with Conflicts During an FDA Inspection

- **Policy to discuss issues prior to inspection close-out**
- **Discuss the issue and present the facts**
- **Limit misunderstanding**
- **Terminology**
- **Contact the district office**

References

- **FD&C Act**
- **PHS Act**
- **21 CFR 600s and 211s**
- **Investigations Operations Manual**
- **Compliance Program**
- **Guidance Documents and Memoranda
Pertaining to Blood and Blood
Products**

GOOD LUCK !

Contact Information:

**Linda S. Mattingly
Investigator, BLT-DO
410-779-5443 (Work)
410-779-5705 (Fax)
linda.mattingly@FDA.HHS.gov**