

**GMP Inspection Surveillance
Program**

Douglas A. Campbell
Compliance Officer
CDER / Office of Compliance
Division of Manufacturing and Product Quality
International Compliance Team

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Presentation Overview

- Where we go...
 - Risk-Based Site Selection
- What we do when we get there...
 - "Systems" Inspection Program

Where we go...

Risk-based Site Selection Approach

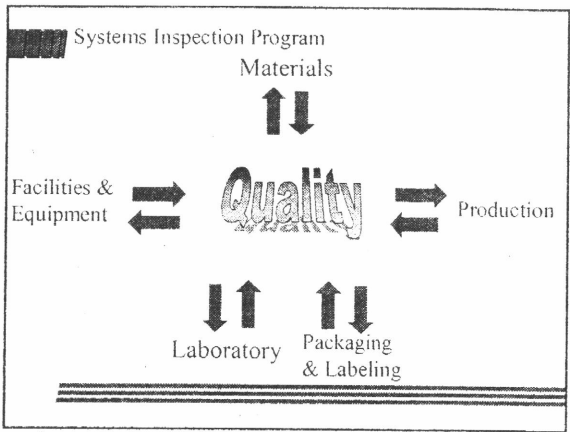
More on this topic later...

Systems Inspection Program
What is the Program about?

- Directs routine inspection to verify conformance with GMPs
- Inspections are to be by systems
- 'Systems' approach provides for a
 - natural grouping of requirements/expectations by GMP regulations
 - inspection of some operations (systems) at each site each inspection
 - a basis for overall GMP decision about site

Systems Inspection Program
What are the systems?

- Quality System
- Materials System
- Facilities and Equipment System
- Production System
- Packaging and Labeling System
- Laboratory Control System



Systems Inspection Program

When can the "Abbreviated Inspection" be used?

- When not doing Full Inspection
- Surveillance inspections (routine)
- Satisfies biennial inspection requirement
- Rotate systems with the Abbreviated Option

Systems Inspection Program

How is a system covered?

- Sufficient details, with specific examples to reflect state of control for every profile class
- If system is adequate, all profiles covered by system are adequate
- Unique profile class material/ process review, under a system, selected at discretion of Investigator

Systems Inspection Program

How covered, cont.?

- Observations related to requirements (e.g., GMP regulations)
- Deficiencies found in one system may indicate deficiencies in other systems.
- This may warrant expansion of coverage to varying degrees of the other systems.

Materials System

- Written procedures, adherence verification
- Quarantine provisions
- Sampling, testing or examination, re-testing, re-exam
- Identification and acceptance / rejection

Materials System

- Storage controls - including validation of handling
- Finished product distribution, return, salvage - including lot documentation -

Facilities & Equipment System

Facilities

- Layout / design, engineering
 - Separation of operations
 - Air handling
 - Lighting water / sewage
 - Cleaning / sanitation, maintenance, pest control
- Renovation, revitalization
- Non-process utilities (waters, gases, HVAC)

Packaging & Labeling System

- Pre-operational preparations
 - Label characteristics (cut, size, color, TEP)
 - Label storage, proofing
 - Identification of equipment, line separation
- Pack / label - Definition -
 - Pack /label record
 - Label specimen

Packaging & Labeling System

- Pack / label Operations control
 - Validation
 - Label issue, exam, reconciliation, destruction (w/lot numbers)
 - Expiration dating (print control)
 - Examination of finished product
- Line clearance, inspection, documentation

Laboratory Controls System

- Staffing & Equipment
 - Adequate numbers of staff
 - Calibration program
 - System suitability
- Specs., standards, sampling plans, change control
- Methods, reference standards, change control, OOS SOP