GMP Inspection Surveillance Program

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Presentation Overview

- Where we go...
 - Risk-Based Site Selection
- What we do when we get there...
 - "Systems" İnspection 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 require ments/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 Materials								
Facilities & Equipment			Production					
Laboratory	Packaging & Labelin							

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.

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# Materials System • Written procedures, adherence verification • Quarantine provisions • Sampling, testing or examination, re-testing, • Identification and acceptance / rejection Materials System • Storage controls - including validation of handling Finished product distribution, return, salvage - including lot documentation -Facilities & Equipment System • 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