Audit Types & Differences

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Audit Types & Differences

Learning Objectives:

• Identify types of audits
• Identify differences in these audits
• Audit specifics and helpful hints
Audits- Everyone’s Favorite Subject!!
Lions and Tigers and Audits……Oh My!!!

- First party/Second party/Third party
- Internal / External
- Compliance/Conformance
- Process/System/Vendor
- Quality/Effectiveness
- Documentation/On-site/Survey

Confused???
Audit Types

Internal
  First Party

External
  Second Party
  Third Party
Audit Types

- Audits
  - External
    - Surveys
      - Second Party
    - Third Party
  - Internal
    - Documentation
    - First Party
Audit Types

Internal or First Party

- An organization auditing its own systems, a self-assessment
- Used to measure the strengths and weaknesses against requirements, and an organization's own standards

Document  Report  Follow-up
Audit Types

External or Second Party

Inspections/Audits of Other Facilities

- One organization auditing another with which it either has, or is going to have, a contract or agreement for the supply of goods or services

- Supplier audit will include the Quality Management System involved in the items or service provided
Audit Types

External Third Party Audits

- Independent of the organization being audited
- Used to certify, register or verify
- FDA, AATB, EBAA, Florida, New York
Audit Types-Internal

Requirements for Internal audits

AATB B2.124 Quality Assurance Program
“The Director shall require a documented annual internal review or Audit to ensure compliance with the SOPM, federal, state, and/or regulations, and these Standards.”

FDA 21 CFR 1271.160 Establishment and Maintenance of a Quality Program (c)Audits
“You must periodically perform for management review a quality audit, as defined in Sec. 1271.3(gg), of activities related to core CGTP requirements.”
Internal Audit - Self- Evaluation

Reasons to perform

- Value added to Management - What value will it achieve for the company?
- Conformance to Internal Procedures - Often a visual of a task or a review of documentation
- Compliance to Regulations/Standards - check the box type of monitoring or documentation audit
- Effectiveness of Corrective Actions - monitor, measure and analyze
- Good business practice and they make sense
  They are meant to detect problems early ..........  
  A Problem solved is a problem defined!
Internal Audit - Self- Evaluation

Who Can perform an Internal audit?

Trained staff not directly responsible for what is being audited

Outside Consultant if no one else is available

Not everyone can be a good auditor...........choose wisely
Internal Audit - Self- Evaluation

What types of records will an Internal auditor review?

✓ Policies and Procedures (SOPs)
✓ Records
✓ Observation of the processes within the scope of the audit
✓ Training records

ANYTHING that can prove ongoing systems are operating as intended and as required!
Internal Audit - Self- Evaluation

What types of records will an Internal auditor not review?

- Personnel records
- Health records
- Disciplinary records
- Human Resource records specific to employees
- Accounting records not under the Quality Management System
Internal Audit - Self-Evaluation

Role of the Internal auditor:

- A catalyst
- An interface between groups
- An advisor
- A reporter of facts

An internal auditor can become a type of internal consultant for the organization
External Audits – Second Party

External – Second Party

- One organization auditing another with which it either has, or is going to have, a contract or agreement for the supply of goods or services.
- Comprehensive evaluation performed by a customer to help ensure that the supplier is operating under a state of control.
- Periodic auditing or AATB requires biennially.

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External Audits – Second Party

Requirements for External audits

AATB B1.521 Inspections/Audits of Other Facilities

- Audit prior to executing a contract, and biennially (every 2 years) thereafter
- Must be documented
- Follow-up verification can be paper audit (desktop) or on-site audit
FDA 21CFR1271.150 Current Good Tissue Practice requirements (c) Compliance with applicable requirements (1) Manufacturing arrangements (iii)

"Before entering into a contract, agreement or other arrangement with another establishment to perform any step in manufacture for you, you must ensure that the establishment complies with applicable CGTP requirements."
External Audits – Second Party

Reasons to perform

- Help ensure the proper capabilities and quality systems are in place
- Promotes understanding of expectations of the customer
- Provides for an avenue of quality transfer between the supplier and customer
- Builds customer confidence regarding compliance to Regulations/Standards

Good business practice
External Audits – Second Party

Who can perform an External Audit?

Staff trained in conducting External Audits

Internal Audits and External Audits quite different in approach and techniques

Outside Consultant

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External Audits – Second Party

What an External auditor will review (not all inclusive):

- Quality Manual or Performance Improvement Plan
- Organizational Charts
- Registrations/licenses/accreditations
- Policies and Procedures (SOPs)
- Records
- Observation of the processes within the scope of the audit
- Training records

Usually a high level sampling of the above documents
External Audits – Second Party

What an External auditor will not review:

- Internal audit reports
- Other organizations audit reports
- Personnel records
- Health records
- Disciplinary records
- Human Resource records specific to employees
- Accounting records not under the Quality Management System

May inquire about last FDA/State/AATB audit findings
External Audits – Third Party

Reasons to Perform:

- Verify compliance to specific regulations or standards
- Required by law:
  - FDA, State, OSHA, EPA, Financial
- Voluntary:
  - AATB, ISO, AOPO, EBAA
External Audits – Third Party

Requirements for External audits-Third Party

AATB B1.520 On-Site Inspections
“A tissue bank that has any of its activities or services performed by another entity will be inspected and accredited only for the specific activity or service that the tissue bank itself performs.”

FDA 1271.400 Inspections (a)
“If you are an establishment that manufactures HCT/Ps, whether or not under contract, you must permit the FDA to inspect any manufacturing location at any reasonable time and in a reasonable manner to determine compliance with applicable provision of this part. The inspection may be made with or without prior notification....
External Audits – Third Party

What a Third Party Auditor will review (not all inclusive):

- Quality Manual or Performance Improvement Plan
- Organizational Charts
- Records including training records
- Observation of the processes within the scope of the audit
- Can review the schedules and procedures for Management Review and for Internal and External Audits

**Usually a high level sampling of the above documents**
External Audits – Third Party

What a Third Party Auditor will not review:

- Internal or External audit reports
- Management Review documentation
- Personnel records
- Health records
- Disciplinary records
- Human Resource records specific to employees
- Accounting records not under the Quality Management System
Audit- Sub Types

Sub-type or approach based on:

The scope of the audit

Why the audit is being performed

Most can be used for any type of audit
Audit - Sub Types

**Compliance** – Assures the organization complies with the requirements

GTP’S

Typically a desktop audit
Audit- Sub Types

**System** – A review of the theory behind the processes (can be a Quality System audit)

A high level review of an organizations systems;
- Document control
- Training program
- Control of measurement and test equipment

Usually spans multiple departments and includes processes
Audit - Sub Types

**Process** – The practices of the organization, the flow and inter-relationships within systems

Most always a part of a systems audit but process audits can be performed separately

This is where the organizations procedures are validated.

How effective are the communications between processes and the systems?
Audit - Sub Types

- Recovery-processes
- Processing-processes
- Distribution-processes
- Quality-processes
Audit- Sub Types

**Product** – The results of the processes
Assessment of the final product evaluated against the requirements (specs, inspection records, procedural requirements)
Could be final inspection
Can be a complete breakdown of the final product that verifies the paperwork trail, inspection and test results, and that the specs were all met
Can be used internally but often used in a Second Party audit of a supplier of specific products
Audit- Sub Types

**Documentation** – Paper trail of compliance or documented overview of an organizations systems

- Paper audit
- Desktop audit
- Survey

Can be used to pre-qualify a supplier but best to perform an on-site prior to accepting product
Audits

When developing your audit schedule, base the need on **risk** NOT just to comply with the requirements.
Consider the Four “R’s”

RISK

Health Risk

Process Risk

Business Risk

Compliance Risk
We Operate Within a Regulated Industry
State Requirements

NY
MD
FL
CA
OR, as of July
Voluntary Requirements

AATB
EBAA
AOPO
ISO
Involuntary Requirements....

Regulations

GTP; tissue

FDA

QSR - processors

Regulations
We all get audited a lot!!!
They all fit together to form the Audit Program in an organization.

1st Party
- Internal Audits

2nd Party
- Voluntary Audits
  - AATB, AAEB
- External Audits
  - Supplier/Audits

3rd Party
- FDA, State Audits

2nd Party
- External Supplier/Audits

AATB, AAEB
Audit Preparation Tips

or How **not** to get caught with your pants down!
Audits

Tips on How to Prepare:

- Assure your high level documents reflex current practices within the organization
- Assure your SOPs are developed, reviewed, approved, revised and archived
- Documented procedures for all core requirements and critical processes
- Corrective and Preventative Action System – Prompt and effective responses
Audits

Tips on How to Prepare:

- Training and Education of Personnel – Current and Documented
- Environmental Monitoring – Current and Complete
- Record Maintenance – Up to Date
- Product Deviation Investigation – System in Place
- Audit Program - Continuous
Auditors rule to live by

In God we trust, all else bring Data........