Making the Most of Internal Audits

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Audit: Purpose

- An audit is a methodical examination of a process or a system to:
  - Recognize problems
  - Detect trends
  - Identify improvement opportunities
  - Implement corrective and preventive actions when necessary
  - Follow up on the effectiveness of these actions in a timely manner
- Processes to be audited should include those for which lack of compliance would potentially result in an adverse event

Audit: Cycle


Select the Quality Indicator
Establish Acceptance Criteria
Determine Audit Methodology
Perform Data Collection
Analyze and Report
Develop Action Plan
Implement Change
Re-Audit
PLANNING
AUDIT
ACTION

Audit: Establishing Acceptance Criteria

- Benchmarking with comparable institutions
- Analysis of internal activities
- Professional organization recommendations
- Academic literature
- Standards and/or regulations

Audit: Developing SOPs and Forms

1. Process/Procedure to be evaluated
2. Purpose
3. Audit Method
   - Review of Records
   - Personnel Interviews
   - Direct Observation
   - Confirmation of SOP Accuracy
3. Staff Member Conducting Audit
4. Source of Data/Location of Observation
5. Frequency: Conducting Audit
6. Frequency: Reporting Audit
7. Sample Size
8. Elements to be Evaluated
9. Reporting Format
   - Individual Data
   - Aggregate Data
10. Acceptance Criteria
11. Action Plan
    - Short term
    - Long term
12. Follow up Timelines
13. Staff Member Reviewing Audit

Audit: Corrective and Preventative Action

- Investigate the cause of nonconformity related to processes and quality system
- Identify the action(s) needed to correct and prevent recurrence of nonconformity
- Verify or validate the corrective and preventive action to ensure that such action is effective and does not result in adverse affect
- Implement and document change necessary to correct and prevent identified nonconformity
- Ensure that information related to nonconformity is disseminated to those responsible for assuring the quality of processes and the quality system
- Submit relevant information related to quality problem, as well as corrective and preventive actions for management review

FDA 21 CFR Part 820.100

Audit: System Review

- Audit programs are not static
- Audit programs should be evaluated for utility on periodic schedule
- Quality indicators should be periodically reviewed and modified, as necessary
- Acceptance criteria should be periodically assessed

Audit: Standards and Regulations

- FDA 21 CFR Part 1271
- FDA 21 CFR Part 820.100
- State Departments of Health
- AABB Standards for Cellular Therapy Services
- FACT-JACIE International Standards for Cellular Therapy Product Collection, Processing and Administration
- NetCord-FACT International Standards for Cord Blood Product Collection, Processing and Release for Administration
- College of American Pathologists
- IND/IDE

Audit: Resources and References

1. AABB Standards for Cellular Therapy Product Services. Current ed.
2. FACT-JACIE International Standards for Cellular Therapy Product Collection, Processing, and Administration. Current ed.
3. NetCord-FACT international standards for cord blood collection, banking, and release for administration. Current ed.
4. Code of Federal Regulations. Title 21, CFR Parts 16, 1270, and 1271. (revised annually)
5. Code of federal regulations. Title 21, CFR Part 820. (revised annually)
6. Comprehensive Accreditation Manual for Hospitals. Oakbrook Terrace, IL: The Joint Commission, Current ed.
7. Commission on Laboratory Accreditation. Laboratory general checklist. Northfield, IL: College of American Pathologists, Current ed.
8. ISO 9001:2008: Quality Management Systems—Requirements
9. Quality Management System: A model for laboratory services; Approved guideline—Current ed. CLSI document QMS01-A4