Creating an Efficient Internal Audit Program

Carol Cekala
TDC Medical

Susan Reilly
Reilly & Associates
Presentation topics

- What is an audit?
- Making it work
- Who audits?
- Selling to management
- Communicating results
What is a quality audit?
What is a quality audit?

- Objective assessment, performed at defined intervals and at sufficient frequency, of a company’s quality system to operate against a given criteria
  - Systematic
  - Independent
  - Documented
What is a quality audit?

- Provide factual, unfiltered information to manage the quality system
- A tool for use by management
- Regulatory requirement (FDA, ISO, etc.)
- Help minimize risk
- “Close the loop” for other elements of the quality system
What is a quality audit?

- Detect program defects and through isolation of unsatisfactory trends and correction of factors that cause defective products, prevent the production of unsafe or nonconforming devices.

- Assure the manufacturer is consistently in a state-of-control.
What is a quality audit?

- Audits are not a quick look
- Audits are *preventive*, not detective
- Audits are planned, organized, and coordinated
- Audits are carried out for the benefit of the company, not the auditor
- A single audit will not find all noncompliant issues or potential problems
Audit Program Definition

Overall Planning

Preparation Phase 1

Opening Meeting Phase 2

Audit Schedule

Audit Phase 3

Management Review

CAPA

Closeout Phase 6

Closing Meeting Phase 4

Management’s Responsibility

Reporting Phase 5

Phase 0
Essential program elements

From ISO 19011:2002
Making it work
Why do YOU audit?

- How many companies perform audits just because “you have to”?
  - Best guess – *at least* 75% of medical device manufacturers
Making it work

Comply?

2 → 3
Making it work

Step 1 - Comply

- Conforming to requirements; to conform, submit, or adapt (as to a regulation or to another's wishes) as required or requested
  - Regulatory / standard compliance
  - Do we have the systems and procedures we are supposed to have and do they meet the regulatory / standard requirements?
Making it work

Effective?
Making it work

- Step 2 - Effective
  - Producing or capable of producing an intended result
    - Collection of and review of objective evidence
    - Do we follow our procedures and maintain the required records?
Making it work

1 → 2

Efficient?
Making it work

- **Step 3 – Efficient**
  - Acting or producing effectively with a minimum of waste, expense, or unnecessary effort
    - Exhibiting a high ratio of output to input
    - Eliminate / reduce redundancy between systems
    - Are our systems working in the best interest of our business / customer?
What’s the difference?

- Think preventive costs
  - Internal audits are the “downstream” assessment
  - FDA / ISO / customers are the “upstream” assessment
How do you score?

- Quantify Efforts vs. Benefits
  - How much time / resources you are spending on auditing
  - How you do it
  - What the outcomes are
  - What is being done with the outcomes
- Effort (<) (=) (>) Benefit?
How do you score?

- Finding significant noncompliant issues during internal audits?
  - Stick with the fundamentals for now (compliant / effective)
  - Understand why they are happening and address the root cause
How do you score?

- Finding minor noncompliances and repeat observations?
  - System may be compliant but too complicated (i.e., inefficient) and therefore prone to error and ineffectiveness
Who audits?
Who audits?

- Dedicated internal auditors
- “Part-time” internal auditors
- Auditors from sister or parent company
- Outsource auditing
- Combination of above
Who audits?

- If using a third party
  - Schedule enough time
  - Continue to conduct internal audits with employees
Audit frequency?

- Series of internal audits addressing all quality subsystems and interactions?
  - Complies, may be effective, not efficient

- One comprehensive audit?
  - Complies, may not be effective, but efficient

- Combination of both of the above!
Auditor qualifications

- The success of the auditing program depends significantly upon the selection of the right people for the task.
Auditor qualifications

- Not everyone can be a good auditor
- Good Communication and Interpersonal Skills
- Interviewing Skills
  - Intelligent and pertinent questions
  - Listen attentively
- Analytical Skills
  - Ability to assimilate data and determine how it relates to the audit criteria
  - Analyze information and report results
- Training and Experience
  - Standards, regulations, auditing techniques, and audit management skills
- Ability to think inside and outside the box
Auditor qualifications

- Understanding of the business operating structure
  - Inputs / Outputs of various systems
  - Interactions of departments
  - Rotation throughout various job functions upon hire (even with prior experience)
Auditor effectiveness

- Do not measure an efficient auditor by the number of observations recorded / not recorded
  - The ability to identify noncompliances and provide recommendations on ways to improve the process should be viewed as a positive
Auditor effectiveness

- Right personnel from cross-functional groups
  - Document training
  - Perform audits on a regular basis
  - Responsibility becomes part of job description
  - Must be taken seriously by employee and manager
    - Part of performance review
Selling to management
Selling to management

- Compliance is a regulatory requirement for our industry!
  - Make it work for you, not against you
Selling to management

- Efficient auditing can identify redundancies in systems
  - To eliminate or reduce is an obvious cost savings
  - For example, redundant manual system and electronic system to avoid validation of electronic system
Selling to management

Efficient auditing can identify those areas where the company has added more requirements than needed from both a regulatory and business perspective.

- Complicated system uses resources and is prone to error (i.e., non-compliance).
- Too many records being completed, more signatures than necessary.
Selling to management

- Efficient auditing can identify inadequate / ineffective / inefficient collection of data & measurements
  - Data not being used, not being used efficiently, wrong data being measure or being measure at wrong point in process
  - For example, data being collected regarding scrap rate, but the data is never presented to anyone OR data has consistently shown a high rate and no action has ever been taken or discussed
Communicating results
Communicating results

- Good auditing cannot be reflected in a poorly documented report
- Issue TIMELY
- Write to your “customer”
  - Write for impact
  - Make the report talk
  - Recognize their priorities
- Lead (don’t lose) the “customer”
Communicating results

- Utilize standard format for consistency
  - Audit scope, purpose, references, standards, procedures
- Executive summary
  - Highlight hot issues (positive and negative)
- Audit summary and specific non-conformances
  - Identify high risk areas
- Audit recommendations for improvement and/or potential issues
  - Part of report or separate document?
Act on results

Assess Risk!
Act on results

- Requires management support to fix root cause of identified non-compliances
  - Not all observations will require a corrective action
    - Correction or other remediation may be appropriate
  - Triage / prioritize based on risk
    - Safety
    - Regulatory
    - Quality
    - Business
  - Re-evaluate during management review
    - Risks may change
Act on results

- Monitor efficiency of closure / CAPA process – adequacy and timeliness of:
  - Response / Investigation
  - Implementation
  - Closure / Follow-up
  - Re-assess
Look at internal auditing not only as a regulatory compliance check, but as a necessary means to continuously improve the efficiency of business practices and product quality.
Questions
Thank You...!

Susan Reilly  
Reilly & Associates  
50 Old Quarry Road  
Wrentham, MA  02093  
617-899-2319  
susan@screillyconsulting.com

Carol Cekala  
TDC Medical Inc.  
261 Cedar Hill Street  
Marlborough, MA  01752  
(508) 481-6233  
ccekala@tdcmedical.com

Feel free to call or email with any questions concerning our presentation.