

# Creating an Efficient Internal Audit Program

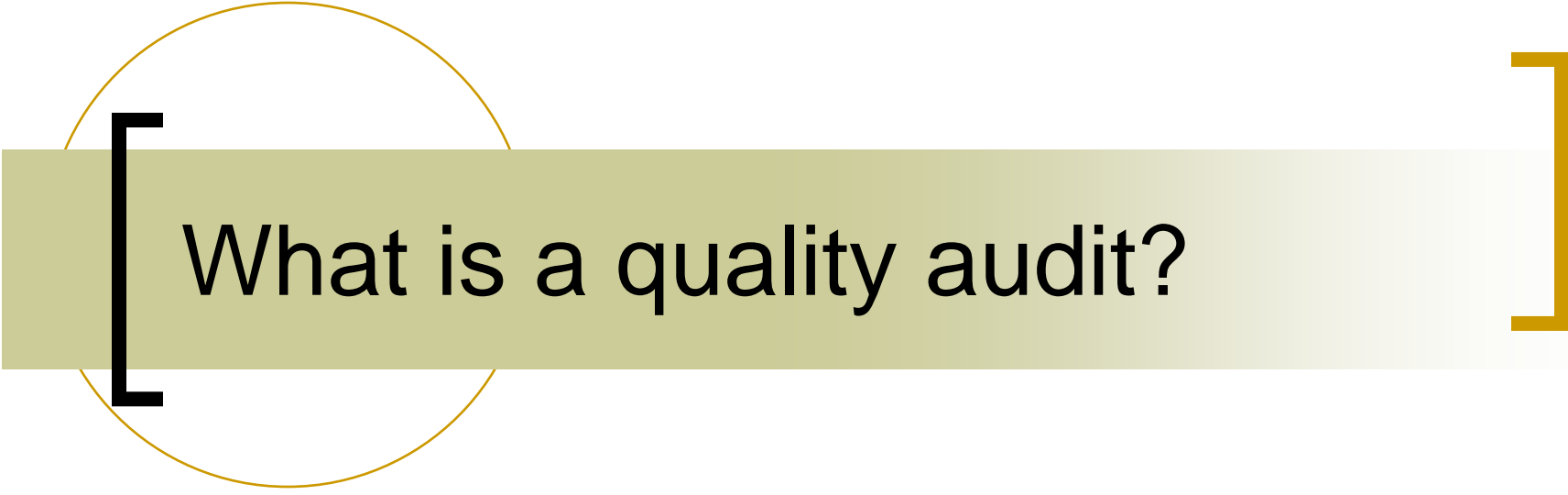
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# [ Presentation topics ]

- 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? ]

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- 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

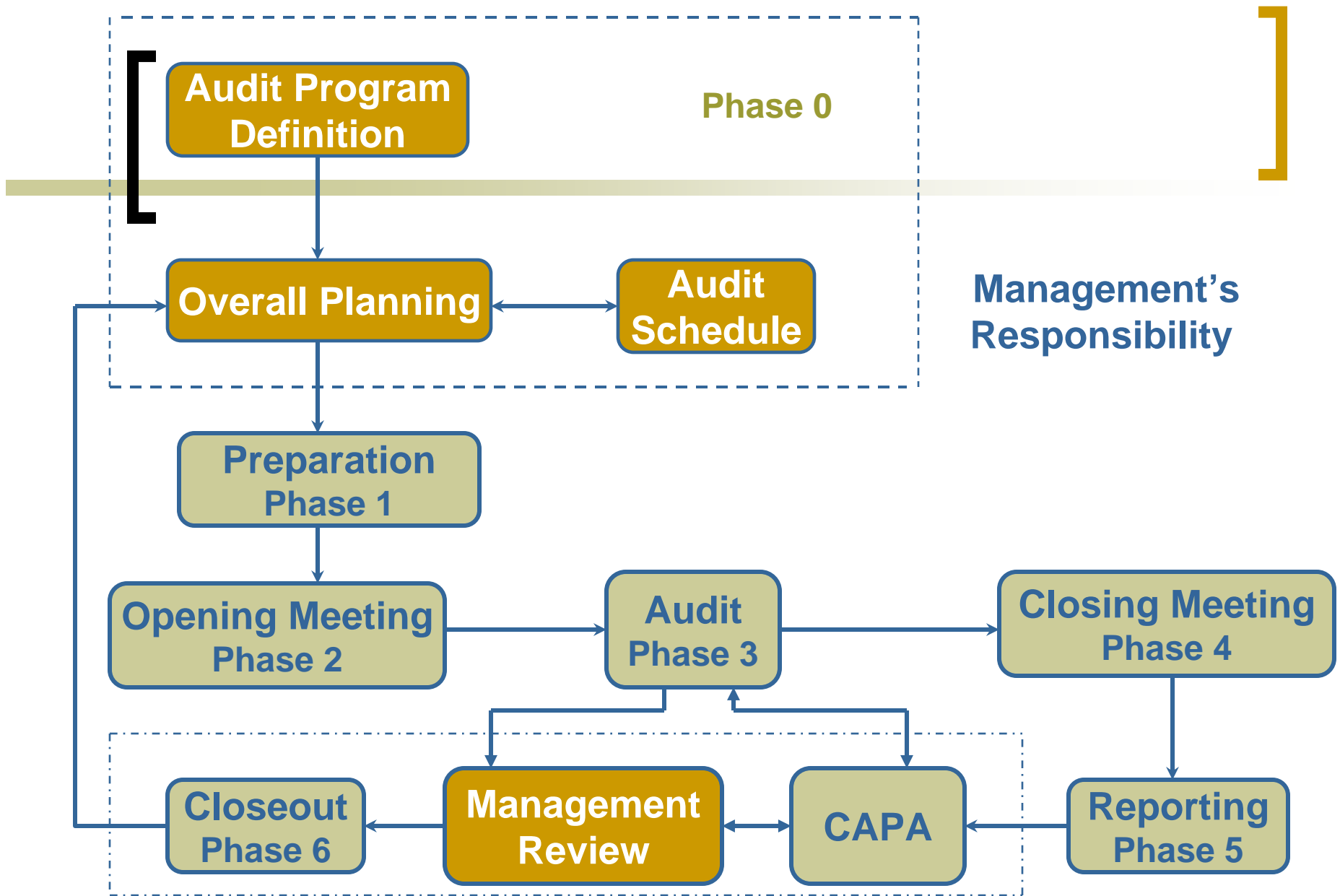
# [ What is a quality audit? ]

- 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? ]

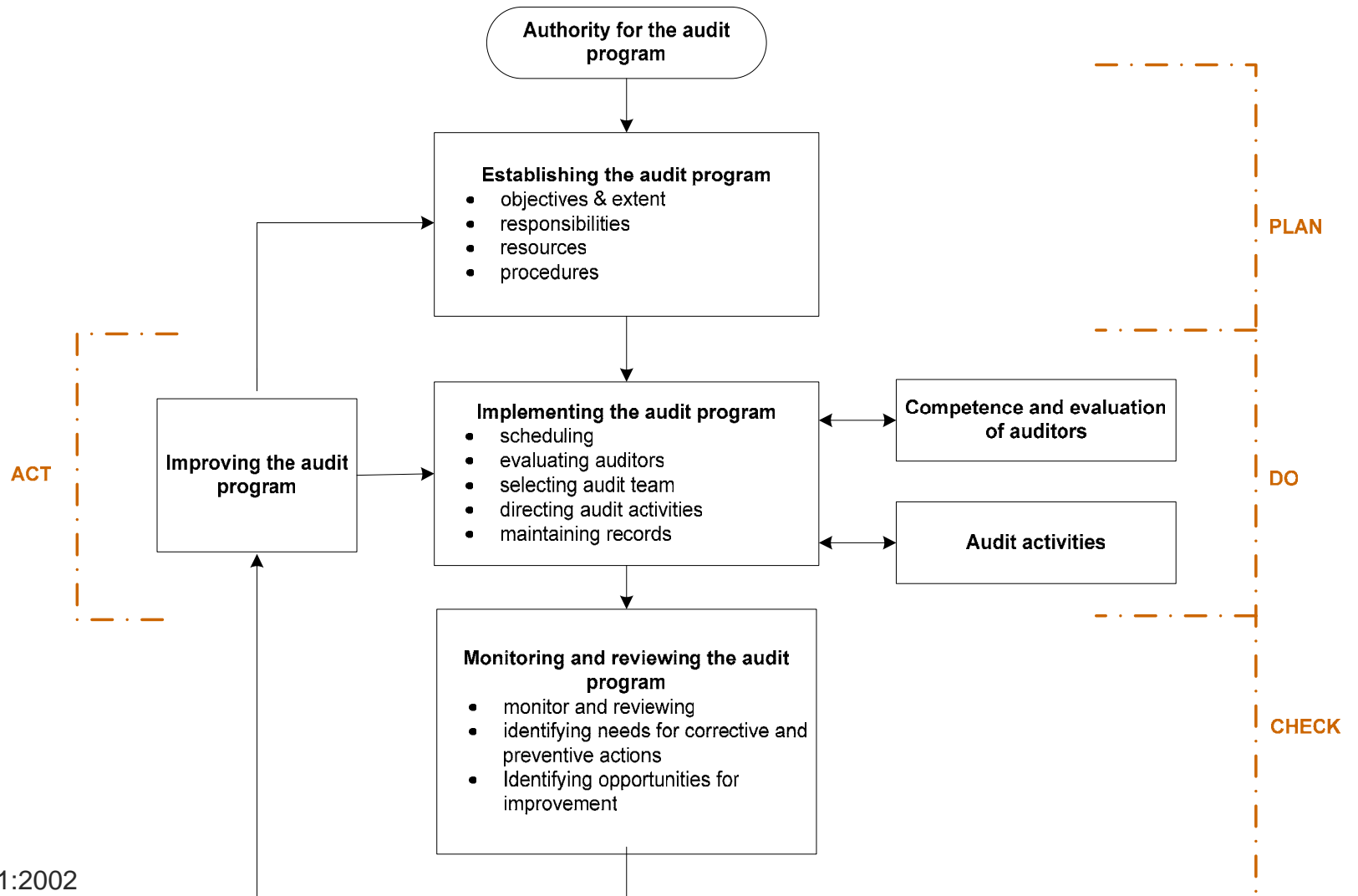
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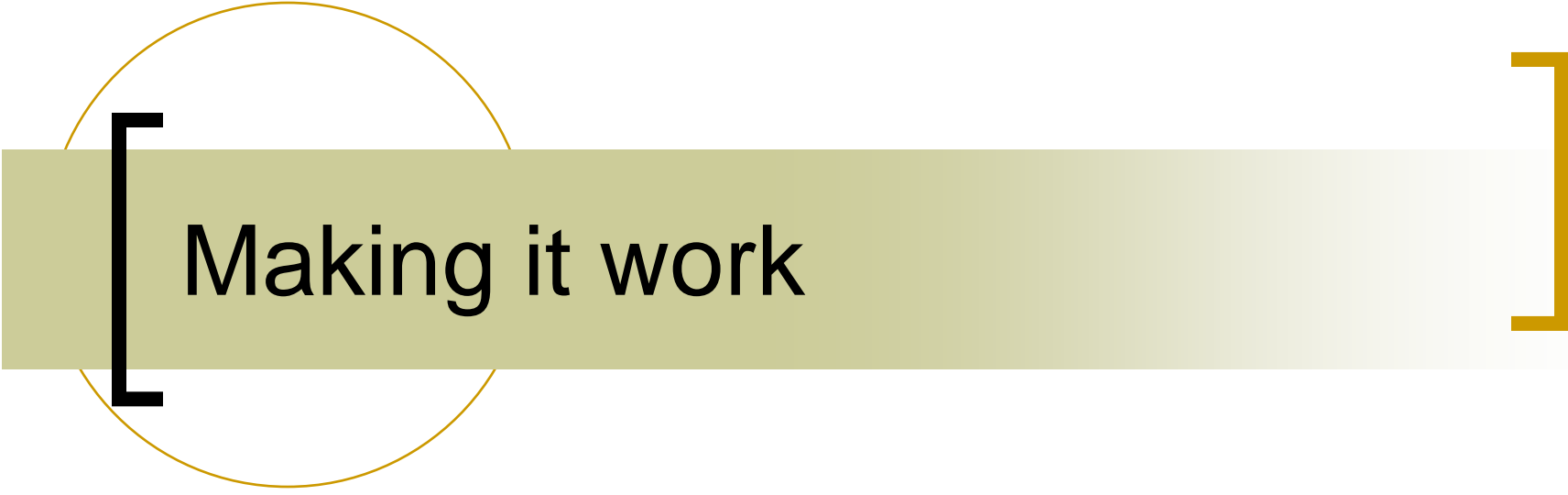
- Audits are not a quick look
- Audits are *preventive*, not detective
- Audits are planned, organized, and coordinated
- Audits are carried out for the benefit of the company, not the auditor
- A single audit will not find all noncompliant issues or potential problems





# Essential program elements





Making it work

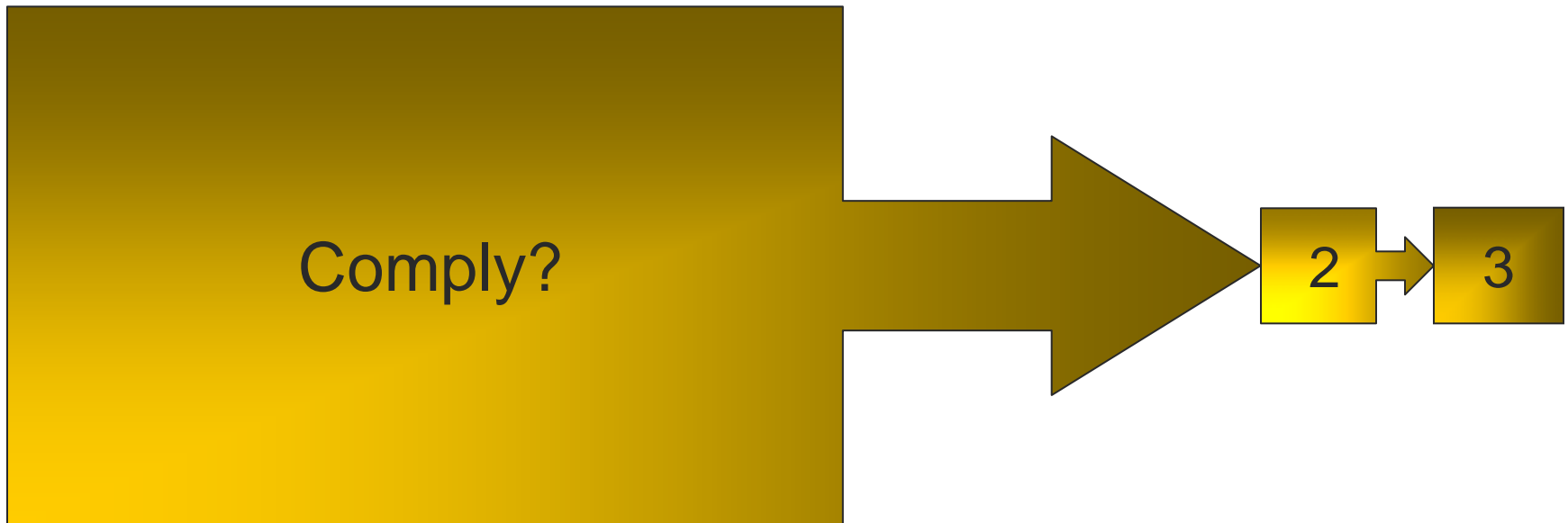
# [ Why do YOU audit? ]

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

# [ Making it work ]

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# [ Making it work ]

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- 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 ]



# [ Making it work ]

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- 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 ]

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# [ Making it work ]

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- 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? ]

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- Think preventive costs
  - Internal audits are the “downstream” assessment
  - FDA / ISO / customers are the “upstream” assessment

# [ How do you score? ]

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- 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? ]

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- 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? ]

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- 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? ]

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

# [ Who audits? ]

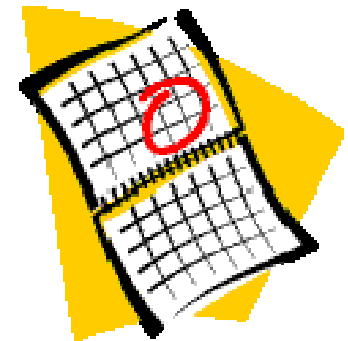
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- If using a third party
  - Schedule enough time
  - Continue to conduct internal audits with employees



# [ 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 ]

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

# [ Auditor qualifications ]

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- 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 ]

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- 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 ]

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- 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 ]

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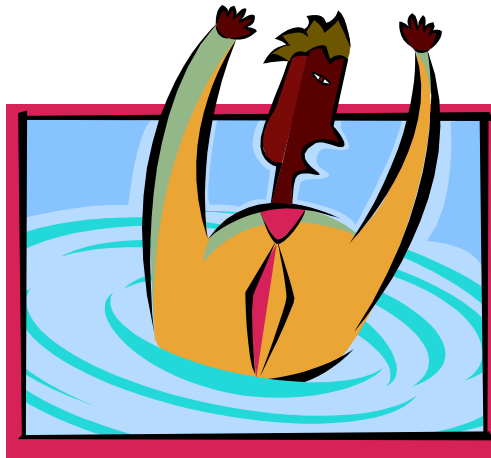
- Right personnel from cross-functional groups
  - Document training
  - Perform audits on a regular basis
  - Responsibility becomes part of job description
  - Must be taken seriously by employee and manager
    - Part of performance review



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 ]

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- 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 ]

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- 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 ]

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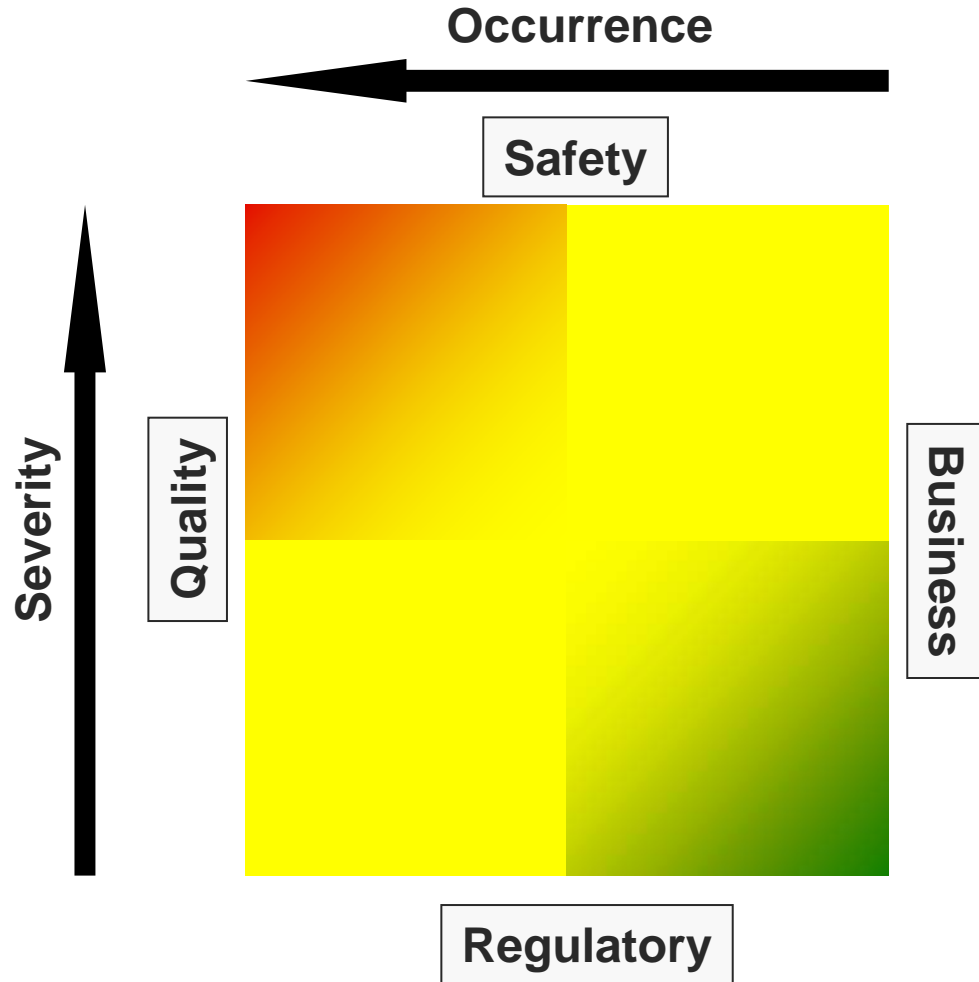
- Good auditing cannot be reflected in a poorly documented report
- Issue **TIMELY**
- Write to your “customer”
  - Write for impact
  - Make the report talk
  - Recognize their priorities
- Lead (don't lose) the “customer”

# [ 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 ]

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- 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 ]

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- Monitor efficiency of closure / CAPA process – adequacy and timeliness of:
  - Response / Investigation
  - Implementation
  - Closure / Follow-up
  - Re-assess

# [ Summary ]

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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 ]

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[ Thank You...! ]

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