



26th Annual ASQ Audit Conference
Blueprint for a Successful Audit

October 9 - 11, 2017 • Pre-conference Courses
October 12 - 13, 2017 • Conference

ASQ

The Global Voice of Quality™ The InterContinental Hotel | Dallas, Texas



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Audit
Division

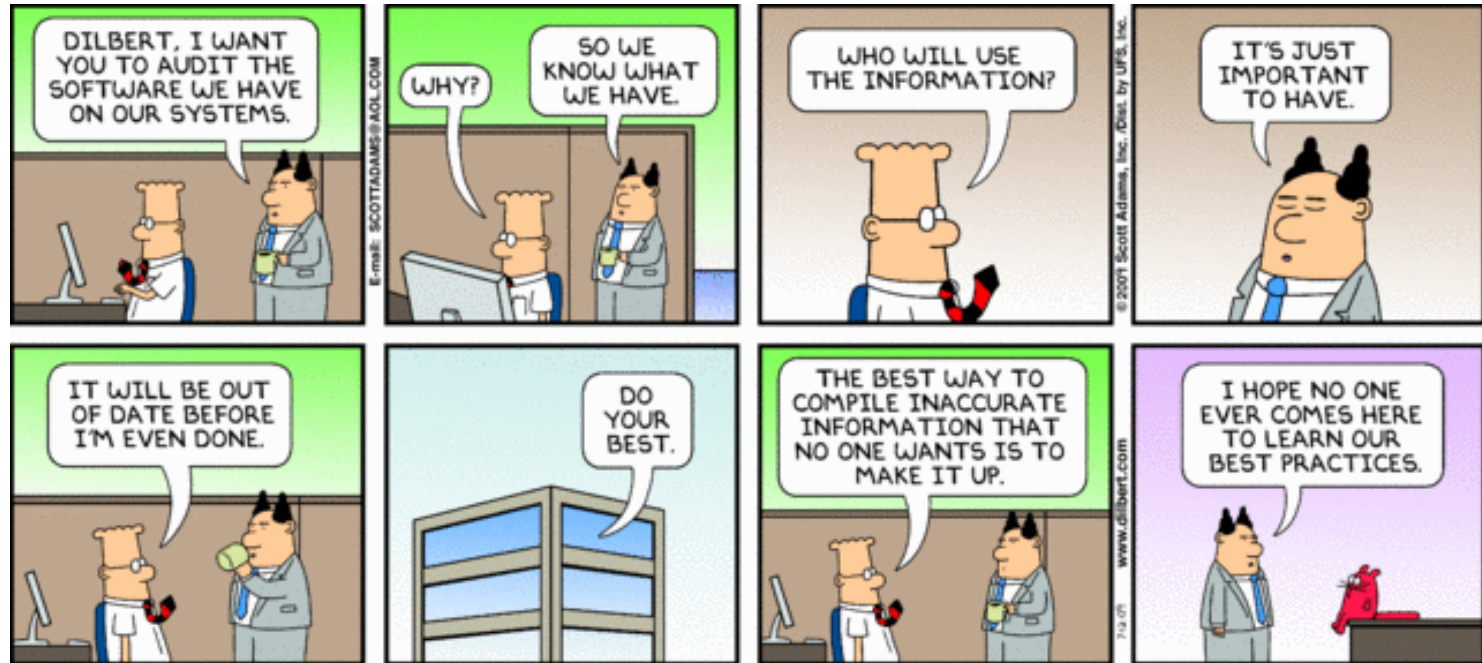
The Global Voice of Quality™

Auditing 101

Practical Aspects of Auditing

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13 October 2017

Auditing 101



Auditing 101

- What is an audit
- Type of audits
- How does an audit fit the ‘big picture’
- Phases of the Audit
- After the Audit – What next?

What is an Audit?

- A review of practices and procedures against an accepted standard:
 - 21CFR210/211
 - ISO2000
 - ICHQ7A

What is an Audit

- A dialogue
- A learning experience
 - Auditor/Auditee
 - Quality Systems
- A relationship builder
 - Customer/Supplier
 - Quality/Quality

Types of an Audit

- Two main types
 - Regulatory
 - Customer

- Scope or Reason
 - For cause
 - Routine

Audit Programs

- Compliance
- Risk Assessment
- Part of Supplier Management

Auditing 101

- Negotiating Date(s)
 - Send audit requests early
 - Include proposed timeframe and number of auditors
 - Be flexible
 - Understand things may change
 - Request travel recommendations

Auditing 101

- Number of Auditors
 - SMEs
 - Trainees

- Audit Standards
 - CFR
 - ISO
 - EU
 - TGA

Auditing 101

- Agendas
 - Developed Early
 - Communication Tool
 - Sets Expectations
 - Starting point
 - List of Basic Documents

Auditing 101

- Opening Meeting
 - Introductions
 - Scope/Audit Standard
 - Agenda Review
 - Auditee Presentation
 - Auditor Presentation (optional)
 - Audit Process
 - Reporting
 - Responses
 - Close out

Auditing 101

- Tour
 - Observe everything
 - Ask questions
 - What is employee doing
 - Why are they doing it
 - What is the relevant procedure
 - Assure understand of the question
 - Take your time
 - Look at Documents/Forms/Logbooks
 - Compare to approved versions/master document
 - Take lots of notes

Auditing 101

- Document Review
 - Start With Questions From Tour
 - Pick Broad Systems
 - Documentation
 - Training
 - Deviation
 - Validation/Qualification
 - Dig into system/documentation until satisfied
 - Keep digging if you have questions

Auditing 101

- Types of Documents
 - Batch Records
 - Master Plans
 - Process Validation
 - Equipment Qualification
 - Water Systems
 - Environmental Monitoring

Auditing 101

- Record every document reviewed
- Ask for clarification/understanding
- Record who was interviewed
- Document, Document, Document

Auditing 101

- Auditors Luck

- Trust it

Good luck!



Auditing 101

- Observation Do's
 - Clearly communicate what requirement is not being met
 - Cite examples
 - Differentiate 'one offs' vs systemic issues

Auditing 101

- Observation Don'ts
 - Hide anything
 - Personal preferences
 - Argue

Auditing 101

- Close out
 - Daily for multiple day audits
 - Positives
 - Negatives
 - Potential issues
 - Final close out
 - Thank Auditee
 - Review each day
 - Summarize observations
 - Don't categorize
 - Review audit process

Auditing 101

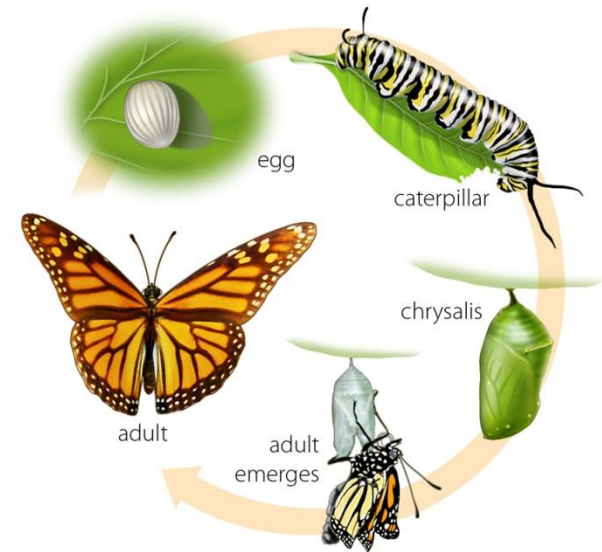
- Next steps
 - Audit report
 - Use as much ‘canned’ information that Auditee provided
 - Level of background detail is dependent on previous visits and changes
 - Deliver draft
 - Draft for review only, not for response
 - Rate observations
 - Final review audit publication

Auditing 101

- Audit close out
 - Review response
 - Routine follow up on CAPAs
 - Level of proof depends on observation rating
 - Continued dialogue from audit
 - Close audit when all CAPAs satisfied
 - Communicate closure to Auditee

Auditing 101

- Final thoughts
 - Audits have a life of their own
 - Build relationships
 - Not antagonistic
 - Auditees requests
 - Keep things focused on issues
 - Don't trust your memory



Auditing 101

THANK YOU



Questions?