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The Simple and the Not So Simple

Managing the transition to ISO 9001:2008

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ISO 9001:2008

Key Differences from ISO 9001:2000

Focus of 2008 Changes

- Clarification of Wording
 - Conformity to product requirements
 - Monitoring and measuring equipment
 - Calibration, calibration verification or both
- Outsourced Process Control
- Verify effectiveness of CAPA action
- No lengthy transition period



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What is going on? ISO 9001:2008

Recent Developments

- Starting with the Not so Simple:
 - How can a system that has been in place have so many problems or even fail an audit to 9001:2008?





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What is going on? ISO 9001:2008

Recent Developments

- Most can fit under one of three headings:
 - Limited understanding of the standard, its purpose or its potential.
 - Not understanding who has ownership of the QMS
 - Soft scoring by both internal auditors and third party auditors.



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Limited understanding of the standard

- Limited understanding of the standard, its purpose or its potential :
 - No support from Top management
 - Limited or no participation during Management Review
 - Not agreeable to changes or improvements
 - Limited utilization of CA/PA
 - Unusually clean internal audits
 - No focus on tracking or evaluating processes
 - Lots of paperwork, lots of hooks that lead to unnecessarily harsh requirements





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Who's is this anyway?

- Not understanding who has ownership of the QMS
 - Relying on third party audits to determine the evolution of the QMS...If it ain't broke, don't fix it
 - Mad dash to get ready for an audit
 - No contribution from the management team on procedures or work instructions





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Good today...Not so good tomorrow?

- Soft scoring by both internal auditors and third party auditors
 - Breezing through audits with little or no findings or opportunities for improvement
 - Little request for objective evidence of processes being followed
 - Most of the time spent on interviewing people





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Ok... So now what?

- Knowing is half the battle
 - Review the last few third party audits for:
 1. Misclassified findings (should have been a finding but was listed as an OFI)
 2. Little objective evidence referenced in the audit
 - Review internal audits also. Remember who owns the QMS. Re-training of internal auditors may be in order if they have been following the soft scoring practice.



...and then?

- Remedy what you can before your recert audit
 - Do not be tempted to do the quick fixes
 - ✓ Give evidence to the third party auditor that you have recognized the issues before they arrived and have already been proactive about arriving at a solution.
 - Do not try to hide the issues





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Keeping it Simple ISO 9001:2008

Recent Developments

- So, how do you make the transition easily?
 - How does an organization with a system that has been certified to ISO 9001:2000 transition to 9001:2008 quickly and easily?





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Maintaining Commitment

Through Cross-Organizational Engagement

Engage Employees at All Levels

- Verify QMS Conformity at Hand-off
 - Does product/process output meet requirements?
 - Were required records/sign-offs maintained?
 - Were issues documented?
- Remove Blame from Quality Issues
 - Report issues ,not individuals
 - Review process activities to identify root cause of issues



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Communicating about ISO 9001:2008

Communication & Training

- **Announcing the Transition**
 - Transition announcement integrated into regular monthly employee meeting
 - Reviewed the changes to activities
 - Explained impact to each operational area
- **Ensuring Understanding**
 - Ensured changed documents were available
 - Monitored completion of revised process activities
 - Reviewed compliance status 30 days before registration audit



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Passing the Audit

A Successful Transition to ISO 9001:2008

Demonstrating Top-Down Engagement

- Top Management Commitment
 - Input to monthly quality/safety meetings
 - Adaptation of quality objectives as needed
 - Regular, documented review of QMS
- Knowledgeable Employees
 - Employees understand their role and keep consistent records
 - Employees report quality issues immediately



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How did they do it?

Communication & Training

- Active management involvement
- Effective internal audit program
- Consistent and regular reviews of QMS health
- Focus on enhancing and improving QMS effectiveness – Document updates, record revisions, metrics calibration, consistent training.



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Thank You
Good luck on your transition!