Role Based Approvals vs E-Signatures

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A copy of this presentation is available from:
ftp://ftp.fasor.com/paper/approval`signature.pdf

Introduction

- Don’t assume all documents having Wet “Ink” Signatures are candidates for electronic signatures.
- We have been conditioned to sign things to indicate our authorship, review, concurrence, or approval.
- This is an unwise assumption that could lead to unnecessary and costly modifications to computer systems.

Regulatory Signature Intent

- 21CFR11.50(a)(3) “Signed Records” Includes the meaning of the sig; (Review, approval, responsibility, authorship)
- Comment 100 states that the agency intends that e-sigs apply to all signed electronic records regardless of whether other regs require them to be signed.
- The key is the word “***Signature***”

Regulatory Approval Intent

- Note that regulations use the word “approval” and “signature” in various clauses.
- Approval is just an approval! Nothing more.
- Can be satisfied many ways, i.aw., internal quality system.

Regulatory Intent

- The intent is only where existing Wet-Ink “regulatory” Sigs become electronic.
- Not required where the regulations do not specify!
- Very narrow GMP, GCP, GLP focus.
- Also considered applicable where internally imposed.

Industry Reaction

- Assume e-sigs for all existing Wet-Ink-Sigs.
- Start to develop an elaborate E-sig system to handle the load.
- Many sigs exist only because it has been the easy, de facto way of controlling process flow.

Perform a Process Review

- What does your internal SOP's require?
- Re-think the business or regulatory need.
- Consider role-based concepts and technologies to provide objective evidence.
- Simply state who is taking responsibility for the content or who entered the information.

Terms of Evidence

- Indicating Authorship
- Indicating Review
- Indicating Concurrence or Responsibility
- Indicating Approval
- Indicating Legal Signature

Indicating Authorship

- The names of persons who contributed to the record content
- No signature is required.
- This can be controlled thru configuration management.

Indicating Review

- Reviewers give credence to the content.
- Indication of name provides objective evidence that the review occurred.
- This can be controlled thru Configuration Management.

Indicating Concurrence or Responsibility

- This indicates awareness and acceptance of commitments.
- Depending on level, indication of name provides objective evidence.
- This can be controlled thru Configuration management.

Indicating Approval

- 21CFR uses the term “Approval” throughout the regulations.
- Approval can be in the form of a signature IF the organization chooses.
- Consider Approval processes thru workflow to satisfy the regulations.

Legal Signature

- The term “Signature” is used sparingly in the regulations.
- This clearly requires electronic Signature.
- This has full legal implication.

Bottom Line

- Avoid E-sigs like the plague!
- Query the laws for “signature”.
- Apply E-sigs only to those processes.
- Query internal SOPs.
- Change “sign + date” to “approve + date”.
- Create an approval work-flow.

Summary

- A sanity review of signatures is prudent.
- A better understanding of Approval vs Signature.
- Workflow can satisfy and control Approvals.
- Be conscious of E-sig commitments.

Where to get more information

- http://www.fda.gov/ora/compliance_ref/part11/
- ISO 17025 "General Requirements for the Competence of Testing and Calibration Laboratories", § 5.10.2
- ISO 12119 "Information Technology – Software Packages – Quality requirements and testing", § 4.3
- ISO 12207 "Information Technology – Software Life Cycle Practices"

Questions?