



44TH
Annual Meeting



Boston 2008

Enhancing Strategic Document Review Practices

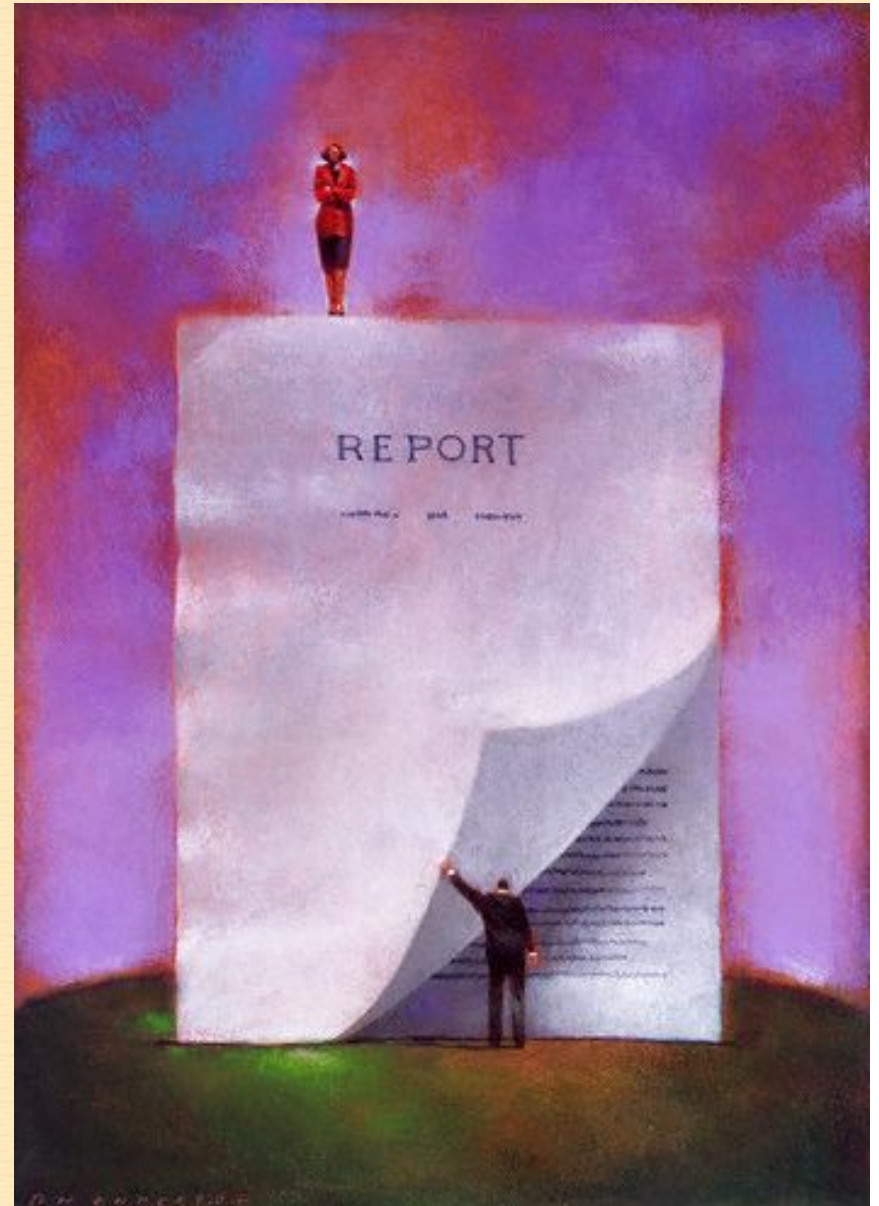
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INTEGRATING R&D WITH
BUSINESS AND REGULATION

Objectives

- Distinguish the different methods for judging/analyzing a document
- Consider the concept of strategic review
- Consider some aspects of “best practice” to improve efficiency and outcomes



Question

What is your characterization of a *good reviewer*?

What attributes/parameters makes for a *good round of review*?



Fact

Review is a misapplied term for what occurs in the judgment/analysis of documents



When a Review is Not a Review?

Consider the differences between these methods of document analysis:

1. Inspection
2. Assessment
3. Critique
4. Review



Most People Do Not Know How To Review

**We were never formally trained in the
practice of review**

Research suggests most people learn (*ad hoc
manner*) how to inspect or critique a document

Practice learnt during academic and business
apprenticeships



What is Real Value Derived from Review?

Consider the following:

- Surveys and project analyses suggest *document review practices* in the majority of pharmaceutical companies are remarkably costly, inefficient, and poorly managed
- ETS study with 53 “distinguished reviewers” showed *inter-reviewer correlation* of .31 on review of 300 documents
- PM Rothwell & N Mayo papers both show that reviewer agreement is *no greater than chance occurrence*



Traditional Review Practice

- Based on long-standing approaches
 - First review on advanced drafts (85%+ of document content is in place)
 - Document analysis (*inspection*) is at surface level
 - Data accuracy
 - Syntactical
 - Lexical
 - Expert-focused method
 - Experts in conduct and analysis of science not necessarily experts in judging suitability of text for a target audience



Traditional Review Practice

- Documents are routed to many people
 - Analysis completed in isolation
 - Comments submitted to author/document owner
 - Author compiles and manages comments
 - Author makes changes in the document
 - For “important” documents—meeting held to demonstrate changes and adjudicate/refine review commentary
- Process starts over again



Traditional Review Practice

- Document authoring and review activities are not in sync.
 - Extensive drafting before buy-in to document strategy
- Key decision-makers get involved too late in review processes
- Perception/expectation do not match practice
- Judgment of document quality is often predicated upon what was done in the past
 - Inspection and critique



Traditional Review Practices

- Inspection methods encourage “local” judgment of document
 - Linear progression, testing for accuracy
- Reviews do not effectively consider issues from perspective of regulatory reader
 - Review comments/discussion often address internal accountability or personal preferences



The Purpose of Review



Purpose

Reviewers:

Are to act as surrogate for the final user (consumer) of a document and verify

- Strategy effectively enacted
 - Messages addressed and defended
 - Issues resolved
- Habitable
 - Readable
 - Usable



Improving Efficiency of Review



Efficiency

- Greater return for each unit of input
 - People
 - Time

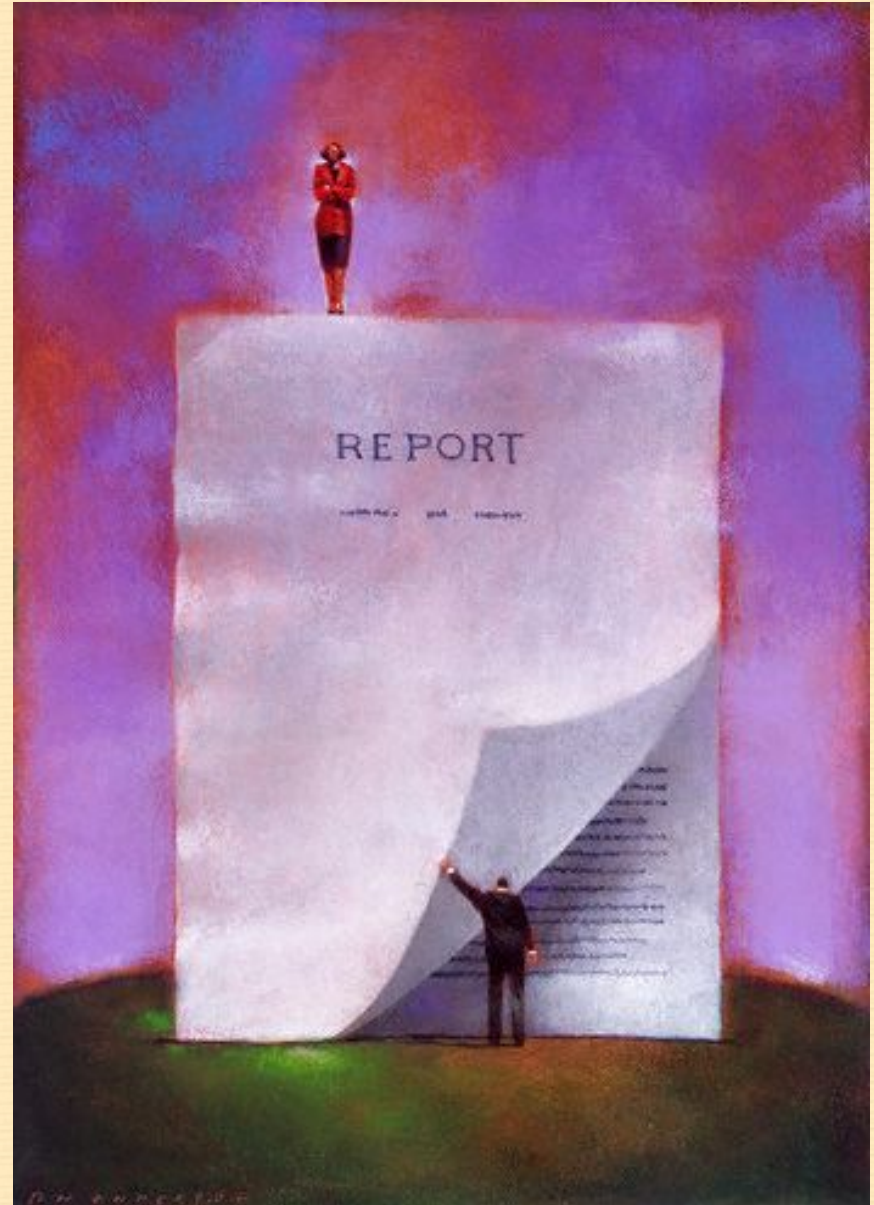


Concepts to Consider to Improve Efficiency

- Strategic review
- Staged review
- Review standards
- Strategic review techniques
- Review tools
- Review commentary



The Concept of Strategic Review



Strategic Review

Definition of *strategic*:

- Important or essential in relation to a plan of action
- Highly important to an intended objective
- Essential for effective application



Strategic Review

- Accomplished on first draft document
- Adopt mindset of the intended reader
- Take *perspective-based* assessment of document quality
 - Focus on document fitness for purpose
 - Focus on how well document attends to issues and states messages
 - Focus on how well document “organization” supports intended use



Strategic Review

- Strategic review involves more than just diagnosis of problem/deficiency
- Effective strategic reviewers always point towards the solution to the problem/deficiency in the document



The Concept of Staged Review



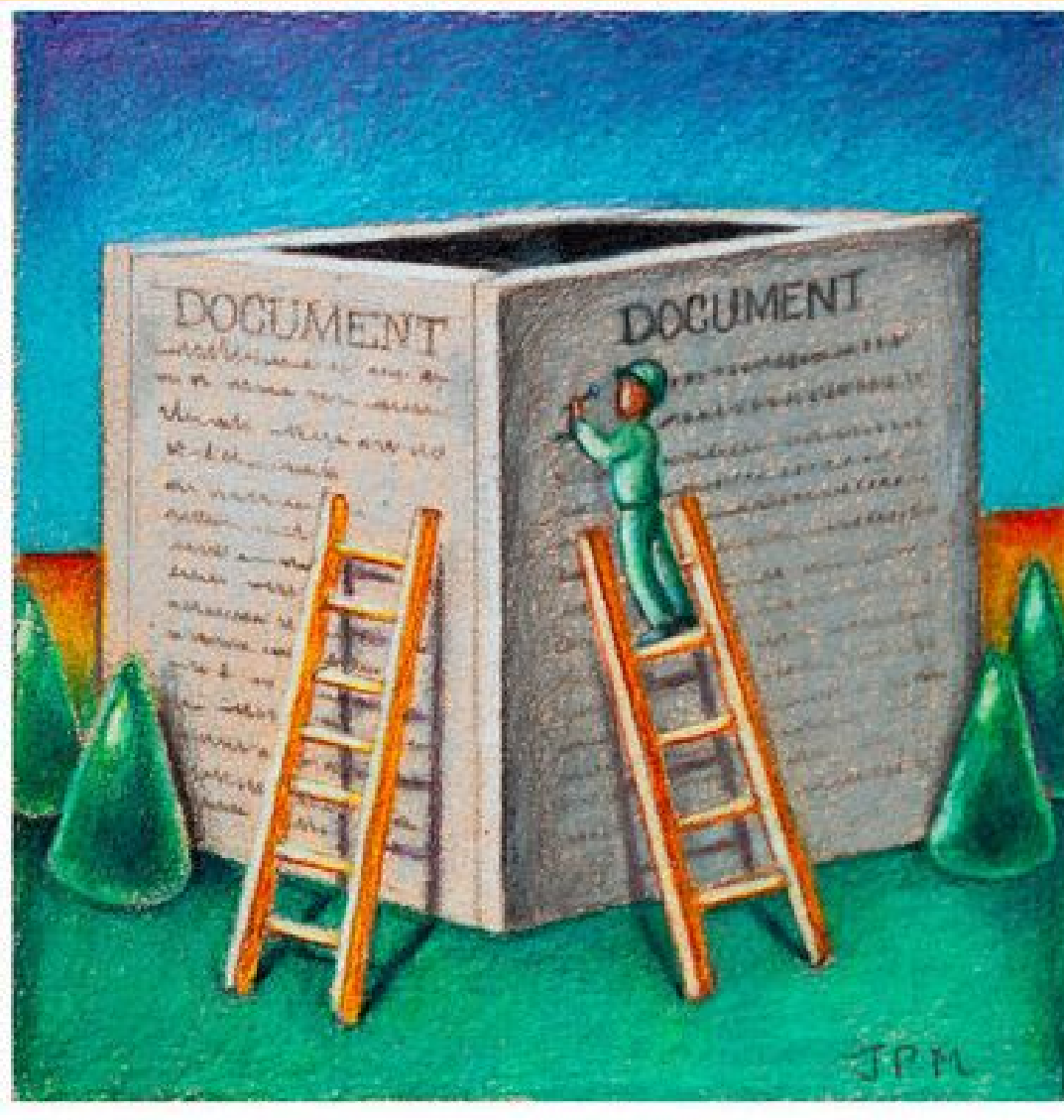
Review Focus Must Vary With Stage of Development

For instance—consider point of focus/goal in review of:

- Shell CSR
- Draft 1 CSR
- Final Draft CSR



The Concept of Review Standards



Standards

When is good, good enough?

- Need meaningful standards and criteria to test for fulfillment of communication quality
- Standards must address *semantical* and *rhetorical* aspects of a document
 - versus just *syntactical* and *lexical*



The Concept of Strategic Review Techniques



- **Key word review**
 - Objectives and endpoints
 - Label claims
 - Specification and conditional terms
- **Logic trail review**
 - Goal—objectives—variables—results—conclusions--significance
- **Key message review**
 - Check beginning of main sections and sub-sections for strong starts and clear positioning of major messages
- **+/- protocol review**
 - Ensures maintain focus as a reader
 - Pass through document twice



The Concept of Review Tools



Be Careful with Technology

- Technology is the *opiate* of the frustrated project or document manager
- Technology generally has little regard for behavior of the user



Review Checklists

Best practice is construction of checklist as a heuristic prompt

- Principally address strategy and fitness of purpose
- Questions posed at two levels
 - General
 - Subsection



The Concept of Review Commentary



Assigning Value to Review Comments

Rank order for review comments

- Apply a 1-3 rank order
 - 1 is of greatest importance and requires team discussion
 - 2 is a comment that as reviewer I want to know author disposition of comment
 - 3 is a comment at local level to be handled by author w/ no regard for feedback
- No more than 20% can be of highest concern





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For further information
on review practices
check out this blog:

<http://brain.brainery.net/mcblog>