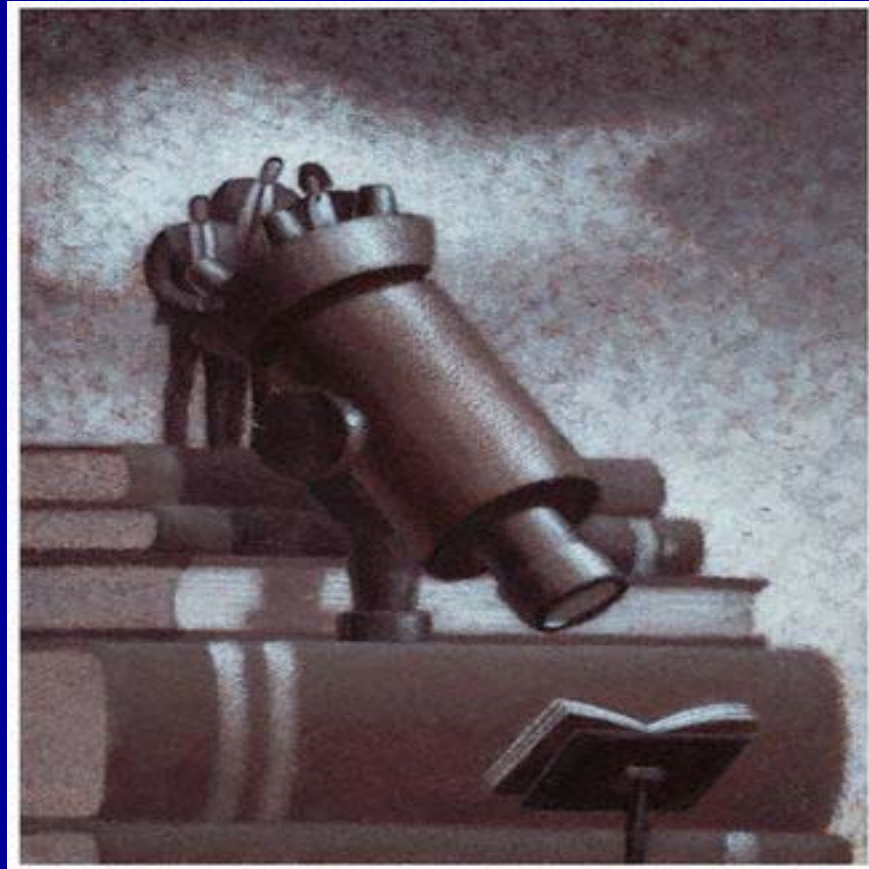


Improving the Review Process and Review Outcomes



Reviews are Identified as a Roadblock in Many Pharmaceutical Organizations

- Task of writing represents smallest portion of total time until document is approved and archived
- Time to complete reviews grows geometrically with the number of people involved
- Reviews routinely provide only incremental improvement in quality
- Document quality is an independent variable
 - relationship is not linear with the number of people involved in the process



Review Practices May Also Be Roadblock To Success

Finding in HHS survey:
Majority of FDA
Reviewers responding
stated the quality of
documents found in
regulatory submissions do
not meet their
expectations



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Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

FDA's Review Process
for New Drug Applications

A Management Review



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Problem Statement

- Despite good intentions, most Pharmaceutical R&D organizations find it challenging to assess the strengths and weaknesses of their review practices
- Organizations need to recognize that producing quality documentation is a collaborative process that takes time and commitment



Why Do Reviews Fail?

- Poor communication
- Lack of preparation
- Lack of management support
- Unclear expectations and objectives
- Insufficient time planned
- Lack of follow-up
- Wrong people involved, or right people involved at the wrong stage of the review



What Makes Reviews Successful?

- Recognition from all involved that producing quality documentation is a collaborative process that takes time and commitment.
- Understanding that the review process should be used to help build in quality and not to inspect for quality.



Need Active Management Support

Management's attitude toward reviews determines whether you're going to succeed:

Managers who consider reviews a burden on top of the “true” set of job tasks often provide little support for the process and can make good reviews next to impossible to obtain, particularly if their staff learn that shoddy reviews carry no consequences

Conversely, managers who encourage conscientious reviews by budgeting review time in the development schedule and making the quality of reviews part of an SME's job evaluation encourage high-quality reviews



Benefits of High Quality Reviews

- Increased document quality over time
- Best possible arguments
- Timely project development
- Highly usable documents
- Effective coordination of knowledge across function areas



Set the Focus for Review

- Create explicit definitions (specifications and criteria) for document quality standards
- Apply strategic review practices
- Plan focus for each stage of review
- Develop guidance for review of mock report, through drafts, to final reports
- Leverage software applications to support best practice
- Develop metrics to assess effectiveness



Strategic Reviews

All reviews should be strategic:

- Strategic reviews help teams create documents that are well designed and highly usable by health authority reviewers.
- Well designed documents put important information in prominent locations and clearly address the issues.
- Well designed documents help reviewers quickly find the information they need.



Strategic Reviews

- Strategic reviews ask the fundamental question of whether the document makes the right argument in the right place. Does the document advance the work of the organization?
- Strategic reviews ask if the arguments are well supported with data and logically sound. Does the document stand up to challenge and justify conclusions (if it reaches real conclusions).



Outcomes of High Quality Reviews

- Message-driven documents that present strong positions and clear arguments to support those positions.
- Issue-focused documents that clearly address all key issues.
- Usable documents that facilitate understanding and help achieve target label and market position.



Using Staged Reviews

- An early review of a document prototype or plan can define the overall framework for a document.
- A review of a draft can attend to issues of content, logic, organization, and presentation.
- A review of an advanced draft can focus on quality assurance, accuracy and completeness of information, and consistency within the document.
- A sign-off of the finished document can check accuracy and consistency of messages among the documents across a filing.



Prototype Review

An early review of a document plan or document prototype helps minimize surprises and extensive rework later on. Reviewers ensure that key issues and messages are identified. The purpose is to define the overall framework for the document.



Prototype Review Questions

- What is the high level strategy? What is the purpose?
- Who are the readers? How will this document be used?
- What messages will be delivered where in the document?
- What arguments can be made on the basis of what data? Are there gaps in the data?
- What issues are unresolved? How will tricky issues be handled?
- Are appropriate data displays being planned?



Early Review

Reviews and revisions of early drafts lead to high quality documents. Human tendency is to procrastinate. Early reviews force authors to create early drafts. Authors benefit from time between drafts, so they can get some distance and objectivity on their own writing. Time can also be used to coordinate the work of various players—leading to a unified document.



Early Review Questions

- Is there sufficient content to support and resolve issues?
- Is the required regulatory content in place?
- Is the document well argued and logical?
- Is there sufficient context to clarify content?
- Is the key information presented in a prominent position?
- Is the document well designed and all visuals clear?



Late-Stage Review

A review of an advanced draft or a final document ensures that the final report presents strong, accurate, and complete arguments and data. Late-stage reviews can be sign-off reviews.



Late-Stage Review Questions

- Are all data accurate, complete, and consistent?
- Are gaps or contradictions in claims and data identified in prior reviews adequately addressed?
- Are late-stage issues or emergent trends in the data accounted for?
- Are visuals interpreted, well labeled, and legible?
- Is the document consistently formatted?
- Is the language clear and correct?



Different Review Perspectives

Author Review

- Ensures that messages and issues identified in the planning stage have been incorporated

Peer Review

- Helps the writer focus on strategy

Supervisor Review

- Assesses how a document represents the interests of the organization

Expert Review

- Leverages subject matter expertise to assess the correctness of the document's content



Create Explicit Definitions (specifications and criteria) for Document Quality Standards



These Standards Connote Practice of *Inspection* not Review

- Accurate
- Compliant
- Consistent
- Clear
- Precise
- Concise



Example Review Standards

- Purpose
- Logic
- Context
- Content
- Organization
- Presentation
- Language



Provide Checklists to Reviewers

Specific Review Considerations

Does each section of the CDP fulfill the intended purpose as described by the questions listed below?

1 Executive Summary

- There is a statement regarding why this compound was selected for development and how the compound is consistent with mission and strengths of the Oncology group.

1.1 Primary Objective

- The development goals are clearly and completely stated.
- The target of development is clearly defined.
- The scientific strategy is sufficiently summarized in this section.

1.2 Project Status

- This section provides indication of current project status and provides overview of actions/events that have occurred to date.

1.3 Key Milestones with Decision Points

- There is an explicit definition of Proof of Concept (POC).
- There is a description of what questions must be answered to establish POC. The description is complete.
- There is an explicit definition of criteria for success.
- The discussion connects the clinical POC strategy to the preclinical strategy and to the overall development strategy.
- The discussion includes a timetable to reach POC.

Guidelines for Effective Reviews

- Provide specific instructions for reviewers.
- Define document purpose and audience for reviewers.
- Ensure reviews are scheduled into the project plan and reviewers have sufficient time.
- Give time limits with a return date for the review.
- Provide necessary additional materials.



Define Expectations and Objectives of Strategic Review

- Educate the team on *what to review and not review*. Team members should be informed of the goals and needs throughout each review cycle.
- Clearly identify the document's purpose, audience, and scope.
- Identify specific issues that need to be addressed in each review.
- Establish criteria that the document must meet at each review phase.



Provide Specific Review Instructions

- Give reviewers directions. Don't just send out a document with a note saying "For your review and comment." Tell them what stage to focus on, and tell them what help you need and why.
- Tell reviewers if you are looking for *help* rather than *approval*.
- Identify specific issues that need to be addressed at this stage of the review.



Define Document Purpose & Audience

- Summarize the document purpose, scope, audience, and intended use for each audience.
- Provide enough context to make sure that reviewers understand the document's purpose and its target users.



Provide Additional Materials

- Make available to the reviewers copies of summaries, articles, or documents that are critical to the issue you are asking the reviewers to consider.
- Do not assume that each reviewer is completely familiar with the latest industry or regulatory standards.



How to Be an Effective Reviewer

- Review with the document user in mind.
- Read “against” the document.
- Familiarize yourself with the entire document before beginning your detailed review.
- Do not edit unless specifically requested.
- Write your comments with the author in mind.



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