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Document review practices in the research and development functions of many pharmaceutical companies can be frustrating and inefficient, at least in part because these practices are poorly managed. Although the literature on review practice is fairly robust, there is a disjuncture between what researchers know and how reviewers work. The author draws on his experience as a consultant and trainer to many pharmaceutical companies to outline the causes and effects of poor review practice. He offers recommendations to enhance the value and increase the efficiency of reviews.

Keywords: *review; writing; pharmaceutical writing; drug development; editing; documentation*

Review practices, even in large, sophisticated pharmaceutical companies, can be remarkably inefficient and poorly managed. This generalization holds despite the deep reliance of these companies on complex documentation for delivering the results of their research and development efforts. In part, review practices are inefficient because the work environments are so complex, and document development reflects that complexity. But it is also true that review as a practice is rarely examined systematically.

Companies tend to be unaware of the research and practice in professional communication that could shape document review. Useful studies go unnoticed, including studies that specifically focus on review practice (Katz, 1998; Kleimann, 1991, 1993; van der Geest & van Gemert, 1997). Broader studies of professional communication also include important information on the role of review in organiza-

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tional practice (Couture & Rymer, 1989, 1993; Henry, 2000; Shwom & Hirsch, 1994). To change existing review practice, companies need to better understand the multiple purposes and value of review activities. They also need to become more evaluative and methodical regarding their own work practices. My consulting experience suggests that these changes are both possible and desirable.

To further our understanding of the general issues related to document review, this article examines one particular organizational context: drug development within large pharmaceutical companies. The article outlines causes and effects of poor review practice and then suggests enhanced practices intended to increase the value and efficiency of reviews. Where appropriate, I bolster my observations with discussion of research that reflects common findings across various industries. Although the article focuses on one industry, readers will likely recognize ways to apply the analysis and recommendations to other organizational settings.

My observations are drawn primarily from my professional experience as a consultant and trainer during the past 8 years to large and small pharmaceutical companies (Bernhardt, 1995, 1999; Bernhardt & McCulley, 2000). My work has been conducted through McCulley/Cuppan LLC (M/C), a consulting and training group based in Salt Lake City that grew out of the specialized training in professional writing and communication provided by Shipley Associates of Bountiful, Utah. M/C focuses exclusively on the pharmaceutical industry, particularly on helping companies produce high-quality documentation as part of the development and registration of new drug products. M/C operates with a full-time staff of five to seven people and a cadre of associates who provide specialized help with projects. In addition to those with backgrounds in technical and professional communication, the consultants on any given project might include a medical doctor, an engineer, a geneticist, a physiologist, a lawyer, a pharmacist, a regulatory specialist, a molecular biologist, a chemist, or a toxicologist.

M/C has worked on consulting and training projects for large and small pharmaceutical companies (with a client list of more than 50 companies). Its projects involve helping companies write and review documentation, training teams in collaborative processes, developing electronic tools to support document development, developing model documents and templates, defining and assessing document quality, and implementing best practices in document development. M/C consultants sometimes train, sometimes coach individuals or

teams, and sometimes join project teams to work alongside industry partners.

Within M/C, we continually refine our approach to review practice because so many organizations express frustration with this activity. On each new project, we work with the client on a needs assessment, conducting interviews and attending meetings to gauge current practice. We develop customized training or intervention strategies and materials in consultation with the client, who in turn gives us feedback reviews of our intervention before, during, and after delivery. The delivery of the training and team interventions are themselves a constant source of feedback, a kind of member check, because clients always tell us their thoughts, and they always formally evaluate the training. Thus, over time, we have refined our understanding of review processes.

In one project, I spent a year working full-time with Hoffmann-La Roche in Basel, Switzerland, alongside Roche employees and four to seven other full-time consultants, to implement team technologies and document development methods to coordinate widely distributed global teams. We attempted to structure review practice and leverage the available technologies so that a well-resourced team could work efficiently from a distance. A daily activity was document review: in face-to-face meetings, via e-mail attachments, on shared drives, or through video and shared computer conferencing.

In a typical year, I work with three to four companies on five to six projects for a total of perhaps 50 to 60 days. Current projects involve specialized training at AstraZeneca to help a medical writing group take on more sophisticated roles as medical communication scientists. A project at Schering-Plough focuses on norming a group of technical reviewers so that those with designated roles in document review respond with consistent standards and useful comments as a form of expertise they offer to the organization. At Aventis, we recently conducted 40 one- to two-hour interviews on review practices with employees who represent the full range of involvement in clinical development studies, up to vice-president level. Such activities highlight for management (and for us) the difficult nature of reviewing to standards within complex organizations.

This article thus reflects cumulative experience gained over time through my multiple encounters as a participant, trainer, team member, and consultant in pharmaceutical companies. Technical communication consultants tend to take their knowledge into workplaces, but they also create new knowledge within those workplaces, and

they take that new knowledge back to university settings (Palmer & Killingsworth, 2002, p. 390). My approach shares some perspective with "action research" in that what I have to say contributes to our understanding of how research and theory can be applied in action settings of work (Greenwood & Levin, 2000). Most accurate, perhaps, would be to portray what follows as a "soft systems approach":

> The researcher (typically an outside consultant) assumes a role as discussion partner or trainer in a real problem situation. The researcher works with participants to generate some (systems) models of the situation and uses the models to question the situation and to suggest a revised course of action. (Kemmis & McTaggart, 2000, p. 571)

The following is a blended representation of my experiences across various companies, not a description of practice in one particular setting. To preserve client confidentiality, I have written this article so that specific statements cannot be attributed to specific companies. Moreover, I intend no specific criticism of the work practices of specific individuals or work groups. My experience tells me that individuals and teams do the best they know how, with good intentions, under the constraints of a stressful, complex, and high-stakes work environment.

DOCUMENT DEVELOPMENT IN THE PHARMACEUTICAL INDUSTRY

To place my comments on review practice in context, I provide in this section some background on drug and document development activities in the pharmaceutical industry. Drug development is document-intensive work, work that is well described in the pharmaceutical literature and well supported at various health authority Web sites, in particular the sites of the Food and Drug Administration (FDA) (http://www.fda.gov/), the European Agency for the Evaluation of Medicinal Products (http://www.emea.eu.int/), and the International Conference on Harmonisation (http://www.ich.org/). Spilker (1991) has published various comprehensive accounts of drug development, including specialized and detailed coverage of clinical drug research. Bonk (1998) focused specifically on medical writing in drug development, providing a useful overview from the perspective of a manager responsible for a medical writing group in a large pharmaceutical company.

A central documentation task for pharmaceutical companies is the New Drug Application (NDA), the large and critical set of documents that companies file with regulatory authorities to persuade them to approve new drugs. To complete the NDA, complex organizations, with staffs representing multiple and highly specialized competencies, must coordinate their work to produce a comprehensive filing dossier: hundreds of volumes, totaling hundreds of thousands of pages, comprising lengthy expository text and arguments. The text is supported by extensive data sets representing chemical development work as well as animal, laboratory, and human-subject study data. The NDA rolls up into one dossier 10 or more years of development work across three broad line functions (representing many individual departments):

- *Drug chemistry:* the synthesis and scaled-up production of the drug substance, development of the formulated product with specific ingredients and production methods, tests for product quality and method robustness, description and testing of packaging and delivery devices.
- *Nonclinical (or preclinical) program:* the testing to determine the drug's pharmacological effects on various tissues, organs, and body systems in animal and in vitro cell models; to determine the likely modes of action; to characterize how the drug is absorbed, distributed, metabolized, and excreted; and to characterize toxic effects and drug/drug interactions for the drug, its metabolized forms, and its impurities and degradants.
- *Clinical program:* the testing to establish the safety and efficacy profile of the drug, comparative effects with regard to existing treatments, statistically demonstrated effects in studies with large sample populations, calculations of benefits and risks, and arguments based on pharmacoeconomics.

The full NDA is presented in a dossier comprising some 200,000 to 600,000 pages. Delivery of this extensive document set is typically coordinated through the company's department of regulatory affairs, whose job it is to interact with health authorities. After approval, relevant sections of the dossier are handed off to business and marketing, with various other departments tracking postmarket safety data, running additional studies, and publishing the results of various studies in the scientific literature.

The documents within the NDA represent a variety of scientific genres. Early exploratory and descriptive studies tend to be conducted on animals or on small populations of healthy human subjects, with the goal of characterizing aspects of the drug qualitatively. Some studies attempt to establish limits (e.g., minimum doses that

cause some observed effect or maximum doses that can be tolerated). Studies on drug chemistry measure some aspect of drug quality or activity and establish specifications or validate certain methods of testing, manufacturing, shipping, or storage. Some studies test for interactions between compounds used in the formulation, or they test specific quantities of various ingredients to achieve an optimal formulation with the desired product qualities. Some documents are purely descriptive, characterizing the synthesis or chemistry of the drug substance. Each excipient used in the formulated product must be described and its purity established, with appropriate documentation from suppliers of raw materials and intermediates.

Many later documents are fairly straightforward clinical studies, sometimes powered by statistical models, frequently addressing explicit hypotheses and objectives within the traditional genre of the research report (though with content organized according to health authority guidance). The approvability of the NDA typically rests on at least two large comparative, randomized, and blinded trials that are powered to demonstrate efficacy and typically present a descriptive comparison of safety against comparators or placebos. Each individual research report tends to be a large document, including 50 to 250 pages of text plus hundreds of pages of tables and graphs. Supporting these reports are the study protocols, accompanying documentation, and the individual records of each patient for each visit to the trial center, capturing health assessments and reported adverse events.

Governing the whole dossier are specialized genres, including the package insert, the label, the package design, and patient information leaflets. The package insert that everyone is familiar with represents the final agreement with authorities as to what can be said about the drug: to whom it can be marketed, for what conditions, and how it must be described in terms of efficacy or safety. The package insert is a keystone document that is intensively reviewed and revised.

Overarching, top-level summary documents (and summaries of the summaries that critically evaluate the dossier and the work it represents) integrate the dossier, pulling together the full story in long evaluative syntheses (30 to 150 pages of continuous text plus substantial attachments).

NDAs are constantly evolving and are currently being restructured in major ways to conform with two sets of important new guidances, one moving the industry toward fully electronic submis-

sions and the other toward what is called the Common Technical Document (CTD), intended to dictate a common structure and content of the NDA so that one version can satisfy global regulatory requirements. Until recently, the NDAs have had to be tailored to specific markets, prepared in multiple versions that responded to various countries' regulations.

During development and preceding the filing of an NDA, the sponsor company must file various documents and schedule a series of meetings with health authorities (primarily those representing the United States, the European Union, and Japan but also including various other markets). Before the drug can be put into humans, the sponsor company must compile everything known about the drug in an Investigational New Drug (IND) application for health authority review and approval. A separate document, the Investigational Drug Brochure (IDB) summarizes all known relevant information for use by those investigators who enroll patients in trials and gather data for the studies. The sponsor company and the health authorities have periodic meetings to share findings about the drug, to agree on filing strategies and necessary studies, and to reach consensus on issues that emerge during development. As a result of these interactions, by the time the company files the NDA, there are shared understandings about what a successful filing needs to demonstrate. The dossier is thus complicated by a history of intertextuality and presupposition.

Once submitted, the NDA is reviewed by the health authorities, using internal teams of agency scientists and external review boards of expert scientists. The intricate review process takes months or years, typically involving further exchanges of information. The health authority issues summary reports and letters identifying deficiencies, which in turn trigger rounds of replies and briefings as the company provides clarification or additional data. The application is eventually either denied, rejected with a request for further data and an opportunity to refile, or granted an approval. The complexity of the submission and review process is indicated by the average cost to the FDA of reviewing a single drug application for a new molecular entity: The figure is approaching 2 million dollars (http://www.fda.gov/cder/pdufa/pdufa_costs.htm). This figure represents only the cost to the FDA.

A large company hopes to file several NDAs each year and might have 20 to 30 drugs in various phases of development. Not every application is for a new drug—there are line extensions to treat new

conditions, filings to qualify new dosage forms or treatment regimens, and safety updates, all guaranteeing a constant flow of reports. Because each document throughout development tends to receive multiple reviews from many experts, review emerges as a central practice within the industry.

CHARACTERISTICS OF CURRENT REVIEW PRACTICES

The preceding background suggests the complexity of the document development environment within drug companies. Many in the industry experience a high degree of frustration with review practices, feeling that review takes (or wastes) too much time and contributes to projects being behind schedule. Many feel that the same issues need to be revisited repeatedly, that too many reports need thorough reworking, and that poor writing forces on others the responsibility for fixing problems. In every company I have worked with, the feeling is, first, that writing in general needs to be improved and, second, that review practices need to be improved.

This pervasive sense of frustration is well noted in the general literature on review practices. Paradis, Dobrin, and Miller (1985) provided a telling list of the frustrating differences in perception related to review practice when viewed from a manager's perspective compared to an employee's. Their subjects (in an R&D environment) perceived review from opposite perspectives and frequently interpreted review commentary in personal terms (p. 301). Van der Geest and van Gemert (1997) pointed to the general sense of frustration identified in the literature on review practice and reported that their own subjects in various Dutch companies across three studies found "reviewing the most cumbersome stage in the process of text production, given that many parties are involved in it and that it is loaded with different expectations" (p. 445). They go on to note that "of all the activities that constituted the text production process, review was clearly the one that caused the most problems" (p. 446).

Working with data gathered by many interns at various work sites, Henry (2000) offered the following synthesis, which testifies to the complex nature of review:

> For professional writers, writing projects are almost always collaborative, engaging coworkers from other professional classes, entailing

> multiple reviews, and often targeting multiple (and sequential) audiences (which might include themselves as citizens), fraught with second guessing on issues of organizational representation above and beyond a document's ostensible "content," requiring interpretations of organizational culture to the ends of adequately and appropriately delivering discursive products. (p. 65)

Overall, the literature suggests that review practices are both frustrating and complex.

Although practice varies across drug companies, reviews tend to begin within an author's specific department and then move up through layers of managerial review. Such document cycling is frequently discussed in the literature (Katz, 1998; Paradis et al., 1985). At some point, often close to the end of the cycle, representatives of regulatory affairs, quality assurance, and publishing then review the document for compliance with regulatory guidances and to check the accuracy, consistency, and completeness of the text and data. Depending on how the company configures its development teams, some reviews may cross line functions so that those in clinical or preclinical review the chemistry reports, for example.

Review is thus a frequent and time-consuming activity—in this industry as in others—one that represents a continuing source of frustration. This frustration can be traced to certain persistent patterns of work:

- Drafts are delivered for review at late stages in a project, when the filing deadline is approaching and work is most pressured.
- Different purposes for review at different stages of document development often conflict.
- Reviewers use habitual but inefficient patterns of review.

I discuss these common work patterns in the rest of this section and suggest ways to improve practice in the following section.

Late Delivery

For various reasons, drafting and review tend to be delayed. In the pharmaceutical industry, as elsewhere, authors tend to view writing as something to be completed after the experiments and development activities have produced their data. Even when the science is completed early, the write-up may not be accomplished until time pressures—represented by the filing deadline—demand delivery. Many

projects and their documents are abandoned in the face of poor data or irrelevance from a regulatory perspective, so there is sometimes a "wait-and-see" attitude played out in the delivery of draft documents.

Authors tend to hold onto drafts until they believe them finished. They then expect their finished draft to need only minor changes before publishing, rather than substantial revision. Authors also prefer to hold onto their draft documents internally rather than release them to the scrutiny of others outside the department. Sometimes authors fail to see any need for, or benefit in, allowing those outside the development team to conduct substantial review, especially early in development. Companies are still working to configure allegiances to line functions with those to cross-functional teams; for example, those companies that seek to empower cross-functional teams must convince chemists that regulatory specialists or business and marketing specialists have valuable contributions to make during review of the chemistry reports.

The complex work environment also tends to delay delivery of document drafts for review. Development operations are busy places, and in recent years, companies have pressured teams to run more studies concurrently and to squeeze time out of development cycles. The result is that drafting a report may not claim sufficient urgency in the face of other work. Implicit negotiation and compromise lead to drafts being delivered later than planned and review time being compressed. In some settings, drafts and final documents are routinely behind schedule.

For authors and teams, it is tempting and sometimes advisable to delay writing up studies until the larger filing strategy becomes clear and especially to avoid committing in writing to positions on issues, statements of conclusion, or discussion of implications. Sometimes, the filing strategy changes if problems of drug safety, efficacy, or marketability emerge. Once a report is signed off in its final "green corner" version, however, it cannot be changed, so it is tempting to delay finishing a report.

Countering this tendency to delay write-up is the expectation on the part of health authorities and some company managers that studies be written up quickly following the close of data gathering—finalizing the study signals efficiency and reassures health authorities that the company is not delaying publication to manipulate the conclusions. Companies are increasingly likely to create procedures that encourage incomplete reports to be written as early as possible in a

form ready to receive the data as it is unblinded (a shell report or prototype). More and more pharmaceutical companies consider an easily measured index of productivity to be a short time from close of data gathering (last patient, last observation) to sign off on the final report.

In pharmaceutical companies, as in other engineering organizations, late delivery prevents writers from using a more efficient, process-oriented approach to document development. Shwom and Hirsch (1994), writing from within other kinds of engineering organizations, noted the problems caused by late delivery of presumably finished drafts. These authors explained that the whole notion of *drafting*, viewed so positively by writing teachers and practitioners, is typically seen as inefficient by managers in engineering organizations. I have seen this attitude in the pharmaceutical industry as well.

Many factors contribute to an environment where late delivery of drafts or finished reports may be the norm. The consequences for effective document development, based on timely reviews, is thus complicated by the pressures that delay delivery of drafts.

Conflicting Purposes of Review

Although the obvious and primary purpose of review is to improve documents, many other sorts of secondary purposes, or subpurposes, are enacted via review practice. These subpurposes, especially when they are functioning at cross-purposes, tend to influence review practice, making it a charged and difficult activity.

Review practice actually accomplishes a number of document and organizational purposes. Many organizations use review, though not always explicitly or intentionally, to determine consensus on arguments, interpretations, and issues (i.e., the official company position). Every review I have witnessed raises arguments about the science, the data, the trial design, or the statistical interpretation. These are obviously important activities that coincide with, and are often occasioned by, the review meeting. Often, only two or three people are involved in the debate while others sit quietly. Such discussions may contribute to the feeling that obtaining closure on review activities is difficult and that the same issues are repeatedly discussed without resolution.

Review also serves to establish consistency across sections of the filing. Parts of any one section may be parceled out to several authors: One chemist might contribute content on drug identification and

purity whereas another reports the stability data, and a third contributes the statistical plan and analysis. Ideally, review helps bring consistency to the various ways these contributors conceptualize and write their sections so that all sections align with the filing strategy. Before publishing, review (or editing) also should establish consistency of style and terminology, accuracy of data and transcription fidelity, application of format and style tags, and accuracy of citations and cross-referencing. With large filings and many authors, however, reviews are hard-pressed to attain the desired consistency across sections.

Review must accomplish other purposes as well. Scheduled review attempts to impose deadlines and keep work on track. Until a review meeting is scheduled, getting a response to a document is often difficult. Sometimes, the meeting is what actually forces people to look at the document and make decisions. Review schedules are thus used to keep work moving and to get certain people to examine the document content.

During review, various political and resource issues are often enacted among teams, managers, and various line functions. Decisions made during reviews of study protocols or reports often have a direct influence on the flow of resources. Departments sometimes use reviews to gain leverage for conducting certain studies using approaches that play to their technical or scientific strengths. If more data are needed or additional data displays are demanded, someone has to allocate people and pay for the added work. Often, companies work through vendors (contract research organizations), and so decisions reached during review may mean renegotiating contracts for work. Development teams work within tight budgets, and these budgets influence and are shaped by decisions made during document review.

Review, in both pharmaceutical and other work contexts, exposes the work of individuals to others, including managers. Review often involves fault finding, with challenges to the work accomplished by other individuals or departments. As noted by several researchers, review offers the opportunity to evaluate employees' performance (Couture & Rymer, 1993) and to discipline workers (Henry, 2000, p. 81). Review is thus complicated by sometimes setting in conflict individual or team evaluation with document improvement. Drug companies have placed heavy emphasis on empowered development teams with flatter organizational hierarchies; in such social configura-

tions, however, the team's collaborative spirit sometimes conflicts with its willingness to be critical of the work of its members.

Review is also used to mentor the growth of new workers as they come to understand the organization and how it works (MacKinnon, 1993). Taking a positive view of this socializing function of review, Katz (1998) cited Lave and Wenger (1990), suggesting that review can serve as a form of "legitimate peripheral participation," an opportunity for newcomers to engage in serious and valuable work within a scaffolded, or structured, situation (p. 8). Many managers in pharmaceutical environments discuss review as a mentoring opportunity—as an important opportunity to transfer knowledge or wisdom.

Sometimes the explicit function of review is to train workers. Katz's (1998) subjects reported that one important purpose of review was to develop writers in the organization whose writing would demand less review effort because they would be able to write more efficiently (p. 32). Managers hope that if they spend review time with writers, these writers will internalize efficient ways of thinking and writing and thus require less review time.

Review thus serves many purposes. As consultants, our efforts to train people in effective and consistent review practices are in part an attempt to help the organization align its practices so that authors think about document quality in the same way that their reviewers do. If authors and reviewers are aware of the various purposes of review, then they can work together, rather than at cross-purposes, to develop effective documents and work practices.

Use of Habitual but Inefficient Patterns of Review

Too often, review practices are not differentiated according to the stage of document development but devolve into habitual and inefficient patterns. Speaking from his position as a document manager at Roche, a large pharmaceutical company, Hager (personal communication, August 9, 2002) noted that insufficient attention is given to establishing clear purposes and setting clear expectations at each phase of the review process (see also Shwom & Hirsch, 1994). In my experience, drafts tend to be routed simultaneously to many individuals—as many as 60 at a time. People with different jobs and organizational statuses might all be reviewing the same draft for whatever they happen to notice (e.g., accuracy, compliance, consistency, format, issue management, data interpretation, marketing implications, or

support for the intended drug label). The result is that too many people spend too much time reviewing drafts concurrently at all levels of detail. Review becomes highly routine, with reviewers selected for a variety of political or historical reasons—or simply because they always are on the list. The distribution list tends to expand rather than contract.

Many reviewers work in set ways: moving down through the file, marking whatever surfaces to attention, and working in isolation from other reviewers. As van der Geest and van Gemert noted (1997), "*The review is generally informal*. Rather than using formal tests and instruments, reviewers just read the draft and respond at the moment and in the form they or the writer(s) think is appropriate" (p. 434). The author tends to be at the hub, collecting comments from everyone and attempting to integrate them into the text. Some reviews are followed by face-to-face roundtable reviews, in which teams move through the documents, debate issues, and agree on changes. Often, these meetings themselves follow a routine of moving down through a document in a process that results in long, unstructured meetings, with editorial comments or terminological disagreements interspersed with arguments about development history and filing strategy. At these face-to-face reviews, small groups or pairs of reviewers frequently engage in scientific debate, and it is difficult to maintain a focus on document improvement. Because participant lists change, discussion frequently turns to issues that were presumably resolved at prior meetings.

Review is a difficult analytic activity, but it is conducted through habitual patterns of practice. People are not typically trained in review practices and often do not have disciplined ways of articulating what goes on in a productive review. Many reviewers can pick out a few isolated problems, inconsistencies, or editorial lapses, but many fewer can see what is written and describe ways to achieve substantial improvement in terms that the author understands, accepts, and can act on. The rare, truly talented reviewer can understand the multiple purposes of a document, assess the broad fit to audience and situation, and imagine ways that complex arguments and data can be restructured to serve the governing filing strategy. Accomplished reviewers describe this level of attention to a report as "finding the storyline," or "finding the thread: seeing how the objectives line up with the results and conclusions," or "seeing the forest for the trees."

TOWARD EFFECTIVE REVIEW PRACTICES

To improve review practice, organizations must break the frame that determines typical practice and reorganize reviews around a new set of practices. This section presents several key recommendations to encourage efficient and productive review practices within organizations:

- Work to a project plan for document development.
- Use staged reviews.
- Structure the review session itself.
- Improve the quality of review commentary.
- Exploit electronic tools.

None is easy to implement, and all involve changes that can run counter to organizational practice, with systemic implications. Some of these changes can be initiated by an author or team of authors, but others would depend on project team leaders, review session coordinators, or others with leadership roles in document development.[1]

Work to a Project Plan for Document Development

This first recommendation is structural. It is important to align project management practices in general to encourage good review practice. Document development should be governed by document management plans and standard operating procedures. Review is not an isolated event but part of a larger system of work practice. Thus, writing activity within an organization should be scheduled and accounted for in terms of resources, time, and money. Too often, writing and review activities are treated as something the reviewer must work into the schedule as time permits, when not pressured by other work activities. As Hager noted (personal communication, August 9, 2002), drug development teams "too often squeeze in reviews and underestimate the amount of time effective reviews require in preparation, execution, and follow-up."

Especially in immature organizations, writing is frequently treated as an unplanned and uncosted activity (Hackos, 1994). Hackos was particularly good at spelling out what should be in a document development plan, and she was quite explicit about how various writing

activities can be planned, timed, and costed. She provided a model for rationalizing work activity so that an organization can be benchmarked at a given stage of maturity in its document development activities. With such a benchmark, improvements on practice over time can be tracked.

The process of creating a document management plan, including the planning time spent with involved participants, can start to change expectations with regard to review. A document management plan can work backward from the filing deadline (allocating time for review, revision, sign-off, and publishing) and thereby allow for drafts to be delivered in timely fashion. The plan can identify critical path activities, contingencies, and dependencies, with perhaps both aggressive and realistic deadlines, giving authors and teams a sense of control and preventing slipped deadlines as routine practice.

Hackos (1994) acknowledged that document development appears to have high costs when a publishing group identifies all the time, personnel, and resources involved in producing technical documentation. Review practices alone look expensive when the involved time of all participants is considered. But figuring the time and resource costs of document development is a positive step toward making principled decisions about who should be involved at what times during review cycles. A cost accounting allows a company to identify ways to streamline activities or gain more value from tasks within activities. Inefficiencies of document cycling can also be identified and rework reduced.

Working from a plan attempts to head off the snowball effects of delivering drafts at a late stage, when documents pile up in front of the filing deadline and when effective review is all but impossible. The plan starts with the recognition that a major outcome of development science is the delivery of the filing dossier. The plan positions writing and review as essential components of development work—part of the work product—to be conducted and delivered in parallel with scientific development. Review periods can be stipulated and reviewers identified according to their functions during each review. Individual reviewers, chosen for certain forms of expertise, can be assigned specific tasks during review.

Where prudent, the document management plan can identify those documents that should be held as drafts, pending finalization when the filing strategy becomes clear. Documents with clear conclusions and implications can be finalized as soon as feasible. If project plans are already in place, but documents are not delivered on time,

then the manager needs to look to the structure of rewards and performance evaluation, to the resourcing of work, and to the various tacit messages the organization members send to each other about deadlines for various sorts of work. Having a plan in place does not guarantee that teams will adhere to the plan. Not having a plan in place, however, does guarantee that drafts will not attain the high quality that follows from efficient and timely review practices.

Use Staged Reviews

Development of a document management plan encourages enactment of this second recommendation—to organize reviews around the particular stages of document development. Review should not be practiced as a one-size-fits-all activity. A staged review explicitly arranges different kinds of reviews depending on the stage of document development. Shwom and Hirsch (1994) provided a useful pragmatic model of staged reviews, in which authors explicitly take control of the process and define drafts as preliminary, review, or near final (p. 4). They argued that the linear thinking that perceives all drafts as near-final documents needs to be replaced with a more pragmatic model, one in which authors advance drafts at various stages that clearly need differing sorts of attention. In their model, the organization intentionally devotes differential attention to document review depending on the document's stage of development.

Becoming intentional encourages the organization to look for situations in which one purpose for review conflicts in subtle ways with other purposes. For example, authors may be reluctant to release early drafts, fearing that having others look at half-formed documents, sketchy arguments, and incomplete data will reflect adversely on their job performance. If an organization does not have an established practice that stipulates review of an early prototype (i.e., a "thinking" or "strategy" draft), then the organization should establish new sets of expectations with convincing rationales through formal standard operating procedures (SOPs) or guidances for work practice. Kleinman (1999) noted that

> standardization of the drafting-review-revision process will result in a faster and more efficient delivery process for a submission-ready CMC [Chemistry, Manufacturing, Controls] section. This can be accomplished by establishing regulatory SOPs that govern style and terminology conventions, as well as those that describe procedures to follow

> in drafting, circulating for review, revising and approving submissions. (p. 34)

The governing SOPs can stipulate that early, high-level prototypes be reviewed by key individuals who will eventually need to endorse the report on the basis of filing strategy, support for the intended label, main messages delivered, and handling of tricky issues. Stipulating such early, strategic review by key players then forces authors who want to hang onto their texts to release them to peers or managers. Such practice can become routine, so authors expect to have their early drafts or prototypes subject to strategic review. Early reviews benefit the author by setting the document on the right course, in alignment with broader organizational goals. The aim is to head off the need for late-stage reworking of a document that has been developed out of alignment.

The organization must establish a zone of comfort within which authors can release early drafts to teams for "exploratory" review, as characterized by van der Geest and van Gemert (1997):

> Often when the province officials saw their policy or its effects in writing or when the engineers consulted them about text passages that they had trouble formulating, the loose ends or the side effects of the regulations became clear. The drafts were discussed extensively among the officials, and then an approved position was reported to the engineers, which could be reproduced in the next draft of the report. For the reviewers, the main function of the review became clarifying the project and its consequences. This exploratory function of review might be especially present when the writing has just started and the topic of the text is still under construction. (pp. 438-439)

The task of the drug development team parallels that of the policy makers and engineers in van der Geest and van Gemert's (1997) study: In both settings, groups must develop consensus on interpretive positions based on complicated sets of information. Van der Geest and van Gemert argued that the exploratory functions of review are underappreciated and underexploited. In drug development, as in other contexts, the organization needs to clarify for its members why it values the exploratory purposes of review.

A consensus-shaping, exploratory review works in part because writing positions thoughts within a visual, shared space (Shrage, 1995) in which team members can examine, debate, consider alternatives, and derive a satisfactory position on some issue. Writing can

help realize Shrage's sense of shared minds. To leverage this powerful function of review, however, the organization needs to distinguish various stages and purposes of review.

Table 1 maps out review questions according to stages of document development. Such a table reinforces staged review, the practice of asking different sets of questions about a document at different stages of development. Early-stage reviews are conceptual, driven by formulating a strategy and getting the big picture in place. Later reviews assume that the strategic alignment is in place, built into the document from the earliest drafts, so they can focus on compliance, completeness, or emphasis. Reviews gradually come to focus on precision, accuracy of detail, and final presentation.

Shwom and Hirsch (1994) proposed similar staged-review heuristics (pp. 5-6). An important outcome of staged reviews is less rework. Authors get buy-in on the document strategy—high-level content, story line, delivery of messages, treatment of issues—before they spend a lot of time drafting the full text. A second advantage is that the important debates about interpreting the science, reading the data, and wording key findings and conclusions are staged as important review activities. If early reviewers devote specific time to arriving at scientific consensus (and then recording those agreements in a tracking system), then subsequent reviews can take certain scientific issues as settled, with everyone knowing the agreed-upon approach.

Implementing staged reviews can work in harmony with the document plan. Draft zero, with attendant conceptual and exploratory reviews, can be clearly labeled as such. Reviewers can be instructed to comment as appropriate given the stage and to refrain from making comments inappropriate to the stage (such as grammatical fine-tuning, editing, or formatting suggestions). Review becomes a more intentional and discriminating activity, governed not by one-size-fits-all review practice but by the purpose of the review according to the draft's stage of development.

Structure the Review Session Itself

Working to a plan and staging the review bring elements of formal structure to a typically informal activity. Reviews can also profitably be structured at the level of the review session itself. Rather than simply routing a document and asking for review comments by a given date, the author can see the review as an event to be managed. The

TABLE 1
Review Activities Appropriate to Various Stages of Document Development

Prototype	*Early Draft*	*Advanced Draft*	*Final Document*
Check study design, interpretation, supporting data, and rationales.	Make sure the right content is in the right places.	Check documents for accuracy of information and scientific content.	Gain quality assurance for regulatory and production compliance.
Define the main messages the document must deliver.	Check key scientific explanations and arguments (e.g., is there a clear story told about the data?).	Check whether the document goes beyond stating results descriptively to making conclusions about the significance of the findings.	Check beginning of main sections and subsections for strong starts and clear positioning of major messages.
Identify the issues associated with development and articulate responses.	Ensure important issues are directly and prominently addressed.	Check the document's structure for emphasis and persuasion on all issues.	Confirm that the document addresses fully the most troublesome issues.
Debate data-driven arguments. Line up data with issues.	Make sure the data is strong enough to support the claims.	Make sure the data warrant the conclusions.	Ensure all issues are fully addressed with data-driven arguments.
Ensure appropriate research and development processes are being followed.	Compare scientific development to regulatory requirements.	Ask what challenges are likely to be posed by regulatory reviewers (e.g., what are the deficiencies?).	Check for full regulatory compliance and complete research data.

Debate issues related to the product label, marketing, and production.	Establish points of reference and support between document, label, and clinical context.	Cross-check documents and product label for full and logical support.	Review the label and the document for exact agreement, consistent language, and label support.
Decide on the most important data that should be presented in visual displays.	Check that each visual delivers a clear message or tells a compelling story.	Check that visuals are well designed, well labeled, self-contained, and supported by the surrounding text.	Check that visuals are accurate, consistently formatted, legible, fully labeled, and well placed on the pages.
Decide what template and style sheet apply, what the page design looks like, how references and figures are presented.	Ask if the document's structure and design meet the reader's needs. Assess the document design for usefulness.	Fine-tune the language to be clear, correct, and forceful. Edit for sentence clarity and correctness.	Do a final edit for accuracy, cross-references, and consistency.

SOURCE: Training materials, Writing Review Workshop, McCulley/Cuppan LLC.

author can work together with the project leader or others to frame the review in the following ways:

- Define the document purpose for reviewers.
- Provide additional materials, if necessary.
- Choose the right review team and define individual roles.
- Provide specific instructions for reviewers.
- Bring structure to the roundtable review through advance preparation and meeting management.

A review can be managed first by identifying its purpose and framing the review. The review request can offer constraining comments on how the reviewers should best use their time and talents. The author can make clear the development stage of the draft—acknowledging sections that are not fully developed or pointing to places where the arguments need attention or the strategy needs to be debated. Authors generally know which parts of their documents are strong and need no attention, just as they know the places where arguments are weak or unsettled, data are equivocal, or interpretation is shaky. Because review is an imposition on others' time and energy, authors should do all they can to frame the task for reviewers. Authors can also usefully advise reviewers about the amount of time they should expect to spend on the review.

Authors should consider what reviewers need to know to perform the review effectively. Sometimes, as when documents are being developed in conformance with new guidances, reviewers can usefully be pointed toward that new guidance so they work from the same assumptions as the author about document requirements. When a document has a history of correspondence and understandings with a health authority, reviewers benefit from knowing that history or seeing the letters that outline the issue.

Authors (or review managers) should also have some latitude in choosing whom they ask to review based on the reviewer's expertise, experience, status, or viewpoint. Typical reviewer distribution lists include individuals who are known to contribute little of substance and omit people with strong reviewing credentials. The best distribution list requests reviews from the right people at the right time. The author can structure the review by tailoring the activity to the expertise of the individual reviewers, calling their attention to particular concerns. Hager (personal communication, August 9, 2002) practiced

such tailoring in his management of document development at F. Hoffmann-La Roche:

> I've also found that it is helpful to have a revolving list of reviewers from whom a doc team can pull to have the right skill sets in reviewing a doc at different phases of the review process—e.g., having project team leaders and regulatory members (and editors) read a later draft after the scientific experts have hashed out the details.

Selecting reviewers (and gaining the authority to select reviewers) is not simple, in part because review is an exercise of power reflecting organizational politics and factions.

Reviewers can also include people who are not on the project team as a way to introduce an unbiased perspective. This perspective is important because team members too frequently become personally committed to a project and its anticipated outcomes—their personal and team sense of success is invested in the development project. Teams also sometimes become committed to a single strategy, pinning their hopes on certain outcomes in the data, and they may fail to develop fall-back plans. An external reviewer can give the team a reality check.

Authors can structure the review by providing tailored requests for reviewers, asking them to attend to specific issues, as in this hypothetical example:

> Mary, this section presents the justification for our specifications and limits. We were challenged repeatedly on our last filing to tighten our limits, and the French reviewers did not accept our arguments for loose limits on degradation products in supplies of active materials and intermediates. They want us to tighten the supply chain, too.
>
> I have tried to be quite explicit with my justifications in this report. Could you review the proposed specifications and limits, and then give me suggestions for strengthening my arguments for the proposed specs? If you put yourself in the reviewer's position, would you accept the proposed limits? Be tough on me.

Here the author anticipates who will do the review and what specific contributions that reviewer can make to the core and contested arguments. The author sets the stage by framing the review. Thus, the author determines who has the needed expertise to review a particular draft and then tailors the instructions for the review request rather than routinely routing the draft to a distribution list with the simple request to review the document.

Many companies follow up the online review of documents as attachments with a face-to-face roundtable review. The face-to-face roundtable review can also be formally structured. Perhaps the least efficient structure is most commonly followed: Reviewers assemble with their comments and march through the document page by page, identifying changes or raising questions. One study director recounted to me a series of four 9-hour review meetings concerning one pivotal study report (a large, complicated study of drug safety and efficacy that serves as the linchpin for approval). Even with four all-day review meetings, the team had not yet reached the findings and conclusions but had gotten bogged down in the historical sections, those sections of the report that are dictated by the study protocol. Nobody knew other people's comments until they heard them at the roundtable, and some reviewers did not appear to review the document closely until they actually sat down in the group setting. Because the document was quite large and complex, changes that had been made to some sections had not been noticed by some reviewers, leading to confusion during the meeting and the need to backtrack to sections that were presumed stable.

An alternative structure for a review consolidates and circulates comments ahead of time, grouping issues by order of importance. Reviewers receive an issue list in advance of the meeting, thereby focusing reviewer attention on the most important issues. Small, uncontested changes or consistency corrections that are easily addressed can be marked as such, eliminating oral commentary at the review session. Standard rules of discussion dictate that a recorder keeps a record of decisions (and rationales where useful) and a moderator runs the review. The moderator can ask that certain discussions be tabled and resolved by key individuals outside the review meeting. Formally structuring the roundtable review in such ways can ensure that the most important issues are addressed in a timely manner.

Improve the Quality of Review Commentary

Reviewers themselves can improve reviews by becoming more systematic in their behavior. Writing review comments is an art in itself. Few people have learned to ask both global and local questions, to offer both praise and critical suggestions, and to ask questions that reflect their experience of reading the text rather than just suggest corrections. Training reviewers to review perceptively—to ask appropri-

ate questions at appropriate review stages, to write intelligible and helpful comments, and to avoid editing when they should be reviewing—would save time and improve comment quality.

By centering reviews on a set of heuristic questions, such as those I suggested for staged reviews, reviewers can produce higher-level, and more strategic, review comments. Instead of just starting at the beginning of a document and marking whatever catches their attention, reviewers can be trained to ask certain questions based on a shared set of quality standards:

- Does the document meets its overall purpose? Does it support the filing strategy and target label?
- Does the document address the most important issues with full responses?
- Is the most important information in emphatic positions?
- Can a reader navigate easily and find answers to questions?
- Can data displays be understood on their own, and do they make a clear point?

Each question challenges the reviewer to take a different global look at the document and produce valuable suggestions for revision. Asking such questions intentionally requires the reviewer to make multiple passes through the document with different questions in mind. This approach breaks reviewers' normal pattern of review—reading page by page—and leads them to pay more global, strategic attention to the document.

Reviewers can also be trained to write useful commentary. Reviewers frequently spend time writing comments that authors do not understand and cannot act on. Sometimes the fault is with a reviewer's idiosyncratic shorthand style of annotation, such as writing a question mark in the margin, writing the word *revise* in the margin, writing illegibly, or writing a comment that is difficult to respond to (one regulatory manager's favorite was a suggestion from a reviewer to "spice it up"). In contrast, the best comments identify a problem, diagnose why it is a problem, and offer a solution. Here is an example that represents the sort of comment that can help an author:

> There is no mention in the report section nor in the SmPC [Summary of Product Characteristics] of the statistically significant delay in time-to-PSA progression. Such information should surface in the SmPC to help differentiate the drug from competing therapies, and such a statement will need to be supported by clear messages and data within the study

> report. Let's present a clear, well-positioned message on this difference between treatment and control groups.

The reviewer is connecting the text under review to the sponsor's need for product differentiation in the market, as reflected in the Summary of Product Characteristics. Because all currently marketed drugs for prostate enlargement treat symptoms rather than the underlying disease, the reviewer suggests that "time-to-PSA progression" (prostate-specific antigen) is critical to the argument and should be included (because an increase in PSA values would indicate higher risk tumors). Here the reviewer identifies missing content and helps the author connect the need for this content to the eventual marketing of the drug. Although the comment uses shared language, including specialized acronyms, the comment is written in fully formed sentences. The reviewer does not actually craft the missing message but allows the author to remain in control of the draft.

Another strategy to encourage global commentary is to create a review form that explicitly asks for holistic comments. When all reviewer comments are marginalia, they are more likely to be local and specific to individual passages in the document. Reviewers need to be encouraged (and shown how) to move to the global, holistic level of assessment and offer comments that will improve the overall quality of the document.

Greater efficiency can also be brought to review processes by separating reviewing and editing functions. Some companies clearly benefit from hiring a copy editor instead of allowing various managers to spend their time correcting the many varieties of English that characterize a multinational workplace. One medical communications group I work with explicitly forbids reviewers to make editorial comments on wording, style, grammar, or punctuation. Reviewers are trained to focus on high-level concerns. Other companies profitably designate a reviewer to be responsible for copyediting—again, timed to deliver editing at the right time. (Sometimes, editing even an early draft is a good idea, so reviewers will not be distracted.) Still, reviewers have difficulty resisting the urge to edit and concentrating on important scientific and development issues. Of course, reviewers will not ignore grammatical or mechanical errors if they believe the errors might remain uncorrected in the published report. Companies must find a way to relegate responsibility for linguistic and stylistic concerns (much of which involves choices between options) to one authoritative editor.

Improving the quality of review commentary is not a simple matter. Review remains a difficult analytic act, one requiring concentration, an understanding of how texts work, and an ability to phrase suggestions in ways that can be understood and acted on. Assessing the overall pragmatics of a document is difficult when texts are long and complex, loaded with data, and shaped by complex histories. Making comments such as "improve the logic" or "there is a problem with organization" is much easier for a reviewer than diagnosing the problem, stating why it is a problem, and articulating ways to address the problem.

Exploit Electronic Tools

The tools chosen to implement review practices have both practical and substantial consequences for how those practices play out. Tools that support review practices can favor either serial or concurrent review, and the mechanisms for comment can either restrict or give reviewers rich options. Electronic review tools can either make review a private activity, centered on the author, or open the review process as a public, collaborative activity, centered on the team.

In many organizations, review occurs in concurrent format, with the author sending an attached file to multiple reviewers simultaneously. In such cases, the text comes back to authors as an attachment with some combination of comments, revision marks, edits, and perhaps a cover note. Such an approach makes review a communicative act between two people—the author and the reviewer—thereby isolating individual reviewers from each other. The author remains in the middle of the process, the only person who knows what others are saying and whether the advice is contradictory or reinforcing. Intellectually and politically, too much control is left to the author to make private decisions about what changes to implement.

There are also negative practical consequences to review by distributed attachments. Concurrent review by attachments spawns many versions of a text in many folders—in Windows temp folders as well as in e-mail folders and in document directories on both local and network drives—filling substantial disk space with huge files and often generating confusion about versions and file names. As texts come back to the author, the author must keep track of multiple versions, consolidate comments, and reconcile issues in the advancing draft.

Some file management systems support serial review. Documentum, for example, will allow an author to route a file to a set of reviewers in turn, automatically sending an e-mail to alert reviewers that a text is coming and later remind them of the due date for passing the text along. Missing the due date may mean missing the right to comment, as the text is automatically forwarded to the next reviewer. Comments from different reviewers can be consolidated by the author or viewed individually. Such a process does not necessarily make reviews more public—the author may still be the only one who knows what individual reviewers said. But the software can help keep reviews moving and help manage file versions.

Another approach is to place the draft on a shared network directory; with this approach, instead of pushing the draft to the reviewers, reviewers are pulled to the server to open the file and comment on it. Lotus Notes works this way, allowing only one person at a time to check out the source file. The system shows who checked out the document, when, and when it was checked back in. Notes keeps track of versions and updates, and it allows reviewers to see comments that earlier reviewers have made on the draft.

Reviewers' ability to read others' comments can be quite important to the review process: Reviewers can reinforce each other's comments, or they can disagree and present alternative approaches. The fact that an author frequently has to reconcile alternative suggestions is brought to the fore, forcing debate about various exploratory positions. Putting reviewers' comments into a shared space makes review less of an individual and more of a team process, whereby people of differing expertise and status come to agree on what positions a text should take (Bernhardt, 1995). The tools and work practices in a shared-file approach can promote exploratory discussion within the organization and help to leverage and consolidate what people know. The discussion takes place in a conversation space above the text—talking over the document.

Furthermore, making review comments accessible to other reviewers means that those who provide valuable reviews are recognized by those who do not. The reviewer who exposes troublesome issues, makes accurate problem diagnoses, and suggests excellent solutions is contrasted publicly with those who make random grammar edits and offer little substance to the review process. The good reviewers serve as models of productive review behavior, so the organization learns from its own members. Managers can reinforce and reward exemplary review behavior.

Various software providers have incorporated enhanced commenting tools. Microsoft Word provides a rich set of tools, with comments appearing in marginal or pop-up bubbles or in a separate frame at the bottom of the screen. Reviewers can make corrections or additions directly in the text, which the author can then accept or reject. Different reviewers are assigned different colors, and Word keeps track of who makes what suggestions when. One frequently noted drawback is that the text surface can become quite complicated once several reviewers have worked on it. Still, many people prefer this powerful tool.

Software from Workshare called Synergy (http://www.workshare.com/) is specifically written to support collaborative development of Word documents by providing tools that consolidate and display comments and suggested changes made by a team of reviewers. Reviewers can see all previous review commentary while they add their own. In a separate frame alongside the document window, the author can see comments listed by reviewer and date. The author can see in a third frame the document as it looks with the suggested changes. Only the author can accept or reject changes, which are then incorporated into the master document. Synergy addresses the difficulties of a text that is too cluttered by surface commentary and change marks.

Adobe Acrobat also has an extended set of comment tools, offering electronic sticky notes that can be closed or opened as well as text markup and highlighting tools. Acrobat allows comments to be printed separately from the text (as does Word), and authors in both systems can combine comment files or versions of files from different reviewers into one master file. A limitation of Acrobat is that it does not allow direct text editing—it supports only commenting on or highlighting areas in the text. Some authors have difficulty working with an Acrobat .pdf file that has been heavily annotated by multiple reviewers. Others do not like writing comments inside sticky notes.

A key virtue of all such markup utilities is that the underlying text is unchanged—all the comments, sticky notes, highlighting, changes, and rearrangements are done on the surface of the text file. They can be rejected, undone, or accepted by the author, so authors retain control over the text itself. The software companies generally recognize the advantages of collaborative document development tools, and recent version upgrades have featured an ever-expanded and more flexible set of tools, including tools for concurrent online review.

Some research suggests that different commenting systems trigger different kinds of review behavior—that the tool shapes the activity (Wojahn, Neuwirth, & Bullock, 1998). Any new tool, however, even if well designed, faces resistance. Some reviewers or editors are more comfortable or feel more productive using one sort of tool or another (Dayton, 1998). Many editors (e.g., those who do grammatical, stylistic, format, or quality-audit editing) insist on working on paper as opposed to computer screens. Some work seems to demand, or at least strongly favor, access to paper documents (Sellen & Harper, 2002); for example, the physicality of paper supports working across multiple texts, making comparisons, or bookmarking a series of related pages. Tools do influence work practice, and organizations that wish to move to best review practices need to consider what their goals for review are and what tools will help them realize those goals. They then need to work to change existing work practices and help authors and reviewers become comfortable with new tools (and accompanying new practices) for review.

CREATING CHANGE IN ORGANIZATIONAL PRACTICES

Like other sorts of organizational change, enhancements to review practices are likely to be realized slowly and only with persistent attention. However, given the time and energy that organizations such as pharmaceutical companies currently invest in review practices, and given the levels of frustration that reviewers experience, it is worth improving current practices.

Suppose an organization wants to pursue best practice with regard to reviewing documents. What should it do to begin to change old, faulty habits of review into newer, more efficient practices? Here are suggestions for implementing change:

Identify change leaders. A change initiative must have the support of people in positions of perceived leadership and authority. It must also have some kind of coalition behind it that reaches across department lines. Some companies have individuals with designated roles in process improvement, and these people tend to have wide and systematic knowledge of what changes are under way and how to successfully implement a new initiative. Lining up managerial support, or even support at director level, is not difficult because there is such

widespread frustration and because review cycles tend to move up the management hierarchy. Opinion leaders within the organization need to stress the critical importance of effective documentation to a successful filing, and they need to stress the importance of review as a step toward effective documentation.

Look realistically at the current practices, current success of document development plans, and adequacy of the time allocated to document development. Review is a complex activity, with many events impinging on it. Often, organizations have already developed document plans intended to rationalize processes such as document delivery. If an organization has plans in place and still experiences a high level of frustration, slipped deadlines, and delayed document delivery, it should collect data to understand the current situation and figure out why document development and review practices in particular are not working as they should. Sometimes reviewers know what they should do but are unable to approach reviews in a consistent and efficient way because of competing events within a highly pressured work environment. Attempts to change review practices are not isolated from other change initiatives. For example, the trend toward subcontracting research studies to contract research organizations has significant effects on review practices.

Update templates and SOPs to reflect best practices. The supporting materials for document development should be well aligned with the goals for the change initiative. Too frequently, if document development SOPs exist, they are merely stipulative, identifying reviewers and formal rounds of review that must be accomplished. SOPs can be written in ways that offer rationales for processes, identify the value in following certain procedures, and give power to certain groups to manage critical processes and make important decisions. SOPs can be a tool to spread understanding of good document development practice, to define leadership roles for authors and teams, and to convince others of the importance of good review practice. SOPs must, of course, be harmonized to work across global sites, across codevelopment partnerships, and across subcontractors, who are all likely to have their own SOPs.

Train in the use of new practices and tools. Training can cover strategic review as a part of document development, reviewing by quality standards, writing effective review commentary, and using review

tools. To change practice, people need to understand concepts, contrast older routines with preferred routines, and develop a shared vocabulary (e.g., knowing what is meant by a *story line*, if that is a local construct, or distinguishing *reviewing* from *editing*). Training can also help people acquire and apply shared standards, so they consistently review documents with an eye toward what is most critical for that document to achieve its purpose. Words that indicate standards—such as *style*, or *organization*, or *logic*—can have diffuse, overlapping, or contradictory meanings within most organizations.

Work from intact teams on real projects. Implementing new practices through team-based facilitation is excellent follow-up to training. A development team can pilot new ways of working. A team leader who understands good review practice can help implement best practices. Good practice can spread in the organization as experienced team members are assigned to new projects. Such a spreading activation model takes advantage of the fact that in today's matrix organizations, the frequent reconfigurations of personnel to project teams provide a route for spreading best practice. Working with intact teams is in many ways preferable to pullout training, in which individuals from various departments sign up for a self-contained training class. Team-based training allows for implementation of best practices in the context of the team's project. Immediate application of recommended review practices allows for testing ideas, which is often important to adult learners.

Maintain some flexibility. Different teams may elect to customize their work practices to suit their own mix of personalities. Team leaders and authors need some authority to control the process, to select reviewers, and to determine the best stages for review. Sometimes, the best practice is to share goals or desired outcomes and allow the teams to decide on the best path toward those goals.

Provide standards of quality and models of products and practices. For authors and teams to create high-quality documents and to engage in best review practices, they need to know what the target looks like. Therefore, organizations need to define what they are looking for in terms of document quality (What does a good report look like? What are our standards?). Organizations should make clear what they expect to obtain from reviews (What does a good review look like? Who

delivers the best reviews in timely fashion? How do they do it?). People within organizations know who the productive, helpful, truly innovative reviewers are. The organization should identify people who model such exemplary behavior and intentionally use these individuals as a coaching resource.

Work to quantify benefits. Rational, deliberate, structured work activities may initially appear to take longer and cost more, in part because inefficient, inherited work routines often have hidden costs and unmeasured inefficiencies. People and organizations tend to respond to urgent, immediate events that demand attention at the expense of important, long-term changes that would make a workplace more productive and efficient. Organizations need to build metrics into change initiatives to demonstrate efficiency and improvements. They need to work to document existing processes and change in the desired direction.

CONCLUDING NOTE

If successfully implemented, the recommendations contained in this article can help reduce frustration with review practices and lead to higher quality documents. I have seen these recommendations work in practice: Document development can be managed, reviewers can be trained, reviews can be more systematic, and tools can support best practice.

No one should underestimate the task, however, of changing the ways people work with documents. Patience is required. People build up their habits in writing and collaborative review during a long period. Changing habits is difficult and takes persistence. But in the last analysis, good practice can and should force out bad.

NOTE

1. Particular staffing and team configurations vary from company to company, so it is difficult to cast these recommendations in exact terms of who can or should do what. I finesse the responsible party issue here by casting the recommendations in passive voice or using constructions that do not stipulate human agency. *Authors* might mean an individual author or a team of authors, who frequently work in consultation with a team leader who has responsibility for helping stage a review.

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