

CHAPTER 3

Using Technology to Support Global Drug-Development Teams

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Drug products reach the market by successfully negotiating health authority gatekeepers (the Food and Drug Administration in the United States, other authorities in other countries) and by having well substantiated claims for new or more effective disease treatment. The New Drug Application (NDA) is the major document set that presents the case for approval to authorities. An NDA represents an immense documentation task, made difficult by multiple global markets with corresponding health authorities and regulations, a changing regulatory environment, and intense pressure to deliver drugs in a timely and efficient manner within tight budgets and timelines. Technology holds great promise for global teamwork; indeed, it is only through technology-supported teams that an articulate vision of global drug development can be realized.

In this chapter, my purpose is to discuss document development and associated technologies that support global teamwork, based on my work within the pharma industry. From May 1995 to June 1996, I was on leave from my professorship at New Mexico State University to work as a full-time consultant to the pharmaceutical industry. As Senior Consultant for Scientific Services, Franklin Covey, my task was to work with globally dispersed teams as they developed new drugs for market. I was based in Basel, Switzerland, working primarily with one large pharmaceutical company and its affiliates in France, England, Germany, Japan, and the United States.

The limitation here is that I will be writing from experience in one industry. But much of what I say, I believe, can be cautiously generalized to other research

and development settings. Pharma development is more document intensive than many industries, and it is much more research intensive than many, with vast resources committed to generating a stream of new drug products, which is the only way a large company can be successful. I hope my audience, whom I envision as other students and professors of professional communication, will find value in a description of document development and its attendant technologies within an industry that has not been a subject of our literature.

Those of us who teach professional communication are typically attuned to application: how what we learn in industry settings can be applied to our own classes and curricula. So a second purpose here is both to confirm current practice and to suggest appropriate emphases in the preparation of students for work as either professional communicators or as professionals who communicate.

It is not meaningful to discuss technologies apart from their contexts of use, and so I will begin with discussion of document development in general and the specific nature of our consulting intervention, and then move to a discussion of global technologies that facilitate drug development within the pharma industry.

SETTING A CONTEXT: DOCUMENT DEVELOPMENT IN THE PHARMA INDUSTRY

The pharma development process delivers drugs from the research lab to the market. The process is notoriously long—some twelve years on average from discovery or recognition of a new drug substance to marketing a drug product. The research is risky and costly—many potential drugs are abandoned during research and development, and those that make it to market do so on multi-million dollar development and marketing budgets. The burden of paperwork associated with a project is enormous. A recent final NDA (New Drug Application) submitted to the FDA (Food and Drug Administration) was a dossier of some 600 volumes containing 120,000 pages, and some of the larger NDAs are over 200,000 pages.

Submission of an NDA is a significant milestone, but not the end of development. Presentations to health authorities follow, with both written and oral question/answer sessions; various publications make the research behind the product known to the scientific, medical, and insurance communities; and extensive marketing plans and product literature position the drug product and ensure that it reaches its customers. Our consulting intervention was intended to improve the quality and efficiency of communication surrounding drug development through coaching teams in document processes, encouraging good team communication, and making effective use of supporting technologies.

There are many threats to the smooth movement of a drug product from laboratory through development to market. Most notably, after years of investment in development, clinical trials may fail to provide compelling evidence of the drug's effectiveness, or fail to demonstrate that the clinical benefits outweigh the safety risks associated with the drug. With regard to the NDA itself, pharmaceutical

writers must confront the challenge of producing an immense document, written by many individuals and aimed at readers with widely varying backgrounds and purposes. Currently, NDAs tend to be too much the product of dispersed and private energies. Too frequently, they represent the separate efforts of different research and development groups rather than an integrated dossier—the product of a team that shares a common vision, strategy, tactics, and language.

A rule of thumb says that for drugs that reach the market, the top 100 sellers will generate average eventual revenues of \$1 million per day. The number of days a drug generates such peak sales depends on its patent protection, which, when it expires, allows generic competition. The company registers the compound out of the laboratory so its claim is protected throughout development, and the patent clock begins ticking as soon as the compound is registered. It is, therefore, immensely important to bring a drug to market quickly.

The successful filing of an NDA is threatened by inconsistent claims, poorly coordinated presentation, or confusing organization. If teams can write more quickly and dependably, if dossiers are more coherent and better coordinated, and if evaluation by readers can be made more efficient and more likely to be positive, then the rewards for the pharma company are large.

DRUG DEVELOPMENT TEAM PROCESSES

The pharma industry has moved toward empowered teams that are assembled from across the organization to shepherd a drug through development to filing and beyond. Close collaboration across functional areas allows teams to develop dossiers that present a unified argument for a drug product, characterized by consistent messages, a focus on important issues, and a compelling presentation of the data and supporting rationales for approval. Close collaboration helps ensure smooth transitions from lab, to development, to market.

Franklin Covey has worked with numerous pharma companies and health authorities to identify and measure specific document quality standards for NDAs and to recommend certain ways of working to our clients. Based on the formal evaluation of multiple dossiers from various pharma companies, on long-term client interventions, and on research inside the FDA, Franklin Covey recognizes that high quality NDAs share these criteria at all document levels:

- The dossier is driven by a clear sense of purpose, organized at every level to emphasize strong, consistent messages about the drug. The dossier explicitly presents and argues a position.
- The dossier and its documents place conclusions up front in emphatic positions, with the presentation of data following deductively from prominent interpretive positions.
- The dossier focuses on critical issues, placing them in context and presenting clear responses to the issues. The dossier does not hide or bury issues in the

documents but turns a bright light on them and offers a considered response, with a stated rationale and support.

- The dossier works as a coherent whole, with consistent messages developed and linked across sections and plenty of signposts as to how the dossier is organized.
- The dossier makes good use of its visual dimension, presenting as much information as possible in visually interesting, compelling, and informative ways.
- The dossier is presented in effective and complementary print and electronic versions.

These are high standards and not at all typical of many NDAs. More typical is the dossier that is a mere compilation of reports and data, where the reader struggles to interpret the data and where conclusions are buried deep within documents, shrouded by a cascade of “objective” facts and a homogenous pool of detail. In the typical dossier, messages are missing or inconsistent across documents, readers are expected to develop their own interpretations, and there is no close harmony unifying the various elements. Frequently, the writer succumbs to the temptation to divert attention from troublesome issues of safety, problems with development, or inconsistencies in the data, hoping that if issues are downplayed they might escape attention in the immense documentation of the NDA.

Developing dossiers that meet high quality standards demands new forms of teamwork. It is increasingly typical across the industry to find cross-functional teams forming early in the development process, with representation from all crucial areas of development:

- **the research laboratory:** where new molecular entities are first discovered, isolated, or synthesized and judged to have potential for development,
- **preclinical research:** where new substances are tested for tolerability, safety, and effect, first in animals and then in healthy volunteers,
- **technical development:** where the compound synthesis is refined and scaled up from the grams and kilograms the lab has produced to large-scale manufacturing campaigns involving tons of active ingredients and various formulations of a drug product,
- **clinical research:** where controlled studies of pharmacology, effectiveness, and safety are conducted with increasing numbers of patients in a range of doses to establish eventually through two large, well controlled studies the effectiveness and safety of the drug product and thus justify approval,
- **regulatory:** where the drug product is ushered through the approval process with various health authorities on the basis of documentation, hearings, and site inspections, and

- **business and marketing:** where markets are forecast, pharmaco-economic models developed, launch plans prepared, and the product is taken quickly and effectively to market.

Cross-functional teams represent different discourse communities—people who belong to different, well established communities within the company. These groups represent differing educational backgrounds (pharmacology, statistics, chemistry, physiology, biology, marketing: all highly educated with many PhD or medical degrees represented), they speak different professional languages, and they have different epistemological positionings. Team members know, for instance, that statisticians speak a different language and possess intimate knowledge of highly specialized argumentative conventions, and team members appeal to the statisticians for permission to pursue certain lines of reasoning, to argue from data in warranted ways, and to formulate the strongest legitimate data-driven claims. Team members know, further, that preclinical scientists will only be willing to make cautious extrapolations from animal data to humans, even when it seems to other specialists that the comparisons are logical or compelling. Additionally, teams are likely to represent different cultures and languages. It is not unusual, for example, to find that the chemists are German, the clinical researchers French and American, the regulatory professionals British, and for the team to include Swiss, Japanese, or other nationalities. The team must be globally representative to address the critical issues related to global approval and marketing. So there are many languages and assumptions in play about how language works, what good documents look like, and how arguments should be made.

Which of these differences are most salient in how teams interact? Education and training? Job function or position? Nationality or language group? I cannot say with confidence on the basis of either data or hunch what most influences communication across the boundaries of various discourse communities. We talked frequently among our team of consultants, agreeing that in some situations, cultural membership seemed to be a strong influence, while in other situations, it was obviously a matter of, for example, chemist vs. clinician that seemed to pose the greatest obstacles to communication. We did agree that team members could be encouraged to talk about the boundaries, could learn to understand differences within the team, and could talk and work in ways that tended to get work accomplished efficiently. We recognized there was little need of invoking stereotypes of nationality or personality, and that the team could refuse easy categorizations of their fellow team members to confront, instead, the particular issues and conflicts that inevitably arose within the development process itself.

DOCUMENT DEVELOPMENT PROCESSES

Franklin Covey, in its contracts with various pharma companies, attempts to bring a message-oriented, issue-driven approach to drug documentation

development. The process encourages drug-development teams to meet early in the development process to articulate a shared vision: the team members try to put *in words on paper* what it is they hope to be able to say about the drug product when it enters the market. We asked certain heuristic questions to facilitate this process.

- What *Messages* can the team deliver about the need for the drug, its efficacy, safety, indications, manufacturability, and marketability?
- What *Issues* are likely to confront the product, to hold up its development, cause safety problems, raise costs, delay delivery, or result in a product that is unable to gain a market share?
- What *Responses* does the team propose for addressing the issues?
- What *Support* does the team have or need to gather? How and where will the data, rationales, and arguments be marshaled in support of the application?

The idea is to let the documentation drive the science, so that the wide range of activity done throughout the development process arrives on time at shared milestones and delivers a product that meets a real need and captures a significant and predictable market share.

Within our practice, the work to articulate the issues with the team results in a table of team messages and issues (here represented in Figure 1 with faked data from two areas, the first preclinical and the second technical):

Messages	Issues	Responses	Support
Cell turnover does not translate into histopathological changes in animal or man; observed changes do not signal precancerous condition.	Study NS5713 found colonic proliferation of mucosal cells in the lower intestine.	Condition only seen in one study, where a high calcium diet probably stimulated change. No histopathological changes in 3 months.	Give history of studies developed in clin pharm and tox; FDA agreed to duration of study. Continue monitoring.
The relatively low melting point of the active substance does not cause a problem for shipping, storing, and marketing the drug product.	Active substance melts and agglomerates at 37-40°F.	Active needs temperature controls on shipping and storage. Use hamsters (temperature tags) to insure continuous temperature monitoring from synthesis through production.	Detail and assure cool room temperature handling from milling through synthesis.

Figure 1. Sample Message and Issues Table.

The table serves as a tool for visual thinking, guiding the team through development. The table serves as a focal point for the team as it is revisited regularly, and it provides a common ground for understanding that can bridge various discourse communities. The table fixes development issues, at least temporarily, in a single place where team members can view, debate, refine, and agree on what they hope to be able to say and how they hope to be able to respond to the difficult issues. The table grows with the project, as the team adds new issues or reconfigures the messages in response to the support, or lack of support, provided by incoming data and developments within the market.

From the table constructed by the team grow various documents during development. Scientists meet with regulatory and marketing team members to plan the drug product development process through prototyping. A *document prototype*[®] is an early map of a document, an elaborated outline that aligns messages and issues with various sections of a document.

The key document that is prototyped early on and that drives the development process is the target profile. This document prototype[®] eventually morphs into various forms of product information for prescribers and patients; for example, into the *package insert* in the United States. (The insert is that piece of paper packed into every drug product, meant to guide prescribing physicians and often read by those patients who wish to be well informed.) The package insert constitutes the contract between the drug company and the health authority, governing what can be claimed, what the indications (disease conditions) are for which the drug is usefully prescribed, how effective and safe the drug is, and what dose is appropriate. Every line of the package insert must have specific, referenced support in reported research. By developing proto-forms of this document early in development, our goal is to encourage teams to be document-driven in their science, with the market product reverse-engineered from the goal (what is written in the package insert) to research and development processes intended to justify and support those messages.

Document prototyping[®] forces scientists to think like business people; it forces team members to agree on where the project is headed and to develop strategies for delivering the key messages and dealing with the critical issues in direct ways. The process is very similar to what we see emerging in the computer industry, where the interface is prototyped first on the basis of what the customer tasks are, or where the documentation is written up front to guide the software development. In our consulting work, we talk about “right-to-left” thinking, because we start with the end of the process (the right side of the project timeline) and map out what must be there (the target profile). We then move backwards on the development timeline to place the milestones, deliverables, critical path activities, key studies, and so on, so that the final picture shows development moving left to right in ways engineered to arrive at a predetermined goal. The process is also similar to those we are familiar with for document production,

working from the deadline back through production, review, drafting, and research to arrive at a timeline that can keep a writing project on schedule [1-3].

Throughout development, the cross-functional team meets frequently, taps the diverse perspectives and expertise of the members, jointly “owns” the developing dossier, and is responsible for seeing that it meets document quality standards. This cross-functional team approach contrasts with typical ways of working through functional areas and publication centers, where individual writers—clinical documentation specialists, for example—are handed the protocols and statistical reports and are expected to write up the various sections of the dossier on their own with occasional routing of the document for review comments and approval. In a team approach, the final dossier reflects the team’s efforts and success, rather than being a compilation of individual documents gathered and bound for submission.

The document processes we implement attempt to encourage team ownership of documents. The high-level reports and summaries are prototyped by the team working as a group. Practically all documents are drafted by specialists working together, with the goal of creating documents that are built from the ground up to be coherent, linked to other documents, and mutually reinforcing. This practice contrasts with the traditional “Everybody write a section and then we will paste them all together” (see Couture and Rymer for distinctions among different forms of document collaboration [4]). Teams revisit prototypes several times during development to create more advanced drafts, to agree on the length of various sections, to develop the rationales and support, and to identify areas that need further scientific work. Area reviews (by specialists with similar backgrounds) lead to later team reviews, where cross-functional expertise ensures that issues are linked and treated in consistent and harmonized fashion. Final team reviews bring together those who, by virtue of their positions, must officially sign off as the final step in issuing authoritative reports in the name of the company.

Most drug products are developed for a world market, so dossiers must be simultaneously prepared for the European authorities (with varying requirements for different countries), for Japan, and for other countries around the world, with document delivery customized to the particular registration requirements of each country. Some countries have more stringent testing standards than others, some countries accept a drug if it is already approved in certain other markets, some countries expedite approval for certain socially important drugs (as for AIDS), some markets do not tolerate certain side effects, while other markets do not tolerate large pill sizes or certain routes of delivery. Development demands careful coordination of knowledge that is highly dispersed across a global company.

All during the long development process, the global team produces a wide array of written and face-to-face communication:

- Frequent e-mail and memos coordinate the teamwork.

- Internal plans, proposals, and reports keep the project budgeted and within the company's portfolio.
- Numerous written filings and oral briefings are required with health authorities.
- Research protocols, interim reports, published papers, conference presentations, and final reports guide the science.
- Huge volumes of data from manufacturing scale-up take the substance under tightly documented controls from lab synthesis to large volume production and packaging.
- Electronic versions of the information make the results of clinical trials of safety and effectiveness accessible for analysis by health authorities using their own statistical applications.

Overall, drug development represents a massive documentation project. The intervention methods described above attempt to tap the collaborative power of teams to deliver high quality documentation efficiently and with appropriate strategic thinking.

GROUP PROCESS NEEDS

In addition to document tasks, a cross-functional NDA development team has many social tasks which technology can support. It is important to realize that designing technology for teams means engineering an environment to support relationships and encourage collaboration.

Teams obviously need a space to meet frequently and work. They need to discuss and come to decisions about various logistical issues: who will do what by when with what resources under what procedures. The team needs to evolve a project timeline, manage a budget, assign tasks and deadlines, and track tasks to completion, paying particular attention to those tasks on the critical path. For a project as complicated as delivering an NDA, the best planning is subject to constant revision as data come in, production problems are discovered, questions arise with health authorities, or market factors develop. When the development project is global and involves planning for simultaneous submission in a world market, the need is heightened for good technological support for the formal processes of project planning and management.

In addition to these more procedural and formal group tasks, there are more social, less formal issues that groups must address. There must be consensus among team members about what their overall goals are, what their standards are, how they will work, and how decisions will be made. It is a complicated and delicate business to reach consensus about what kind of team they belong to and what their obligations are to the team, especially in organizations where staff have obligations to line management as well as team management. These social tasks of

arriving at group definition and consensus on goals and ways of working should not be underestimated. The best teams achieve a cohesiveness, a bonding through working toward a shared goal, and they find energy and identity in belonging to a project team. They feel recognized and rewarded for their individual contributions to the team, and the team itself feels as though it is recognized and rewarded by the larger organization.

The processes of document development and teamwork described above are idealized, representing how the process unfolds with the teams and leaders most willing to change traditional practice. What I have described represents the goals of our consulting intervention, not necessarily the outcome for any particular team.

We recognize the success of interventions through such indicators as the following:

- We helped a major project transition from reliance on external consultants to an internal department function, with new hires, a regular budget line, and a place on the organization chart,
- We witnessed dramatic improvement in document quality, as measured against benchmark standards established at the beginning of the project, based on document quality scores for some 60,000 pages from the four different dossiers, and
- We watched employees use the language, theoretical constructs, and practices of the intervention in natural contexts of team interaction. When, as a consultant, you begin to hear people speaking your language, making your arguments, and urging fellow team members to follow practices encouraged by the project, you know you have achieved some measure of success.

The next section will examine ways in which technology is a key component of the project, a lever of change, and a natural way to encourage global, team-based, document-driven development.

CHOOSING ENABLING TECHNOLOGIES

Pharma companies are interested in new tools that can help global drug-development teams deliver quality documentation in timely fashion. The emergence of groupware technologies over the past few years holds much promise [5-8]. Technology can help bridge distances, allowing NDA teams to “virtually co-locate,” to find ways to meet and work together without physically being in one place. Traveling is costly, inefficient, and results in considerable wear-and-tear on a team. Physically co-locating teams triggers serious hardships for employees and their families and costly expatriate compensation. So there are very pragmatic rationales for meeting and working electronically.

The definition of the technological systems to support global, cross-functional teams follows the need to support both collaborative document tasks and group communication processes [9]. Shrage usefully identifies and describes the *shared space* that collaborative technologies can create, wherein team members focus their intellectual energies around project goals [10]. The essential step for Shrage is the movement from assignment to a team to the true collaboration of individuals in the act of leveraging their intellectual energies to accomplish work. The title of his book, *No More Teams*, reflects his disparagement of many so-called teams which are actually people assigned to work on something together and who never realize the benefits of true collaboration (and the title of this same work as previously published, *Shared Minds*, reflects what Shrage considers the goal and benefit of true collaboration). In our writing classrooms, we might compare collaborations where individuals contribute sections or perform discrete functions (researching, reviewing) with situations where a team actually collaborates by inventing, drafting, and revising in close partnership.

A wide range of software and systems can coordinate and expedite the activities of globally dispersed teams seeking to form collaborative working relationships. Tools like voice-mail and e-mail have become so ubiquitous that we sometimes fail to remark that they are really groupware tools. Nevertheless, how teams use such tools has important consequences for the structure and success of teamwork [11, 12]. Spreadsheets, charting, and project management software can keep teams on track toward planned outcomes, and really should figure into a discussion of groupware. My interest here is a bit narrower, however. The following section highlights several key tools currently in use that help create shared space for team collaboration involving key communication activities of documentation creation and presentation.

Videoconferencing

Videoconferencing is the most widely sought and most immediately comfortable technology for bringing together globally dispersed teams. For the team, videoconferencing is a “turn it on” technology, as familiar as television sets and microphones. While videoconferencing is quite expensive (phonelines carry the signal and can run to \$40,000/month for a multipoint connection), pharma companies are accustomed to providing videoconferencing studios and operators, and telecommunications companies are accustomed to providing support and troubleshooting.

Videoconferencing is critical to drug development, as it allows teams to work together on a daily basis, even though members are located in different countries or cities. For traditional meetings, where work is conducted by talking and keeping minutes, videoconferencing is widely accepted as an adequate substitute for face-to-face communication. Videoconferencing gives a sense of personal immediacy—others present, personable, and knowable—almost like a

conversation. High bandwidth connections (for example, dedicated T1 lines working at >1.5 Mb/sec), although expensive to run, offer a sense of personal immediacy that greatly improves communication over the slower, jerkier video that some of us have seen on computers or older video systems.

Good sound is possible with high quality microphones and speakers. Sound quality should not be underestimated in its contribution to distance communication, especially when participants come from different language groups. More than one of our non-native English speakers observed that sound quality was more important to understanding than the video image. Even good video and sound transmission, however, are frequently marred by poor connections, timing lags, or feedback from the audio system—not to mention that the systems don't work well when piles of notebooks, reports, and notepads cover the microphones.

Precisely because it mimics face-to-face communication, videoconferencing is deceptive, often lulling team members into false feelings that good communication has taken place and that substantial work has been accomplished (somewhat like leaving a classroom thinking, "That was a good discussion," without wondering how students might be changed, or not, as writers or readers). In fact, video frequently impedes good communication and has not proven to be anything like a full substitute for face-to-face meetings [13]. Though participants seem immediately present, much non-verbal communication is lost—many gestures, facial expressions, and discourse structuring cues are likely to be missed or misinterpreted. If participants are to be heard, they must speak forcibly, and the attendant interpretation can be that the speaker is being aggressive or obstinate, which, in turn, encourages others to adopt strategies for dealing with boors. Those who speak in normal tones (and again, especially across language groups) risk not being heard. My estimate would be that in videoconferences involving two sites with five to eight team members at each site, some 25 percent of the utterances are not understandable at all to those at the other site and that only a few, perhaps 10 percent of the utterances, are heard by everyone. This means that conversational repairs are continuously being made, with requests for speaking more loudly and repeating what one has said occurring on every fourth or fifth utterance. Those who interrupt for repairs risk being perceived as offensive or nagging. For whatever reason, those who speak in small voices tend to do so even with constant requests from the team not to, and though they might begin their next utterance in a pronounced voice, their volume quickly tails off. It becomes aggravating to everyone never to be able to understand certain people on the team. Such problems are evident in face-to-face meetings across language groups, but they are exacerbated by the remove of videoconferencing.

Many other communicative actions are muddled by videoconferencing. The pattern of talking over another's sentences, or finishing another's utterance is devastating to the conversation, as are side conversations or *sotto voce* moves. Turn-taking is much more difficult, and controlling a conversation through pauses or other subtle signals does not work well. I frequently witnessed participants

whose facial expressions indicated they were about to speak, but who lost the floor to people at the other site. Those at the other site interpreted the momentary pause, slightly longer than customary in face-to-face situations, as lack of inclination to speak. Participants must learn to speak deliberately, with obvious signals when finished and a space break before the next person takes up the conversation. Exaggerating normal conversational cues is not ideal, though, since so much meaning is conveyed through hesitation, rhythm, and timing.

There was rarely a feeling of equal partnership in video team meetings: one site or another always had more people or more dominance, as though they were having a meeting and the other site was dropping in, trying to get what they could out of it. At its worst, the two sites would give up and begin each talking among themselves, often in different languages, until someone would take the lead to pull the conversation back to a dialogue.

These problems can be alleviated if not obviated. A group facilitator can remind the team of how communication must be different when mediated via video, and the facilitator can break in to comment on why certain people are not being heard or to call attention to miscommunication. Team members can be coached on their verbal style, and the team can engage in direct conversation about how people interpret tone of voice or how turn taking is normally signaled, so that the team members can use such metalinguistic awareness to work toward better meetings. Because many team members are not comfortable with technology, the facilitator can make sure the cameras and mics are adjusted and that technical assistance is brought in when necessary.

A consultant/facilitator with a background in professional communication, one who understands group process and conflict, conversation structure and effective meeting organization (and who is comfortable with communication technology) can provide significant benefits to companies who want smoothly productive video meetings. If teams become accustomed early in their development to talk directly about team communication in both face-to-face and mediated situations, then raising issues of how other team members communicate, or fail to communicate, is made easier down the road. Such discussions can include cautious observations about cultural and linguistic differences, realizing that individual differences are likely to contribute as much variation as those attributable to group membership, and that any attempt to generalize on the basis of nationality risks stereotyping. Team leaders can also be coached to pay attention to team dynamics, to invite quiet participants to speak and to speak up, and to alter the pacing of conversation to increase participation across language groups.

Whiteboard Software

Videoconferencing has serious limitations for document-intensive work, as for prototyping reports or reviewing long and complex documents, and must be usefully augmented with other collaborative technologies. Whiteboard software

allows teams to prototype documents or develop ideas, using a single computer screen or linked computers to create a shared space for visual thinking. The idea is fairly simple (not much more than a flipchart, really) but quite powerful in its effects on meetings. Instead of merely meeting to talk, a team with whiteboard software can meet, talk, *and* see their words (and work) displayed. Making thinking visible helps teams see what they say and thereby agree on what they think and will do.

Several companies market whiteboard meeting software, including LiveWorks™ (a spinoff from Xerox; point your net browser to <http://www.liveworks.com>), which has a program called MeetingDesk™ that will work on a PC or displayed on LiveWorks' large format LiveBoard (see below). Fujitsu markets Desktop Conferencing™ (DTC) software, which includes a whiteboard function, and Microsoft has a new product, NetMeeting™, that supports whiteboard functions in Windows 95™. In essence, whiteboard software offers a dynamic surface for writing freehand with an infrared light pen directly on a screen or palette. Whiteboard software answers a traditional criticism of PCs, that they are good for writing, but not very good tools for brainstorming and planning because they lack the graphic capability of a blank sketch pad.

Whiteboard software allows handwriting to float in the public space of a computer display. It supports invention and planning with built-in features that allow words and phrases to be selected, moved, ordered, copied, or deleted. Because it is not restricted to typed input but supports free pen movement, a whiteboard allows groups to develop diagrams or flowcharts, mindmaps, storyboards, or doodles. It provides a more dynamic space than a flip chart, in that "pages" can be as long as one likes, and multiple pages can be sequenced to reflect the group's work and accessed via an index or "go to" function. Whiteboard software is superior to flipcharts in its revising capabilities, so that during a meeting a team can move from brainstorming to ordering ideas and emerge from a meeting with a well ordered document prototype, development matrix, or working plan. Vendors of whiteboards have partially addressed the limitations of flip charts by creating pressure sensitive whiteboards with built-in printing facility. But for flexibility and ease of revision, it is hard to beat whiteboard software running on a computer.

Whiteboard software works equally well as a stand-alone application for a single-site meeting as for meetings that bridge two or more sites with linked computers. As a stand-alone tool, whiteboard software offers the functionality of a blackboard (a familiar thinking tool with a revered history), with the added virtue of unlimited space and ability to print at the close of a meeting. Using whiteboard software is relatively easy, though it does suffer from the same kinds of disorientation common to computer users who must view large scrolling texts through the small windows provided by an operating system and monitor.

I helped facilitate a day-long meeting of preclinical scientists and regulatory experts to review drafts of an expert report, a document that critically assesses a

company's development program. We worked throughout the day on the computer whiteboard, generating about thirty pages of notes for the three authors, detailing what they were doing well in their sections and what they needed to attend to. We identified key messages and issues to be incorporated. We also prototyped introductory and concluding discussion sections, and identified page lengths for each part of the document. We used a series of whiteboard pages to list issues that needed scientific discussion and resolution outside the review meeting, a timetable with dates for the next draft cycling and review session, and a list of action items involving other team members (links to critical issues in clinical development and items to take up with the FDA at the next meeting).

The whiteboard file we generated was large, about 1.6 MB, but we were able to print it and distribute it at the end of the day. All during the day, the group's attention was focused on the whiteboard, ideas were refined, work was accomplished and documented in a public space for all to see and agree to. The efficiency gains were significant over meetings that are largely undocumented talk, where everyone would leave with their own interpretations of what was agreed to. And nobody had to gather up fifteen flipcharts at the end of the day, try to make sense of everything that went on, type it up, and distribute the notes.

Document Projection Systems

There are several technological solutions to creating shared visual working space. Desktop computers can simply be linked to each other, so that users share the same screen while they sit at their own desks, sometimes with small video cameras mounted on top of each computer so a low resolution video picture-in-monitor is projected across computers. However, since one of the goals of our intervention was to get individuals away from their desks and to collaborate in team spaces, we looked for displays that could accommodate team viewing.

One option that works fairly well is to link the computers to computer projectors, preferably not the flat panel LED displays that work in tandem with overhead projectors, but units that contain their own projection systems and that project the VGA output from a computer. These portable units (which retail for somewhere between \$4,000 and \$12,000 from such companies as InFocus and Polaroid) have been much improved in recent years in both portability and affordability, and they can project truly high quality screen images even under normal ambient light. Conferencing software can join remote computers, so that more than one site can see the same image, and pen palettes support working with a light pen, which is much easier than attempting to draw with a mouse (though it is best to have both input devices).

Even better than a projector is a product that we used from LiveWorks, called the LiveBoard™, running MeetingBoard™ software, the parallel software to MeetingDesk™ (which runs on a desktop PC). The LiveBoard™ is a large unit that contains a PC, a large, rear projection screen, and a light pen. Anything you can

do on a PC, you can do on a LiveBoard™, only it is displayed in high resolution with good readability in an image that measures 67 inches diagonally. LiveBoards™ can be connected via a multipoint bridge, so that people at multiple locations share the same computer screen. The company has built some nice features into the LiveBoard™: a lightpen interface with limited character recognition, Olé (Object Linking and Embedding) so that application files can be embedded in MeetingBoard™ files, some capabilities for bringing in document snapshots, and flexible list creation and comment tools. The shared space itself is the real advantage, however, since team members at different sites can view and contribute comments to the same document space.

The LiveBoards™ are tremendous tools for allowing globally dispersed teams to conveniently plan, develop, and workshop complex documents across sites. There is a deep qualitative change in the ways teams work during meetings once their group intelligence is focused on a dynamic display, where their thinking, decisions, and language can be recorded and reordered. During electronically facilitated meetings, our teams were able to work up and rehearse presentations, display and annotate PowerPoint™ slides, prototype scripts, and offer critical commentary to presenting team members. Our teams regularly prototyped documents, reviewed and annotated drafts, and engaged in careful discussion about whether their documents delivered clear messages in prominent positions (with sometimes extended debate on such burning issues as whether it is appropriate to bullet key findings in a scientific report!). Just prior to filing, the teams used the technology to review various documents for consistent delivery of messages and treatment of issues, using the LiveBoards™ to record necessary links and specific language that should be consistent throughout the dossier. All of these tasks are document intensive, and stand in contrast to videoconferences featuring talking heads.

Conferencing Software

Whiteboard software is one of several kinds of conferencing software, designed to work on linked computers so that users at several sites share the same screen. With our teams, we made extensive use of MeetingBoard™ for the LiveBoard™, which allows a Word™ or PowerPoint™ (or other) file to be printed to disk and then displayed as a bitmapped file on the LiveBoard™, where the file can be annotated using MeetingDesk™ tools. In essence, we were able to make notes on top of the image of the file (but not edit the file itself).

What the LiveBoard™ didn't have, and what our teams really wanted, was true application-sharing software, so they could run standard Windows™ applications and work on actual document files during meetings. The MeetingDesk™ designers imagined, logically enough, that a bitmapped image of a document would suffice for annotating, marking trouble spots, suggesting corrections, and so on. But much of the work of team reviews involved very detailed discussion of

complex messages and supporting responses within highly complex documents. The teams wanted to enter a review meeting ready to debate document issues. They needed to have before them a dynamic representation of the actual file, so that as substitutions, deletions, or additions were suggested, they could see the new language on the screen and agree that the new language was indeed what was needed in the document. Seeing annotated text is never the same as seeing the actual text in context.

True application sharing is demanding in terms of system resources and operating system functionality. The need, however, is well recognized, and the software market is integrating such functionality with the latest operating systems (Windows 95™ and Windows NT™). Fujitsu Desktop Conferencing™ is designed to support application sharing, as is Microsoft's NetMeeting™. LiveWorks™ now has a Windows 95™ version of its software with application sharing.

While many other kinds of groupware are available, for the most part designers have not made the assumption that groups need to work intensively on complex documents in real time. Rather, much groupware is founded on the presupposition that the goal is to model or facilitate oral behaviors typical of face-to-face meetings: brainstorming, listing, building consensus, and ranking or eliminating suggestions (see [14] for an assessment of the empirical research). Synchronous discussion is supported by groupware such as IBM's Person-to-Person™ and classroom software such as Daedalus™, and the nature of such conversations is well investigated in the literature of computers and composition. But because phone and videoconferencing are so ubiquitous and familiar in pharmaceutical workplaces, there is little perceived need for chat facilities. One merely picked up the phone and dialed a conference call or reserved the videoconference facilities. There may be benefits of realtime talk via computers, but they remained unrealized in the pharma workplaces where we were involved.

Shared Drives

Shared drives from central servers allow team members to have access to current project files on an anytime/anywhere basis as long as they have sign-on privileges. In our intervention, the shared drive allowed team members to access current versions of files, pull them up on the LiveBoard™, at their desks, or from affiliate sites when team members were on the road. We organized separate drives for each development team, passworded so only team members could access the files. Uses of the shared drives grew over time, with teams organizing files for their presentation scripts and slides, frequently asked questions, development matrices, strategic documents, meeting notes, MeetingDesk™ files, budgets, timelines, prototypes, and NDA documents.

Using a shared drive raised concern among team members about who had access to what files, at what times, and for what purposes. Shared drives make information public within a company, and there are always a variety of reasons for

not sharing information. Some authors simply did not want their files in a public place until they felt comfortable that the files were ready (final draft stage). Others did not want early drafts of information on the shared drive because they thought there might be inaccuracies that would find their way into other documents. Because the drives had open directory structures with open access to everyone on the team, files could have been subject to malicious or inadvertent damage, though there was never evidence of such.

Significant indirect learning was an unexpected benefit of the move toward shared drives. Team members learned routines to log onto remote drives and navigate directories set up by others. Reading and writing to remote drives revealed machine and network bottlenecks, which led to technical changes and overall improvement of the network efficiency.

The shared drive also raised problems of creating directory structures for large groups of documents, including prototypes, general information files (schedules, directions, memos), and data files. Just figuring out naming conventions was a challenge within the eight-character name stricture that is a DOS legacy. All the chaos that typifies the hard drives of many individuals is suddenly amplified by team members who come and go, leaving discarded files and versions of files, temporary files, and just plain garbage files in their wake. The best-laid plans, the carefully set out directories, the guidelines on file naming conventions—all mean very little in the hurly-burly of people rushing about to get work done. These difficulties with shared drives exemplify the more general challenges of the transition from the computer as a tool for personal and individual work to the computer as a tool for social interaction and teamwork. While some teams gave up in frustration or never really made good use of a shared drive, others quickly took to the tool and came to rely on it and own it as a tool to enhance teamwork.

We have a long way to go in developing protocols for working in shared directory spaces; in deriving a logic of file structures that will seem logical to diverse, creative minds; and in finding ways to train or support new users who are intimidated by moving from personal computing to social computing.

Revision Software

Word processors that offer revision mark-up features provide a relatively simple groupware tool with important implications for how teams handle document review and revision. Our client had standardized around Microsoft Word™, which allows files to be protected for revision marks and passworded to the author, meaning that the original file is preserved, but reviewers can annotate, change, or delete right on the text. Word™ marks all suggested changes and the author can then review and accept or reject any suggested changes. Up to eight reviewers can mark up a text, and Word™ keeps track of who suggested what changes when with color-coded revision marks.

With files on a shared drive, passworded to the author, and protected for revision marks, team members could be notified via e-mail that a draft was ready for review on the shared drive, and team members could open the file, indicate various revisions right on the text file, and save it to the shared drive. The next team member to open the file could see the original text and the first reviewer's changes and remarks, and then add additional commentary and contribute to the dialogue among the author and other reviewers. On one team, we followed this procedure with the prototype and developed drafts of the package insert for the drug, with three authors contributing sections, several team members posting commentary, authors reviewing the comments, and then meeting to review the proposed revisions and discuss further changes. The process made document development and review a public, team-centered process, with authorship and ownership of the document passing from individual control to the team.

Making reviews public changes business as usual. The typical process would have an author attach a file to an e-mail message to all reviewers and then integrate the comments and suggestions. Reviewers would be unaware of other reviewers' comments, and the author would have full control over responding to suggestions. The combination of keeping files on a shared drive, having the comments of various team members recorded with revision marks, and then meeting to review the marked up text meant that the control that would have been centered in the author was now distributed across the team. This change, toward team ownership of documents, was alternately welcomed and resisted, depending on who the key players were for a given document and how far they endorsed collaboration.

BRINGING THE TECHNOLOGY TOGETHER

All of these team technologies can come together in a physical and virtual space in the form of a *team room*, where the technologies are clustered and the room is designed to facilitate global work. Team rooms can be augmented with printing and faxing, with direct phone connections and personal computers, all tied into a network of rooms where teams meet and work. Such a room can be built to accommodate from four to sixteen people, with tables arranged in a semi-circle oriented toward the video cameras and the large display, either a projected image of the computer screen or a LiveBoard™. Shelves can hold printed resources and eventually the team's output of documentation, in draft or signed-off versions, and tracking charts or other visuals that convey the team's positioning and accomplishments can line the walls. The room can be a place not just to meet, but to work. The concept is similar to a war-room that is sometimes set up for major proposal initiatives, but with full global connectivity. The connectivity can be extended to team members' individual workstations, so they can join the working

space on the spur of the moment, as their participation is needed for a meeting, or when it makes sense to meet desktop-to-desktop.

Such team rooms will not come cheap, though the growth of the net is forcing the cost of high bandwidth communication down and, as we all know, more computing power is available for less money each year. A cost estimate of \$200,000-400,000 is within range, with something on the order of \$200,000 per year to run one. That is a significant investment, though it is worth remembering an earlier remark, that the top 100 drugs at peak sales generate one million dollars per day, with blockbusters generating \$2 to \$3 billion per year. Technologies that speed time to market can be rationalized around those numbers.

NEW FORMS OF TEXT

New forms of text are emerging in the pharma industry. For example, *hypertexts* are being constructed to supply the health authorities with electronic copies of new drug applications. The primary objective is to provide data files so the authorities can run their own statistical analyses of the data on safety and effectiveness, but it doesn't take a lot of imagination to see advantages in delivering new drug applications in electronic form. As in other settings, the initial electronic files are simple dumps of the data tables, with a few pointers and links. But hypertext holds real promise for the industry, and companies are moving quickly to provide hypertexts that provide efficient tools and structures for visualization and manipulation of the data. A new drug application represents years of time and millions of dollars invested in what one hopes is a coherent research and development process, and the application must show links among the studies, within the chemical and manufacturing processes, and among the various arguments made in various sections of the document. Graphical browsers, nested information, layered structures, glossaries, bookmarks, menus, indexes: all are usefully beginning to inform hypertext presentations. It is quite natural to hear the medical researchers, toxicologists, and chemists talk about *links* among various documents, and while what they have in mind is not a dynamic hypertext link, but a textual reference across volumes, the notion is the same and the technology holds promise as a medium suited perfectly to the messages that must be delivered.

Document databases will increasingly organize the huge amounts of information and complex sets of related documents occasioned by NDAs. In the pharma industry, DocumentumTM, from the company of the same name, another Xerox spinoff company, is the leading document database software (for a description of its use at Glaxo Wellcome pharmaceutical, see <http://www.documentum.com/glaxo.htm>). DocumentumTM in tandem with publishing software such as Xerox Document AssemblerTM (XDA, described at <http://www.xerox.com/XPS/newpage/nrxda.htm>), allows for various levels of document production and

control, insuring accurate data transfer from one document to another, consistent format across documents written by many different authors, and high-level coordination of versions and links among complex documentation sets (indexing, tables of contents, pagination, links across volumes). Such systems have check-out systems for documents with various levels of access and authority over documents. Once a document routing slip is filled out, Documentum™ will send out e-mail notices to reviewers that a text is coming their way, route the electronic text in and out, keep track of versions and revisions, allow annotation and text markup, remind reviewers when their comments are due or overdue, and record signatures on documents that need signed approval.

The thrust of software development has been integration across platforms and applications, so that a company with a mix of hardware and existing expertise with publications software such as InterLeaf™ can preserve and leverage that experience. Like any software system, the logic of any chosen piece of software will to some extent run counter to the logic of work established by an organization or a team, and some refitting of the software to the organization or organization to the software will be necessary. It is not an assumption of Documentum™, for example, that anyone other than the author is interested in seeing the comments of reviewers, but as noted above, there is good reason for encouraging dialogue within review cycles.

Increasingly, teams will be aided by shared intelligence via *intranet sites*. Opper and Fersko-Weiss [8, p. 26] model groupware around three essentials: electronic communication, a group focus, and management of shared information. Such tools as shared drives, document databases, and more recently intranets, play key roles in information management. Teams need access to current versions of reliable information, information that is typically widely spread around an organization. Intelligent systems, or expert systems, navigated with Web browsers and managed with document databases, are quickly emerging as key information-support tools. Sites can be constructed for internal use, or with areas passworded to provide or deny access to individuals within and outside the company. File management tools such as Documentum™ provide the server structure for intranet development with clients accessing files with their net browsers.

Hybrid intranets can allow team members to access reference literature on regulations, discuss issues with or post questions to other team members or to experts throughout the organization via bulletin board functions, look up files or versions of reports, and enter the Web for access to sites on pharmaceuticals, diseases, and healthcare. The WWW will increasingly be a place where information about drug products and disease management is found—a place for support groups, prescribing physicians, and disease sufferers to find the information they need. Pharma companies are rapidly migrating to the WWW for many purposes.

IMPLICATIONS FOR PROFESSIONAL COMMUNICATION PROGRAMS

Team communication needs in the pharma industry are complex and demanding. NDAs are large, complex objects, and they represent just one example of documentation produced by the industry. When the needs are to work across sites, to access the documents on an anytime/anywhere basis, and to engage in document-intensive tasks such as application sharing, the network, hardware, and software resource demands are substantial.

Applications of technology to document-intensive group tasks push the leading edge of technology development. The information-technology staff within pharma companies and even the technology vendors themselves are only beginning to understand why and how to make technology work in such highly social and highly textual ways. Computers were not developed for such purposes. They evolved from data-manipulation machines, morphed into personal productivity tools, but have only recently been reconfigured to support socially structured work. They only awkwardly meet the challenge of work that centers on massive documentation tasks. But each new operating system enhances network functionality in support of group computing, and the future promises expanded connectivity and resourcefulness.

We are only now discovering how we need to work with global teams to produce complex documentation sets. How should a team review be structured when the documents are complex and the team members dispersed around the globe? How can team members be encouraged to communicate effectively across the distances and the separation imposed by new media? What are the best ways to develop documentation so that a huge submission is actually a carefully orchestrated, coherent, message-driven issue-oriented dossier? Each cautious step toward implementing new systems demands new user knowledge, new mental models for how computers enable work processes, bigger and faster hardware and networking, and significant technical support for assimilating and accommodating the designed software to existing work processes.

I think it is worth pointing out some of the more obvious ways that our practices in professional communication (and, indeed, in composition teaching generally) can help prepare students to contribute to the processes of document development through social technologies within industry. Within our programs, as we think about preparing our students, we might consider whether we build and reinforce the following kinds of understanding and skills:

- **Writing should be developed as a tool for visual thinking.** Students can use writing as a learning tool, to capture and articulate what they know and share. Students can come *to see what they know* by arranging ideas within something resembling a messages and issues table and transforming the table

to an early document prototype[®]. Technology enhances visual intelligence and provides a visual space for creating and manipulating ideas.

- **Writing is best treated as a process.** Good writing is best created by dividing work into stages in a managed process, from conceptualizing via a messages and issues table, to creating an initial document prototype[®], to revising the prototype and advancing it toward increasingly mature drafts, to taking drafts through several rounds of focused revision, to publishing for various markets. As exemplified in this chapter, prototyping around messages, issues, responses, and support can be a powerful heuristic during the planning stage of documents. Technology can enable the process.
- **Professional communication classes should integrate writing, speaking, and working.** Through interdisciplinary studies, our students should be encouraged to develop their understanding of leadership, teamwork, and communication (small group, cross cultural, organizational, and technologically mediated). They should study project management and engage in the production of document libraries so they understand the dynamics of large documentation projects.
- **Writing must be understood and practiced as social and collaborative.** Cross-functional teams attain a synergy from involving people of different expertise, experience, and cultures in a common task. At every opportunity, students should be encouraged to work in teams, to contribute differentially based on their expertise, to read about teamwork, to experiment with various forms of leadership and work structures, and to reflect on their experiences as members of teams. Whenever possible, technologies should be exploited for their support of collaborative interaction.
- **Technology should be developed as a social tool.** We should use shared drives, e-mail, soft-copy review, and mark-up systems to explore the ways that people can work collaboratively across a network. We should use technology to bring writing into public space and to collect distributed knowledge in a shared space. Many tools (such as revision marks) are available but unavailed within our classes and our work; we tend to ignore the ready-to-hand tools embedded in our familiar applications as we seek some powerful new form of groupware. We would do well to rethink the tools we have in the interest of helping students and ourselves develop social uses of technology.
- **Technologies should be used to bridge distances.** We should pursue class collaborations across universities and with industry, even if the results at times tend toward chaos. Dealing with unexpected contingencies, technological breakdowns, and imminent disaster is perfect preparation for the modern workplace. We should encourage our students and become involved ourselves in working with distance education, virtual classrooms, and video and intranet delivery of courses. At the same time, we should research the effects of various technologies on group communication.

- **Electronic texts in various forms should be explored as a rapidly expanding alternative to paper-based texts.** All students, including those in technical communication, have an unparalleled opportunity to become information managers and designers of new forms of hypertexts, Web sites, and document database systems. In all our classes, we should be moving back and forth between paper and online sources for research, writing, and communication. We should participate in designing technologically rich environments that accommodate the special demands of working with complicated texts in electronic space, using writing classrooms as our labs.

Many writing programs in our colleges and universities are already actively engaged with the sorts of learning outlined above; their students will discover useful roles in industry settings for technical and professional communicators. The challenges are great and intensely interesting, since the work brings together the document-development practices of rhetoric and technical communication with the social dynamics of globally dispersed teams, all within an environment constructed out of the complexity of emergent technologies. We should, above all, encourage our students to think imaginatively about the intersection of work, technology, and communication, and to be prepared for a workplace that will change faster than we can imagine. Our students' resourcefulness, their agility, and their willingness to work creatively within technical environments will ensure a valued place for them in the workplace.

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