Considering Users When Implementing New Pharmaceutical Technology

by James L. Vesper

For the successful implementation of new technology in pharmaceutical manufacturing and control, the potential users must be considered. Of the several different types, one key consideration that is the users have the knowledge and skills required to safely and effectively utilize the technology. Instruction and training can provide this to the users. This article will discuss a systematic approach to determine the specific knowledge and skills required and how they are best delivered to the learner.

Introduction

The pharmaceutical industry is a technology-intensive one. A walk-through any new manufacturing facility or laboratory confirms this: computerized CIP/SIP systems, banks of HPLC instruments running around the clock in an analytical laboratory, fill-seal equipment operating with minimal human intervention.

With the increasing use of and investment in technology, those involved in its planning and implementation sometimes neglect the users. While the role of the operator may shift from a central to supportive one, people are still involved. They:

- install
- validate
- operate
- maintain
- investigate and solve problems

Those involved in the implementation or management of new technology need to be aware of what can happen when users are not considered, categories of user/technology considerations, and how to address one particular type of consideration, knowledge and skill requirements.

What Can Happen If Users Are Not Considered?

Three non-pharmaceutical examples will illustrate the following:

- complexity of the technology can adversely affect other implementation and operation elements
- "impossible errors" can occur
- implementation has a high probability of failure.

Example One

In the book, *National Defense*, James Fallows[1] discusses the extremely complex technology used by the U.S. Department of Defense, such as the "Worldwide Military Command and Control System" and "Command-Control-Communications-Intelligence" network (Figure 1). His analysis shows that the use of costly and overly-complicated technology:

- diverts resources from other elements of implementation, such as training
- makes hands-on training and practice too expensive or too impractical

In other words, in situations where training is critically needed, time and money for instruction and opportunities for practice are not available.

User training is typically a high priority item in the initial planning of a project. However, since it is usually done in the project's later phases, time and resource issues have a greater probability of negatively affecting it (e.g., less training time available, fewer dollars available for design and development of instructional materials, etc.).

Example Two

On May 4, 1982, during the height of the Falklands War, a British destroyer, the Sheffield, was sunk by a missile launched by an Argentine fighter-bomber. The ship, built in 1975, "was fitted with the most modern weapons and electronic systems."[2]

Later investigation showed, because of the ship's design, the British were "forced to turn off their warning radars to clear the waves so that they could use the radios to receive instructions. It was at this point that the Argentines released their missile and sunk an unsuspecting ship."[3]

This is an example of an "impossible accident"[4]: in the mind of the user, it should not or could not occur. "The operator had no inkling of the ramifications of the system designs under the current operating conditions."[5]

If operations personnel were intimately involved in the design and development of a new technology, there might be fewer "impossible accidents". Alternatively, if such potential situations exist, they need to be identified and prevented from occurring by training, practice, and other human performance techniques.

Example Three

A survey conducted in 1991 by Deloitte & Touche, Chicago concluded that the biggest barrier to implementing new technologies was inadequate education of management, workers, and technical personnel.

Based on the 872 respondents to the survey, "the most significant barriers to implementing advanced manufacturing technology result from the education and skill deficiencies of their work forces. These barriers are closely tied to the failures in the U.S. educational infrastructure to produce students with fundamental technical and communication capabilities."[6]

If direct and indirect users do not have the appropriate knowledge and skills, there is a high probability that implementation will not be successful. Conversely, if those involved in the operation, maintenance, and management of the new technology do have the knowledge and skills required to safely and effectively use the technology, the probability of success-

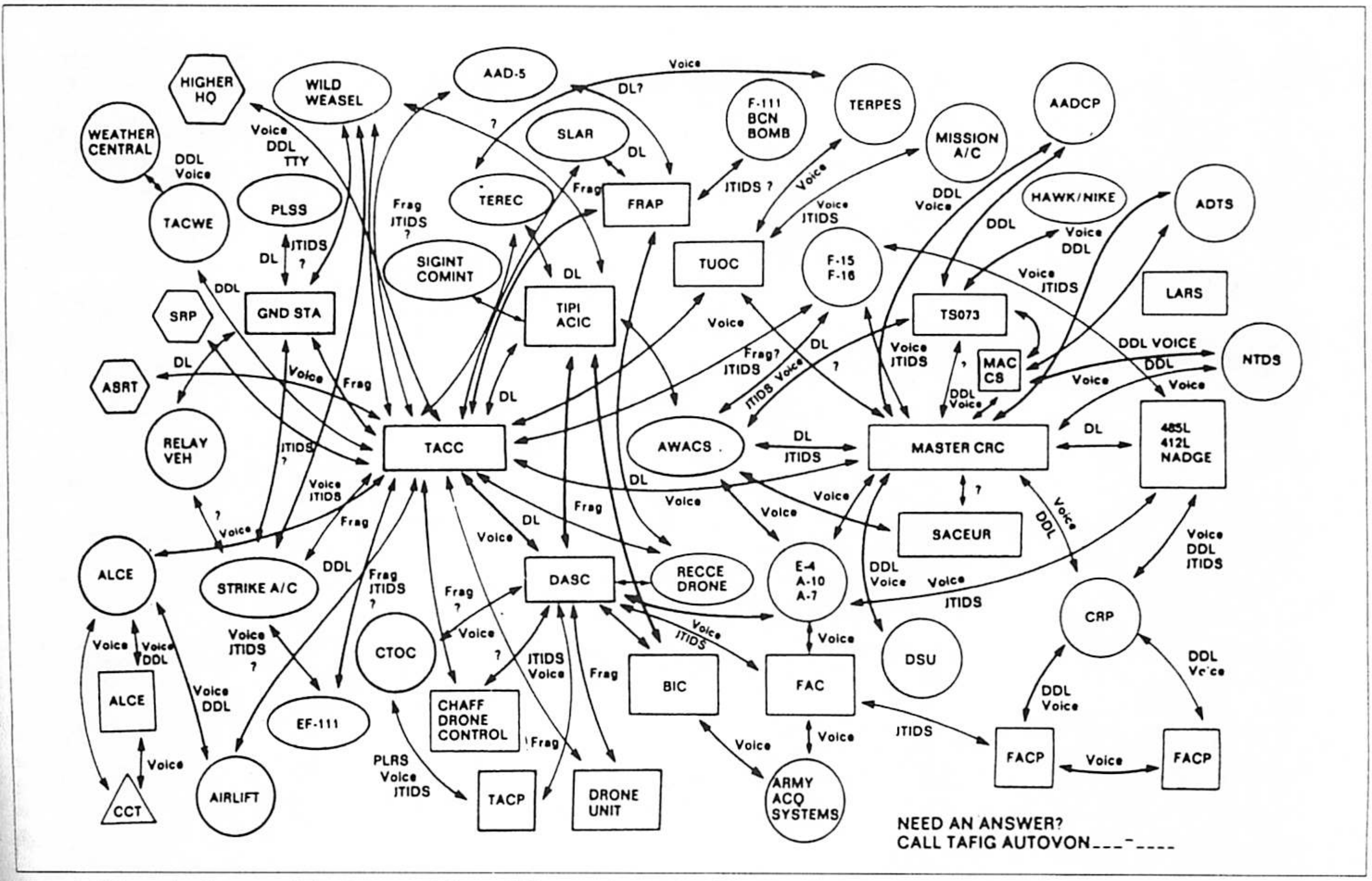

Figure 1. Schematic diagram of the Command-Control-Communication-Intelligence network (U.S. defense contractor's chart.)

ful implementation will be greatly increased.

Categories of User/Technology Considerations

There are several different categories of user/technology considerations that should be made by an organization implementing a new technology. These include:

- person/machine interface
- health and safety factors
- organizational environment
- performance environment
- knowledge and skills required

Person/Machine Interface

This consideration, also called human factors or ergonomics, is concerned with how the worker interacts with the equipment involved in the process. In the broadest sense, this can mean assuring the technology is compatible with "real-life" usage. More narrowly, it looks at the physical and psychological links between the user and the equipment. For example, as word and data processing became more widespread in the 1970's and 80's, so did problems associated with using the video monitors and keyboards. Studies showed that glare on the screen, unstable displays, and poorly designed workstations were frequently to blame for many of the vision, back, and wrist-related complaints. Improved design of the worker/computer interface corrected many of these problems.

Health and Safety Factors

New technologies can affect the physical, chemical, and biological stresses with which a user may be challenged. These challenges may be real or they may only be perceptions in the minds of the users. In either case, they must be thoroughly investigated and addressed to assure the health and safety of all those involved.

Organizational Environment

Management and those involved in initiating technological change have considerable power as to how the impending changes will be communicated to those affected by them and in how the users will react. Change of any sort can be painful. Uncertainty about what will happen, "how will it affect me", and other real and perceived concerns need to be dealt with honestly by the organization[7].

Performance Environment

In order to achieve the desired level of performance from the users of technology, there are frequently tools, devices, and resources that need to be provided. If an autoclave installation is to be successful, all the proper utilities must be present in the required amounts, pressures, voltages, etc. An engineer would not implement such a device if even one utility was not adequately available. Similarly, in the area of human performance, one must look at even the most basic tasks and consider if the performers have all the tools and information required for safe and effective performance. For example, if users must record time using a 24 hour clock (i.e., military format) accurately and precisely, what tools should be present so this can be easily accomplished? Obviously a clock, but one that displays the time in a digital, 24 hour format, will be more precise and prevent mistakes because of the conversion from a 12 hour format.

Knowledge and Skills Required

New technologies may require those directly and indirectly involved to know and apply certain facts and be able to perform certain intellectual and motor skills. In most situations, knowledge is simply not enough; being able to do is the most important thing. Someone may be able to describe and discuss intricacies of heart surgery. The successful surgeon, however, must have the knowledge, abilities, intellectual and motor skills; he or she must be able to perform.

Training As a Critical Issue in Implementing Technology

As content of jobs change due to technological, business, and international economic pressures, new things are being demanded of workers. Jobs for "routine production worker" in the U.S. are declining, while positions for problem identifiers and solvers are increasing[8]. Repetitive, labor intensive jobs are being shifted to those requiring workers at all levels to analyze and solve problems, help implement solutions, etc. The amount and complexity of knowledge and skills required of the users increases as the complexity of society (and technology) increases[9]. Education and training are critical mechanisms in equipping workers (including technical personnel and management) with the knowledge and skills they, and the organization, need.

Technology planners and implementers, as well as management and investors have expectations that the technology will provide a certain return on investment. Training helps accomplish this in two ways. First, it helps to protect the investment. If a manual shut-down task could damage the equipment and facility if not performed correctly, training and practice (along with the performance tools) can minimize the chances of a problem. Second, training helps to optimize the return on the investment by providing a standard and consistent approach to the use of the technology. Training is not only important from an operational and business point of view, it is a requirement of the FDA's Current Good Manufacturing Practice regulations (cGMPs): "Training shall be in the particular operations the employee performs..."[10]. Economic forces did not drive the agency to this requirement, rather, it was an understanding that people are one of the most important elements in consistently producing a well controlled, high quality product.

Discovering and Delivering the Essential Knowledge and Skills Required

We've seen what can happen if users are not considered when a new technology is introduced, some of the user/technology considerations that should be made, and why training is critical. Now, focusing on the knowledge and skills required, how can one discover what specific knowledge and skills those involved must have? And, how can one determine the best way the information and skills should be presented to the learners?

Instructional Systems Design (ISD) is a systematic process to analyze what the training needs really are; design how the information will be presented and in what sequence; develop the instructional lessons, courses and materials; present/evaluate the instruction; and finally evaluate and maintain the course materials. (Various ISD models use four, five, or six phases; the one discussed here uses five)

Phase I: Analysis

The scope of the project is determined, data is collected and analyzed. Output includes prioritized training needs, characteristics of the learners, and the linking of training goals with the strategic goals of the organization.

Phase II: Design

In this phase, a "blueprint" is created for developing the instruction. Included in the output are instructional topics, curriculum (or learning plans) objectives, evaluation tools, and the selection of appropriate instructional methods and materials.

Phase III: Development

Here, instruction is prepared according to the design plan. Specifically, lessons, instructional materials (e.g., visuals, video, booklets, etc.) and a "pilot" course are produced.

Phase IV: Implementation and Documentation

The instruction is now delivered to the specified audiences using the particular methods and media. As appropriate, ample opportunities for practice and coaching are available to the learners. Participation is documented; learning and performance is evaluated.

Phase V: Evaluation and Maintenance

In this phase, learner feedback and evaluation information is collected and used to make the course even more effective. The course and materials may be modified and updated as necessary. Also, the course is evaluated to determine if the goals have been achieved.

As one uses the ISD model, the designers and developers must keep in mind another set of factors: principles of adult learning. According to Knowles[11], these include:

- involving the learner
- letting the learner become a partner in the training process
- respecting the individual
- focus on "real-life" problems

Using the ISD Model

The ISD model may seem more complicated than the "spray and pray" method of training that is typically done, and in fact, it is. However, if the training is to be effective and part of the investment in implementing new technology, it needs to be done in a systematic way. One just does not start constructing a new facility. First there are needs, requirements, various studies, blueprints, etc., before ground is broken. A similar approach needs to be taken to develop correct performance in those doing a task, whether they use existing or new technology.

The benefits of using a systematic approach for developing training include:

- more effective learning, with greater performance and less time spent in training
- the learning is learner-centered
- instruction is based upon what the learner needs to know and do
- there are typically decreased costs over the long term[12].

Conversely, the ISD model does have costs that differ from those encountered in a less systematic approach, such as:

- the investment is usually up front
- considerable time is spent in the earlier phases, prior to actually delivering training
- it differs from "the way we used to do it".

Conclusion

Consideration of the users is critical for the successful implementation of new technologies that are introduced into pharmaceutical manufacturing, control, and support operations. In particular, users must have the skills and knowledge needed for safe and effective operation. As technological, business, and international economic pressures change, what is expected of workers at all levels, having trained personnel who can perform is a critical success factor for an organization. Determining and providing workers with the required skills and knowledge can be done by using a systematic approach called Instructional Systems Design.

Following the ISD model typically involves investing more initially into a training program; however, the instruction produced by this method is more effective and efficient than training by other, more traditional methods.

Introducing and implementing new technology is an investment a firm makes in its future. Equipping the users of the technology with the knowledge and skills they need is not only an investment in the most important resources an organization has, its people, but is helping assure the success of the technology.

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