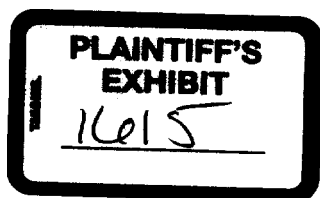


MANAGING CONDUCT AND DATA QUALITY OF TOXICOLOGY STUDIES

Sharing Perspectives Expanding Horizons



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OF QUALITY ASSURANCE FOR ENVIRONMENTAL PROTECTION AGENCY REGULATED PRODUCTS

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ABSTRACT

Quality assurance in toxicological studies is an important management function for both industry and EPA. For the most part, quality means "doing it right the first time." Management **has** many incentives for that to happen. Using an analogy with safety, the importance of quality, the responsibility for quality and the consequences of poor quality are outlined. Scientist-scientist interactions with EPA are also discussed in terms of their impact on quality. The role of industry and EPA management in setting goals and insisting on adherence to them is viewed **as** a way of minimizing adversarial relations between scientists and quality assurance staff.

A FABLE

Once you have sat through presentations from **NTP**, **FDA** and the pharmaceutical industry on quality assurance in toxicology, there really isn't much more you want to hear, even if the topic is defined in terms of **EPA's** needs and regulations. For novelty's **sake**, I thought of reciting aloud the full set of **EPA** quality assurance regulations. (Our **QA** Manager expects us **all** to have them memorized anyhow.) The result of that would probably be lunch at 11:10, not **12** noon **as** scheduled.

Instead, I decided I would tell a fable. From that story I **will** attempt to extract the role of management in the quality process and close with **an** analogy that, in our organization, we feel well describes the purpose and status of quality assurance.

"In an earlier, more peaceful time, the *animals* carried out the toxicity studies on new pesticides or industrial chemicals in an informal yet somehow orderly

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2. Key words: goal adherence, industrial management, quality assurance, toxicological studies.

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fashion. Many studies were conducted in the same rather large house, often with more than one species present. The animals assigned themselves to their cages **as** they wished. They also assigned someone to snap the lights off each day for activity time and on again later for rest time. The **humans** were **permitted** to leave their offices each day and were trained to feed and care for the **animals**. Because humans were slow learners, many times the animals failed to receive the proper dose of agent, or failed to be provided with adequate feed and water or failed to **have their quarters cleaned**.

The leaders of the animals concluded that this way of doing the studies was wasteful, inefficient and could even produce misleading results. They were especially concerned at the number of humans who could not do simple mathematical computations correctly, operate simple weighing devices or even record numbers accurately. These leaders of the animals sought to bring order to the conduct of the studies by the humans, and they did so in the following way. Reasoning that it was their lives that were at risk in these experiments and yet these studies were needed for new products, the leaders reviewed the work of the humans; assessed the needs and shortcomings; put in place the necessary facilities, training, procedures and controls; appointed several of their number to oversee the humans and found in a short time that there was a vast improvement in the overall operation.

This project became known **as** 'Doing it right the first time.' **Alas**, however, not all animals in the house seemed to be interested in it. They found many excuses for not participating—'things were all right **as** they were,' 'who cared if there were occasional errors,' 'it's too expensive.' The humans, of course, knew nothing of this. They merely went about their daily tasks of feeding the **animals**, caring for the quarters, etc. Some were involved in the new project; the others associated with the nonparticipants, totally unaware of 'Doing it right the first time.' **So** with time there came to be two classes of animals in the house. Most were active participants in the project; a few weren't.

The difficulty came in the utilization of the data from these studies. In the earlier times, the principal users were other **animals** in gray houses in a humid city by a river. They knew, because they themselves had done such studies, who was committed to 'Doing it right the first time' and who wasn't. But with the passage of time and changes in circumstances, the animals in the gray houses changed and these, along with other animals, were not so likely to believe the humans had really learned. They began to talk about certain animals looking in on the humans to assure that they did their work properly. In time these 'checking animals' wrote guidelines and procedures and ultimately convinced their fellows in the gray houses in the city by the river that only 'checked' studies were acceptable. The rest is history. Today the animals are of three kinds. The first are those who were always 'Doing it right the first time.' These are somewhat unfriendly to the 'checking **animals**,' finding their role superfluous. The second group of **animals** became convinced of the value of 'Doing it right the first time' and saw the 'checking animals' **as** a way to help them achieve that goal. The third group **is** fortunately a diminishing type. They never did comprehend that there **is** no market for their studies, and are slowly disappearing from the house. The

animals in the gray houses in the city by the river take full credit for this improvement in quality." But then, this is only a fable.

MANAGEMENT AND QUALITY

Classical textbooks on management (meaning those written in an age of alliteration and before our heightened awareness of sexist language) describe the role of managers in terms of men, money and machines. Management employs these resources in the most effective fashion to provide a needed product or service. Where does quality fit in? A shoddy product or service certainly stimulates no repeat business. The marketplace is a fine discriminator of quality. In the fable, the value of "Doing it right the first time" was evidence to the "doers," and there was in place the best of all quality systems. That consisted of a conviction from the bottom up and from the top down of the value and importance of quality.

In the ideal case, the concept of quality permeates an operation. Workers strive for it, management encourages and recognizes it, and the marketplace selects on that basis. Management needs no lectures on the value of "Doing it right the first time." Waste, loss, inefficiency, downtime, rejection, user dissatisfaction, worker disaffection, loss of customer loyalty, the contagious nature of sloppy practices in any endeavor, all flow from lack of quality. Management is aware of all this. The cutting edge of the issue for management is in the verification of quality, especially by third parties. Who will define quality? How is it recognized? At what point have things progressed beyond "Doing it right the first time" and into the realm of inappropriate expectations? In the fable, the "checking animals" were valuable in seeing that the studies went along properly. If the "checking animals" lose sight of their support role and wish their function to be the final product, then the animals may no longer have a quality problem, but they will have substituted a problem of scientific credibility and research purpose.

Most managements view their responsibilities in the sense of team function, with leadership. Visualize a symphony orchestra. Each instrument makes its own contribution. The quality of the product is a function both of the quality of each performer and the ability of the conductor to blend and integrate so that the whole is harmonious.

So as not to do violence to the published program, I would like to make some specific observations about the interaction of industry scientists with their counterparts in EPA. This is a quality assurance item on the broadest scale and one in which management has a strong interest. At the outset, this interaction has a potential for conflict, but not of the sort which you would expect. We are long past the image of government scientists clanking about Washington in white armor defending a hapless public from sinister, fire-breathing industrial dragons. Today, in my view, our conflicts are largely those of thoughtful scientists seeing the same data with different eyes. Conflict resolution, on the part of management in industry and the EPA, consists in large part of establishing open lines of communication, insisting on documentation and/or verification of scientific positions, making possible the use of referees or other third-party participation, insisting that good science makes for sound regulation and realizing that bad

science, especially bad toxicology, will haunt you for years. One of the best guarantees we have that EPA management **will** hold that position is the presence of Dr. John Moore **as** Assistant Administrator for Pesticides and Toxic Substances. He has consistently shown himself to be open to ideas, suggestions, new approaches, different interpretations, etc. *if you have the documentation*. Are we that open?

CONCLUSION

I'd like to close with a final analogy that is full of meaning for the petroleum and chemical industries. Management views quality in the conduct of toxicology studies the same way it views safety in the laboratory. (See Figure 1.)

It doesn't take much imagination to substitute the word **quality** for **safety** in Figure 1 to have an unmistakable profile **of** quality studies in toxicology. (See Figure 2.) Most of us believe this to our very core and have tried throughout our

FIGURE 1. Management's View of Safety.

1. Safety is the responsibility of each individual in the laboratory.
2. An unsafe act can not only hurt you but your fellow worker **as** well, so everyone must take precautions.
3. Unsafe behavior can result in loss of life, limb and jobs.
4. Safety **is** a state of mind, an attitude, a constant presence influencing each person's behavior.
5. Safety is not inherent but must be learned by repeated training and reinforcement.
6. There is no excuse or justification for doing a job in **an** unsafe fashion.
7. The evaluation **of** a manager's performance should include safety **as** one of the job elements.

FIGURE 2. Management's View of Quality.

1. Quality is the responsibility **of** each individual in the laboratory.
2. Poor quality can not only affect you but your fellow worker **as** well, so everyone must be involved.
3. Poor quality can result in loss **of** jobs.
4. Quality is a state of mind, an attitude, a constant presence influencing each person's behavior.
5. Quality is not inherent but must be learned by repeated training **and** reinforcement.
6. There is **no** excuse or justification for doing a job in a sloppy fashion.
7. The evaluation **of** a manager's performance should include quality **as** one of the job elements.

careers to put these attitudes **and** behaviors in place among our people. We were doing it not only before there were **EPA QA** guidelines but, for many people here in this room, before there was an **EPA!** For the most part, literal compliance with the guidelines is easy once the mind set is created in the individual. If we let the activity become adversarial or, even worse, if it becomes a contest between industry and **EPA** ("you'll never find out what we're doing," or "I'll **find** something if I dig hard enough"), that's the time when management on both sides must exercise another of its functions—discipline—and be sure that the goals and priorities of the workers are consistent with the **goals** and priorities of the organization. The kind of behavior just illustrated is not on the priority list of either industry or **EPA**.

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