Book Reviews

Good Laboratory Practice Regulations
Second Edition, Revised and Expanded
Edited by Sandy Weinberg
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It is now almost a quarter of a century since the twin scandals of Watergate and dubious laboratory practices shook the American political and pharmaceutical communities. Whereas Watergate has largely disappeared from the public memory, except as a handy label for any uncovering of political misdoing, the latter has had a more permanent effect on the conduct and attitude to modern drug research and development. This has been in the establishment of Good Laboratory Practice Regulations, the subject of this excellent book in the Marcel Dekker series on Drugs and the Pharmaceutical Sciences.

Jean M Taylor, the co-author of the first chapter, on the history of GLP, is described as a retired FDA team leader and should I suppose know more than most of the history of the phenomenon. Nevertheless, the implication that the problem of poorly conducted safety studies in the drug industry was unearthed by observations by FDA review scientists may be claiming some undeserved credit for the agency. In fact it was the pharmaceutical company concerned, G D Searle, that drew the attention of the FDA to discrepancies in studies already submitted by them. The discrepancies, it must be said, did not invalidate the studies, nor did they compromise safety, but the FDA investigators, and some politicians, seized on these incidents with enthusiasm and very quickly other, more serious items (in other companies and testing laboratories) came to light. The flurry of investigations and promulgation of guidelines and regulations that followed made a bureaucrat's dream and the working scientist's nightmare. The FDA claimed that the initial findings on malpractice in the laboratory were but the tip of the iceberg, with the implication that scientists were not to be trusted and had to be watched like hawks by, presumably, more honest and upstanding administrators. The research-minded scientist was appalled at the implication that he did not know what good laboratory practice was unless it was spelled out with capital letters.

In the event, the initial draconian measures, as contained in the FDA's 1978 GLP Regulations, were reviewed in 1984. The FDA proposed revisions to the regulations to reduce the regulatory burden on testing facilities on the grounds that its inspections had shown that the violations uncovered in the mid-1970s were the exception rather than the rule, something many of us had suspected all along. Nevertheless, a vast GLP structure was now in place and is an essential part of the research and development process, as the rest of this book makes clear. The 1984 proposals also suggested changes to the information collection requirements, subject apparently to the Paperwork Reduction Act of 1980. I had not come across this before, but I shall treasure the name.

The second chapter by Wendell A Peterson, is by far the longest in the book, covering some 90 pages. It is an extremely useful and detailed interpretation of the regulations as they now exist. Among many of the valuable insights in this chapter is the warning that the lawyer- bureaucrat will, like the character in Alice in Wonderland, use a word to mean what he wants it to mean rather than follow the rest of the English-speaking world. Thus, the Environmental Protection Agency's Resource Conservation and Recovery Act defines "solid" to include solid, liquid, semisolid or contained gaseous materials. Peterson wryly refers to this as rewriting the laws of chemistry and physics, and warns that anyone following the GLP regulations would also be well-advised to be clear on the definitions of such commonplace words as "person" or "sponsor" as determined by the authorities. This chapter, in conjunction with George W James' chapter on the FDA's inspection program provides an excellent exposition of the current workings of the GLP Regulations.

The remaining chapters address some of the misgivings of many people that the early, and sometimes definitive statements on GLP were being made at a single place in space and time, that is in the United States in 1975. There was no regard for different attitudes in other cultures, nor was there a recognition of the rapid pace of change in scientific knowledge and introduction of new techniques. A particular example was in the recording of raw data, assumed to be in hand-maintained laboratory note-books but now often only existing in electronic form. Happily, sense and sensibility have prevailed in the intervening years and there are chapters on the interface with Environmental Protection Agency regulations and with GLP regulation in countries outside the United States, on automated laboratories, and on the role and validation of computer systems.

The editor has produced a well-integrated book on an important topic and rounds it off well with a final optimistic chapter that is more laudatory of GLP than any this reviewer has read before. I am not sure that the loss of serendipity in the research laboratory is so overwhelmingly compensated for by the increased certainty of solid knowledge that Weinberg claims. In other fields, such as artificial intelligence and neural networks, the philosophy of the long painstaking route to the right answer is being challenged so that future computers will solve problems in ways closer to the workings of the human brain.

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