Statistics in Pharmaceutical Safety Assessment

1 INTRODUCTION

This chapter is intended for both practicing and student toxicologists as a practical guide to the common statistical problems encountered in drug safety assessment and the methodologies that are available to solve them. The chapter has been enriched by the inclusion of discussions of why a particular procedure or interpretation is recommended, by the clear enumeration of the assumptions that are necessary for a procedure to be valid, and by discussion of problems drawn from the actual practice of toxicology and toxicological pathology.

Studies continue to be designed and executed to generate increased amounts of data. The resulting problems of data analysis have thus become more complex and toxicology has drawn more deeply from the well of available statistical techniques. Statistics has also been very active and growing during the last 35 years—to some extent, at least, because of the parallel growth of toxicology. These simultaneous changes have led to an increasing complexity of data and, unfortunately, to the introduction of numerous confounding factors which severely limit the utility of the resulting data in all too many cases.

A major difficulty is that there is a very real necessity to understand the biological realities and implications of a problem as well as the peculiarities

Pharmaceutical Sciences Encyclopedia: Drug Discovery, Development, and Manufacturing
Edited by Shayne C. Gad