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Book review

***Pharmaceutical Experimental Design*, G.A. Lewis, D. Mathieu, and R. Phan-Tan-Lu, Marcel Dekker, Inc., New York, 1999, 498 pages, ISBN 0–8247–9860–0.**

The authors' claimed objective was to present an integrated approach to statistical experimental design. The book covers an extensive range of such designs, either used or potentially useful for the development of pharmaceutical dosage forms and processes. The book is divided into ten chapters. The Introduction contains some very important comments on the need for a careful planning of experiments, which must thoroughly consider the statistical data evaluation to be employed. The object is to ensure that the experiments and the data analysis answer the problems to be solved. All other chapters then show how this can be achieved for different types of problems.

The strength of this book lies in the construction of the chapters, which follows the principle of 'problem based learning'. In most chapters and sub-chapters, the authors start with a clear definition of the problem to be solved. There follows a mathematical analysis of the problem and the introduction of possible designs. A large number of examples are then provided to demonstrate the application of these designs and interpretation of the results. In the next step, a generalisation of the problems is derived, so that the reader is enabled to construct similar designs for more complex problems. The examples chosen cover a wide range of pharmaceutical problems such as formulation, pharmaceutical analysis, stability, and incompatibility studies and process validation. At the end of a chapter, the contents are summarised, and conclusions about the applicability and limitations of the designs studied in the chapter are drawn.

While the overall impression of the book contents is very positive, there are some issues, which also need to be considered. At times, the authors mention mathematical methods only very briefly, so that a reader with no mathematical or statistical background will have difficulty in understanding the points made (for example, 'interaction diagrams', 'Bayesian analysis', or section 7D5. In the latter case, the examples are not very illustrative.) The use of R^2 as opposed to residual analysis as a means of evaluating the quality of the models derived is open to debate. Chapter 6 on optimisation does not provide the latest approaches available. Methods such as Multicriteria–Decision–Making ('Vector–Optimisation') or the use of Lagrange–functions offer benefits over the methods presented. Also, as the methods outlined are restricted to the optimisation of one response variable, the 'combined response variable technique' briefly mentioned on p. 284 should have been explored in more detail. The animal experiment described on p. 173 does not fit in the overall context of the book, and the problems involved in such tests are oversimplified both in statistical and practical terms. Appendix IV is not helpful. It aims to assist the reader in the purchasing of appropriate software. However, possible commercial software packages are neither mentioned nor explored in this respect.

Overall the book is not easy to read. Readers with experience in statistical design and data

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analysis will be delighted by it, because it will provide them with new prospects and help them explore new possibilities. However, newcomers might be overwhelmed by the enormous amount of information provided, if they do not have a solid statistical background, which is really required for effective understanding.

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