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International Journal of Pharmaceutics 223 (2001) 93–94

international journal of pharmaceutics

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Book review

Quality in the Manufacture of Medicines and Other Healthcare Products

John Sharp, Pharmaceutical Press, 2000. ISBN 0-85369-4311

Quality assurance of the manufacture of medicines is one of the most complex tasks undertaken on a large scale by organisations and companies. It is a continually evolving activity — every mistake and incident identified creating a learning opportunity. It is therefore hardly surprising that there are few, if any, comprehensive treatises on the subject. John Sharp's book is a substantial and welcome addition to the literature in this area.

Intended as a 'practical survey and critique' rather than a 'how to do it' book (not that one could ever be written!), *Quality in the Manufacture of Medicines and other Healthcare Products* is a review both comprehensive and detailed. The author writes from an extremely deep pool of knowledge and experience, and has a unique insight into the history and development of Good Manufacturing Practice (GMP) in Europe. The book is largely comprehensive in its coverage. It places pharmaceutical quality assurance firmly in context — both within the broader literature of Quality and Quality Systems, and within the pharmaceutical industry itself. A scan of the contents pages will show the broad range of topics covered-Principles, Premises and Equipment, Personnel, Documentation, Quality Control, Sterile and other products, Validation and Self Inspection/quality audit and other techniques. It provides an excellent basis for study and reflection by those responsible for manufacture on the adequacy of both them and their systems and procedures.

Part of the purpose of the book is to provide the readership with opinion as well as fact. Readers of the *UK's Industrial Pharmacists Newsletter* will be familiar with the views of the author on such topics as the Food and Drug Administration (FDA), and validation. Although less critical than some of the author's writings, it is very clear that the author prefers the European to the American approach to good manufacturing practice. This will undoubtedly seem odd to US readers, and in the opinion of the reviewer may be a significant impediment to achieving widespread acceptance of the book in the USA. The author's understanding of the basis and context of US regulation of GMP may not be as great as that of the European situation.

Inevitably, a few areas are not all I would like. The training programme suggested for GMP compliance is likely to be regarded as inadequate to an FDA inspector; the FDA requirement for regular, documented refresher training in basic GMP from top to bottom of the organisation is not discussed. The chapter on training spends more time on how the training should be delivered rather than what people should be trained in or on, and I would like to have seen more attention devoted to my own technical speciality of solid dosage form manufacture. The use of the inclusive form she/he is not consistent, 'he's being used in most chapters to the likely irritation of some readers.

The writing style of the book will strike the reader immediately. It is discursive rather than terse, and so quite readable. The breadth of the

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PII: S0378-5173(01)00724-4

author's knowledge of the English language and English mannerisms is evident throughout. This will challenge non-English readers, as some idioms used are not translatable.

Overall, I found this a useful and interesting book that I would recommend to those who wish to understand the subject–Quality in the Manufacture of Medicines.

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