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Book Review

John Sharp, **Quality in the Manufacture of Medicines and other Healthcare Products**

London: Pharmaceutical Press, 2000. 528 pages hardback. UK £69.00 Overseas £75.00 UK Member £59.00 Overseas Member £65.00.
ISBN 0-85369-431-1

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It is very difficult to overstate the importance of controlling the quality of manufactured medicines. Unfortunately, however, there are all too many examples in the literature of what may happen if sub-standard medicines are administered to a patient, who is, by definition, already in a position of compromised health. This book sets out to explain what ''Quality'' is in relation to a medicinal product, not such an easy task as it might at first appear, and to describe the various factors in the manufacture of medicines which may, singularly or severally, affect the quality of the final product. The regulatory framework (European and American) is discussed, but the book is essentially concerned with the science and philosophy of ''quality'' and the practical measures needed to guarantee that a medicinal product is fit for its intended use, and is therefore not a handbook on how to survive regulatory inspections. The author is well-placed to present such a book, having been the editor of the 1977 and the 1983 issues of the *Guide to Good Manufacturing Process* (the ''Orange Guide''), regarded by many as the ''bible'' of GMP.

This book is structured into Part 1 dealing with the principles of quality, including definitions of various terms and a brief overview of the regulatory system, and Parts 2 to 8 dealing with specific issues such as Premises, Validation, etc. The author consistently makes the point that someone actually takes the medicines that we make, a point that is arguably sometimes forgotten, and which is the reason why ''Quality'', ''Good Manufacturing Procedures'', etc are important. There is an interesting comparison of the requirements of the (currently highly topical) ISO 9000 series of standards with what would be expected via the ''normal'' GMP regulations and guidelines. Essentially, any individual responsible for the manufacture of medicines whose procedures cannot pass the ISO 9000 series requirements with flying colours should be looking for a new job, as these standards are fundamentally lower than the GMP regulations and guidelines currently applicable to our industry. The most lengthy sections in Parts 2 to 8 are those dealing with Personnel and Sterile Products, recognising that personnel form the most variable and least controllable aspect of the manufacturing process and the very special concerns with sterile products and the difficulties associated with assurance of sterility. The section on validation very laudably suggests that we ''get back to basics'', with the purpose of validation being to guarantee, to the best of our ability, that a process will do what it purports to do, rather than to generate forest-loads of impenetrable reports.

The author's rather droll sense of humour comes through in some of his comments throughout the book. For example, a question on one of the suggested GMP test papers reads as follows: ''Medicines Inspectors are – a) junior civil servants, b) experienced chemists and pharmacists, c) generally incompetent, d) always men?'' There is apparently only one correct answer to this question.

The book itself is a high-quality production, being carefully and clearly laid out and printed on glossy paper. The cover rather self-consciously reflects the colour of the ''Orange Guide'', but as orange has come to be regarded as the colour of publications on the topic of quality, this is perhaps appropriate.

In my opinion, this is an excellent book and it will serve as an essential reference source for a number of different groups. For example, it may form the basis of (re)training for personnel involved at any level or stage in the manufacture of medicines. Additionally, it will be useful as a reference text in undergraduate modules on Industrial Pharmacy and in post-graduate courses on

pharmaceutical quality assurance. This book should be ''cover-to-cover'' required reading for QA personnel, Production Directors and Financial Directors who seek to reduce the quality of medicines to a (small) entry on the financial balance sheet. To paraphrase Mr Sharp, quality is not an optional extra for manufacturers of medicinal products, but rather it is (or should be) the very heart of the operation.

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