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Book review

Good manufacturing practices for pharmaceuticals: a plan for total quality control from manufacturer to consumer **(5th edition, revised and enlarged), Sidney H. Willig, Marcel Dekker Inc., New York, ISBN 0-8247-0425.**

There are a variety of possible ways of looking at good manufacturing practice (GMP). Two polar extremes are exemplified, on the one hand, by the view (expressed in the 1983 edition of the UK "Guide to Good Pharmaceutical Manufacturing Practice" Sharp, 1983) that "The object of GMP… is initially the assurance of the quality of the product and ultimately the safety, well-being and protection of the patient". On the other hand there is the view generally adopted in the USA, where "GMP" is considered to be a set of rigidly enforceable Federal Regulations (CFR), the "Current Good Manufacturing Practice Regulations", or "the CGMPs". In the US, the major task confronting the manufacturer is considered to be that of convincing visiting FDA investigators (whose interpretations of the regulations, as this book acknowledges, may well vary) that their company is "compliant with" or "non-violative of" the "cGMPs".

This book is positioned firmly on the latter camp, so much so that its full title might be considered to be somewhat misleading. It is not really a "plan for total quality control" (whatever that may be, as distinct from ordinary, common or garden, quality control). A more accurate statement of the book's nature appears in the back cover "blurb", where it is declared that it "…examines US law and governmental policy affecting …pharmaceutical manufacturing, recommending… ways to interpret and comply with FDA Current Good Manufacturing Practice Regulations and related criteria".

It needs also to be noted that it is written in an extreme (advanced?) form of AmerEnglish, a mode of expression which has now diverged so far from its source (standard or English English) as to have become an entirely new language with its own vocabulary, grammar and syntax, and thus to have become virtually unintelligible to those acquainted only with English English. Two examples, selected from the many which present themselves in this text, must suffice: "Advances in the design of pharmaceuticals, to at once expand and make more specific their applicability to modern armamentaria have added complexities to the entire production process…" and "In my long-term pharmaceutical experience, whether or not consultants are used, the role of company counsel in explaining self-evaluative privileges along with attorney-client and work-product protection is essential".

Following a preliminary chapter on "Status and Applicability of US Regulations" the main substance of the book consists of eleven chapters (2–12) each devoted to one of the "Subparts" (A–K) of the US CGMP Regulations. Each subpart, and its various sub-sub-parts, is quoted in full, and then enlarged-upon, with suggestions on ways and means of compliance. Relevant "Compliance Policy Guidelines", as and where issued by the FDA are also reprinted in full. It seems however that, although the FDA publish these guidelines on how to comply with their own regulations, they disclaim any responsibility for accepting any manufacturer who follows them as

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being "in compliance". Each of these chapters concludes with a set of "Examples of observations from FDA 483 citations", some of them bordering on the risible. ("Form 483" is the document upon which FDA investigators record "non-compliances".) Further chapters follow these first twelve, on such topics as "Bulk Pharmaceutical Chemicals", "The Pharmacist and Total Quality Control", "Other GMPs" and "Other Approaches to Quality". There are then five appendices, including the "Food and Drug Modernisation Act of 1997 – in Pertinent Part" and "Hearing Procedures when FDA proposes the Imposition of Civil Money Penalties".

This book will no doubt be of some value to manufacturers operating in the USA. Those outside the US and who export to America, and thus may be subject to inspection by the FDA, may find some value in it, provided that they are able to penetrate the language. However, with the current progress of the various Mutual Recognition Agreements (MRAs), the threat of a visit from the FDA may be presumed to be a declining one.

References

Sharp, J., (Ed.), Guide to Good Pharmaceutical Manufacturing Practice, third edition, 1983, London, HMSO, ISBN 011 320832 4.

Code of Federal Regulations 21 CFR, Parts 211, Current Good Manufacturing Practice for finished pharmaceuticals, US Food and Drug Administration.

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