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Book Review

Good Design Practices for GMP Pharmaceutical Facilities; A.A. Signore & T. Jacobs, editors, Taylor & Francis, 2005, Hardcover, 550, 0-8247-5463-8

In today's highly regulated, global pharmaceutical manufacturing industry, each company is continuously searching for proper guidance on how to stay in compliance with the ever changing expectations and regulations of the various regulatory bodies worldwide. Nowhere is this more evident than in the design and construction of the facilities where these pharmaceuticals are manufactured. The task of building (or retrofitting) a pharmaceutical facility is a balancing act, where teams need to meet the quality and regulatory requirements as well as budget and schedule constraints. This act is confounded by the continuous shifts in the cGMP requirements pertaining to these facilities. There are numerous recent examples of plants that do not quite meet the requirements and have trouble passing inspection. More often than not these plants are also well over budget and behind schedule. Poor planning, including not understanding the current design practices or even the regulatory requirements that pertain to the finished plant, cost companies dearly in time and money. The authors of this text have attempted to collect, in one text, these current design practices and take some of the guess work out of that half of the balancing act.

The text covers most aspects of pertinent design practices. It opens with overarching topics and profiles the industry. It then covers various engineering disciplines and validations in some depth. From there it delves into four types of pharmaceutical facilities. Covered specifically, are Oral Solid Dosage Facilities, Sterile Manufacturing Facilities, Biotechnology Facilities, and Active Pharmaceutical Ingredient Facilities. The text finishes up covering a number of associated and sometimes tangential topics that give the text more breadth and some extra detail. One glaring omission from the text is the topic of Good Engineering Practices. Several chapters reference the subject but only in an attempt to skirt around the subject. This is unfortunate and somewhat undermines the text in reaching its goal.

Overall, the chapters are thorough, well written, detailed, and interesting. Several are not up to the same standard, particularly with respect to the details of the topic. Some chapters stay at a higher, general level and lack sufficient detail. In some cases, this is appropriate as with the overview chapters, but this lack of structure, consistency, and quality control is noticeable in other chapters.

This text is a good reference for many in the Pharmaceutical industry, mostly design and construction professionals that are new to the industry and peripheral professionals that need to know why (and how) projects must balance all the aspects, cost so much, and take so long. Specifically, various managers not directly involved in the design and construction, such as Project Managers, Product Managers, Financial Managers, and those involved in the capital project approval hierarchy within operating companies may find this text useful. Those that have a few recent years of experience (or a set of ISPE Baseline Guides) probably will not get much value out of this text.

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