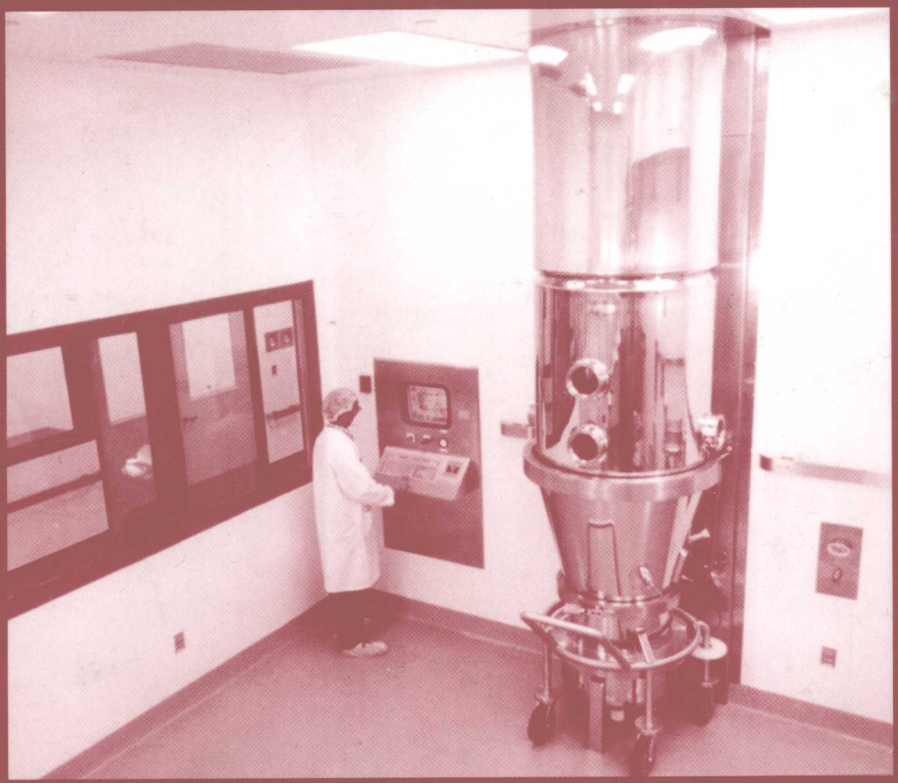
DRUGS AND THE PHARMACEUTICAL SCIENCES VOLUME 146

Good Design Practices for GMP Pharmaceutical Facilities



edited by
Andrew A. Signore
Terry Jacobs

Good Design Practices for GMP Pharmaceutical Facilities

Andrew A. Signore
IPS
Lafayette Hill, Pennsylvania, U.S.A.

Terry Jacobs
Jacobs/Wyper Architects
Philadelphia, Pennsylvania, U.S.A.

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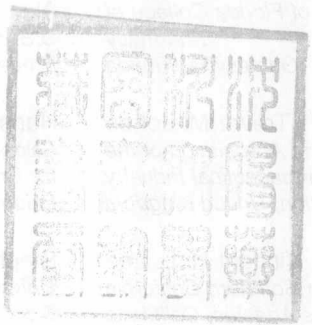

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Todd Allshouse
David Barr
Michael Bergey
Eric Bohn
Jack C. Chu
Robert Del Ciello
Stuart Dearden
Phil DeSantis
David Eherts
Jon F. Hofmeister
Terry Jacobs
Dave Kerr
William Kesack
David Lonza
Daniel Mariani
Art Meisch
Joseph Milligan
Miguel Montalvo
George Petroka
Denise Proulx
Andrew A. Signore
Charles Sullivan
Ed Tannebaum
William B. Wiederseim
George Wiker
Julian Wilkins
Peter Wilson
Gary V. Zoccolante

Advisors

Peter T. Bigelow
Robert E. Chew
Jim Dougherty
John Dubeck
A.J. (Skip) Dyer
Anthony Felicia
Robert J. Hoernlein
Thomas Jeatran
Sterling Kline
Larry Kranking
Brian Lange
James Laser
Stanley F. Newberger
George Petroka
Joseph X. Phillips
Wulfran D. Polonius
Denise Proulx
Hank Rahe
Eric Sipe
Teri C. Soli
Ashok Soni

Preface

Ask any busy pharmaceutical facility professional about their work and invariably you will hear, among a series of everyday challenges, such responses as "there's just too little time for me to do a good job," "new regulations keep coming but budgets aren't increasing," and "I simply do not have a enough experienced staff to achieve stated objectives." Designing a modern, compliant pharmaceutical facility is a daunting task within an increasingly complex and demanding business environment.

Successful pharmaceutical facilities are continually challenged to respond to evolving developments in technology and external regulation. This book aims to help the facility professional provide facility services that deliver faster, better, and more valued products to market. We herein provide useful tools in the form of relevant materials, practical advice, lessons learned, and insights into prevailing practices.

Good Design Practices (GDPs) provide a set of essential references for planning and delivering business-aligned, capital projects. GDPs, which include Good Manufacturing Practices (GMPs), form an essential aspect of project delivery and, when applied properly, help organizations deliver facilities that "perform and conform" to the growing body of regulatory requirements and business imperatives.

Webster defines "design" as "intentional functionality." GDPs offer a framework and a mindset to achieve acceptable functionality while meeting stringent tests of "fitness for purpose" in pharmaceutical facilities. Imaginative and effective application of GDPs can also achieve prudent risk management for manufacturing operations. GDPs also incorporate non-pharma specific public statutes, including environmental, occupational, safety, health, and local business code issues.

Pharma manufacturing facilities are increasingly considered strategic assets. Whether the firm meets its production requirements through fully integrated in-house manufacturing operations or obtains goods and services through external, third-party sources, pharma manufacturing facilities occupy a growing strategic role for the enterprise, where the bar is being raised for global compliance and competitive achievement.

GDPs also offer a framework for quality assurance to ensure that products are consistently produced and controlled by application of appropriate standards to their intended use as required by marketing authorization. GMP issues are also clearly a part of a quality program and form essential elements of facility planning. GDPs and, in turn, GMPs raise the importance of documentation and the process by which facilities are designed, built, and validated to demonstrate their ability to meet intended functionality and to confirm that what has been done is in accordance with what was planned. In addition to including GMPs, GDPs also help projects align with business objectives as captured in design standards and procedures, and assist the firm to achieve speed to market, flexible capacity, and conformance to other standards of care at acceptable cost and risk. Facilities professionals can increase

their contributions through prudent application of GDPs where techniques provide additional tools to deliver valuable services.

It was not our intent to definitively and comprehensively treat all aspects of underlying engineering and science upon which good design practices are built. This book, however, does gather current practice and offers a convenient source of information provided by practicing professionals who are experts in their respective fields. Our contributors also encourage a strong awareness of the vital role that manufacturing plays in the modern firm and how prudent application of GDPs can increase the impact that each facility can have on the success of the firm and society as a whole through delivery of safer, cost-effective medicinal products.

Our approach encouraged each author (i.e., chapter expert) to frame their materials in the context of why the information was relevant to good design practices; how cost, schedule, and related project management issues are affected; and how historical insights and emerging trends can be highlighted for possible future development.

The successful application of scientific and engineering principles to the task of "practical design" remains a lifelong professional challenge. Incorporating affordable innovation into business-aligned facility solutions at acceptable risk is a worthy goal. We trust this book will prove helpful to those who set out on the wonderful "facilities" journey and will put to good use the wisdom inherent in "good design practices."

Andrew A. Signore, PE
Terry Jacobs, AIA

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A.A.S.
T.J.