Pharmaceutical and Biopharmaceutical Manufacturing: Understanding Your Process Series

Risk Management Library, Volume 7

Risk Problem Solvers: Inadequate Facilities, Procedures and Process Control

Edited by
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ABOUT THIS BOOK

This book is about failure in pharmaceutical manufacturing — its causes, detection, correction and the teachings and lessons implicit in it.

No human endeavor is perfect and the manufacture of pharmaceuticals is no exception. People simply make mistakes and even well-conceived systems occasionally fail. As evidenced by the examples in this book, when errors occur pharmaceutical manufacturing systems are usually robust enough to detect them and prevent defective products from reaching consumers, but not always.

The errors that occur can provide valuable information to improve imperfect systems and lessons to improve personnel performance and understanding. Often these lessons provide the foundational "why" that is so necessary to put into perspective for manufacturing and quality control personnel the need for a particular practice or procedure. People learn best when they understand why a procedure or practice is important and what can happen if it isn't followed.

This book provides many examples of failures that have actually happened. Careful study of these failures will lead to better understanding of why they occurred and what might have been done to prevent them. The "lessons" in this book can be used, through training and systems review, to prevent these types of failures.

Many thanks to the people who contributed to this book. Their insights and investigations into the causes of failure are invaluable. We have chosen not to link the lessons to their authors to preserve anonymity and to "protect the innocent" so to speak. Further, we believe candid presentation and discussion of these lessons increases their value and may encourage others to share their experiences.

One final thought before you begin your journey through these lessons: "Murphy" is always watching.

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