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Book Review

Process Validation in Manufacturing of Biopharmaceuticals: Guidelines, Current Practices, and Industrial Case Studies, A. S. Rathore and G. Sofer, editors, CRC Press, 2005, Hardback, 600, ISBN #1574445162

This book is a well-written collection of current validation practices for the manufacture of biopharmaceutical active substances. It begins with a general industry perspective on the guidelines of process validation. The book also includes a discussion of the comments that manufacturers may receive from regulatory agencies when designing process validation strategies. These comments often reflect the concerns of the regulatory agency and the challenges that the manufacturers should consider and evaluate in the course of designing process validation strategies. There is an overall emphasis in the book on the importance of setting up high-quality process development programs that effectively characterize the operating parameter limits of the process. An up-front investment of time and effort in process development will minimize the probability of process deviations occurring outside the established operating parameter limits during the qualification or commercial phases.

A distinguished group of subject-matter experts from the pharmaceutical industry have written standalone chapters, and each chapter focuses on selected parts of validating the complicated process of manufacturing biopharmaceuticals. The Failure Mode and Effects Analysis model and its process risk assessment tools are discussed and the various applications of these tools are illustrated with real-life examples of process characterization. A very innovative "scale down" model is described and this model contains practical paradigms for evaluating purification at much smaller volumes that effectively represent larger production scale volumes. Several chapters are devoted to detailed explanations of previous agency audit validation focus points, such as adventitious agents, lifespan studies for chromatography and filtration media, analytical methods, filters and computer systems. One key chapter not to be overlooked is Chapter 9 on the regulatory expectations for facility requirements and the control of the facility's environment.

Finally, the editors have collected real-life case studies which can be read and evaluated as instructive lessons about the validation of a purification process, a matrix process validation strategy for a multivalent bacterial vaccine, and a viral clearance validation. The results and conclusions of these case studies bring the book full circle in that they stress and illustrate the importance of the early process characterization work for fully understanding the operating limits of the manufacturing process.

This book is recommended for drug substance managers, scientists, and operators in the validation, development, manufacturing, and quality groups of pharmaceutical companies who may be interested in the guidelines developed and the lessons learned by key subject matter experts in the industry. The specific subject-matter experts who were asked to write these chapters lead me to believe that the validation approaches described herein are those that have generated numerous approved products in the past and that provide the building blocks for consistent controlled manufacturing practices.

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