

PHARMACEUTICAL MANUFACTURING VALIDATION PRINCIPLES

E. B. SOUTO,^{1,3} T. VASCONCELOS,^{2,3} D. C. FERREIRA,³ AND
B. SARMENTO³

¹*Free University of Berlin, Berlin, Germany*

²*Laboratory of Pharmaceutical Development, BIAL, S. Mamede do Coronado, Portugal*

³*Faculty of Pharmacy, University of Porto, Porto, Portugal*

Contents

- 1 Introduction
- 2 Scope of Validation Processes
- 3 Validation Master Plan
- 4 Validation Protocols and Reports
 - 4.1 Validation Protocols
 - 4.2 Validation Reports
- 5 Facilities Validation
 - 5.1 Generalities
 - 5.2 Design of Facilities
- 6 Manufacturing Process Validation
- 7 Analytical Methods
- 8 Equipment and Computer Systems
 - 8.1 Equipment Systems
 - 8.2 Computer Systems
- 9 Cleaning Validation
- 10 Conclusions
- References

1 INTRODUCTION

The pharmaceutical industry has been a pioneer in the development of quality and safety procedures assuring that the risk of its work is reduced to a minimum. The

Pharmaceutical Sciences Encyclopedia: Drug Discovery, Development, and Manufacturing

Edited by Shayne C. Gad

Copyright © 2010 John Wiley & Sons, Inc.