

SCALE-UP AND POSTAPPROVAL CHANGES (SUPAC) REGULATIONS

PUNEET SHARMA, SRINIVAS GANTA, AND SANJAY GARG

University of Auckland, Auckland, New Zealand

Contents

- 1 Introduction
- 2 Scientific and Regulatory Rationale for SUPAC
 - 2.1 Supporting Documents and Extent of Change
 - 2.2 Supporting Documents for Change in Specifications
 - 2.3 Comparability Protocols
 - 2.4 In Vitro–In Vivo Requirements
- 3 Regulatory Agencies and Guidelines
 - 3.1 FDA SUPAC Regulations
 - 3.2 Regulatory Guidance on SUPAC by Pharmaceutical Unit of EU
 - 3.3 Regulatory Guidance on SUPAC by Agencia Nacional de Vigilancia Sanitaria
- 4 Harmonization
- 5 GMP Issues: Change Control and Process Validation
 - 5.1 Change Control
 - 5.2 Process Validation
- 6 Conclusion

1 INTRODUCTION

Product development aims at formulating active drug ingredient in a palatable form. Technology transfer of a pharmaceutical product from research to the production floor (referred to as “shop floor”) with simultaneous increase in production outputs is commonly known as scale-up. In simple terms, the process of increasing batch size is termed as scale-up. Conversely, scale-down refers to decrease in batch size in response to reduced market requirements.

Pharmaceutical Sciences Encyclopedia: Drug Discovery, Development, and Manufacturing
Edited by Shayne C. Gad
Copyright © 2010 John Wiley & Sons, Inc.