SCALE-UP AND POSTAPPROVAL CHANGES (SUPAC) REGULATIONS

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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.

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