

Pharmaceutical Regulatory Essentials - GxP: An Industry Introduction

GeneEd Staff



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This electronic book (PDF format) introduces the governmental authorities that regulate the drug development process and the standards that they enforce to ensure the safety, efficacy, and security of drugs, biological products, and medical devices. This book is divided into 2 sections: The first section, PIPELINE AND PLAYERS, describes the process of identifying, developing, and testing new drugs and introduces the regulatory authorities that oversee this process. The second section, GxP REGULATIONS, describes the standards maintained by regulatory authorities to guide laboratory testing, clinical trials, and drug manufacturing.

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