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Nota di contenuto

1. Overview of Medicines Regulatory Systems in the Gulf Region -- 2. The Regulatory Review Process in the Gulf Region -- 3. Regulatory Review Times in the Gulf Region -- 4. Quality Measures in the Gulf Regulatory Practices -- 5. The Current Status of the Common Technical Document -- 6. The Current Status of Drug Safety and Pharmacovigilance -- 7. The Centralized Regulatory Review in the Gulf Region -- 8. The Gulf States Assessment and Experience With the Centralised Procedure -- 9. The Pharmaceutical Companies Assessment and Experience With the Centralised Procedure -- 10. Proposal For an Improved Centralized Regulatory System -- 11. The Strategic Planning Process of the GCC Regulatory Authorities: Barriers And Solutions -- 12. The Regulatory Dilemma in the Gulf Region: The Way Forward.

Sommario/riassunto

The Middle East represents the next growth market for the global biopharmaceutical industry but to date there has been limited information about the regulatory review processes employed in these countries. A thorough examination of the strategies currently being implemented by the Gulf States is considered critical to the future regulatory environment in this region. This book compares national and centralised procedure practices and key performance metrics, including current approval times, review practices and pharmacovigilance standards, in the seven Gulf States. Opportunities for an improved regulatory system are identified, which, if fully implemented, could have a significant impact on patients' access to new medicines. *Pharmaceutical Regulatory Environment: Challenges & Opportunities in the Gulf Region* is a must read for those interested in pharmaceutical regulation in the Gulf region.