Record Nr. UNINA9910787716503321 Autore Weisfeld Victoria D. Titolo International regulatory harmonization amid globalization of drug development: workshop summary / / Victoria Weisfeld and Tracy A. Lustig, rapporteurs: Forum on Drug Discovery, Development, and Translation, Board on Health Sciences Policy Washington, District of Columbia: .: National Academies Press. . Pubbl/distr/stampa [2013] ©2013 **ISBN** 0-309-28482-1 0-309-28480-5 Descrizione fisica 1 online resource (128 p.) Disciplina 615.19 Soggetti Drug development Lingua di pubblicazione Inglese **Formato** Materiale a stampa Livello bibliografico Monografia Note generali Description based upon print version of record. Nota di bibliografia Includes bibliographical references. ""Front Matter"": ""Reviewers"": ""Contents"": ""Boxes"": ""Acronyms"": ""1 Nota di contenuto Introduction""; ""2 Principles and Definitional Considerations""; ""3 Overview of the Current Global Regulatory Landscape""; ""4 Areas of Need for Harmonized Standards and Barriers to Progress in Addressing the Gaps""; ""5 Characteristics of Harmonized Regulations and Regulatory Structures"": ""6 Finding Solutions: Options and Systemic Approaches"": ""7 Tactics and Strategies for a Way Forward"": ""References""; ""Appendix A: Workshop Agenda""; ""Appendix B: Participant Biographies"" "The past several decades have been a time of rapid globalization in the Sommario/riassunto development, manufacture, marketing, and distribution of medical products and technologies. Increasingly, research on the safety and effectiveness of new drugs is being conducted in countries with little experience in regulation of medical product development. Demand has been increasing for globally harmonized, science-based standards for the development and evaluation of the safety, quality, and efficacy of medical products. Consistency of such standards could improve the

> efficiency and clarity of the drug development and evaluation process and, ultimately, promote and enhance product quality and the public

health. To explore the need and prospects for greater international regulatory harmonization for drug development, the IOM Forum on Drug Discovery, Development, and Translation hosted a workshop on February 13-14, 2013. Discussions at the workshop helped identify principles, potential approaches, and strategies to advance the development or evolution of more harmonized regulatory standards. This document summarizes the workshop"--