Record Nr. UNINA9910828319503321 Building a national framework for the establishment of regulatory **Titolo** science for drug development [[electronic resource]]: workshop summary / / Institute of Medicine of the National Academies; Yeonwoo Lebovitz, Rebecca A. English, and Anne B. Claiborne, rapporteurs Pubbl/distr/stampa Washington, D.C.:,: National Academies Press,, 2011 **ISBN** 0-309-20959-5 1-283-01910-8 9786613019103 0-309-15890-7 Edizione [First edition.] 1 online resource (95 pages) Descrizione fisica Altri autori (Persone) LebovitzYeonwoo EnglishRebecca A ClaiborneAnne B Disciplina 615.1 Soggetti Pharmaceutical policy - United States Drug development - Government policy - United States Pharmaceutical industry - Government policy - United States Lingua di pubblicazione Inglese **Formato** Materiale a stampa Livello bibliografico Monografia Note generali "Forum on Drug Discovery, Development, and Translation, Board on Health Sciences Policy." Includes bibliographical references. Nota di bibliografia ""Front Matter""; ""Reviewers""; ""Contents""; ""Figures and Boxes""; Nota di contenuto ""Acronyms""; ""Preface""; ""1 Introduction""; ""2 Defining Regulatory Science""; ""3 The Urgent Need for Regulatory Science""; ""4 Barriers to Enhanced Regulatory Science""; ""5 Potential Models for Building a Regulatory Science Infrastructure"; ""6 Challenges in Engaging the Public Policy Community""; ""7 Envisioning Successful Regulatory Science at FDA""; ""8 Considering Next Steps""; ""References""; ""Appendix A: Agenda""; ""Appendix B: Participant Biographies"" Sommario/riassunto "The Food and Drug Administration (FDA) is tasked with ensuring the safety and effectiveness of medicine. FDA's science base must be strong enough to make certain that regulatory decisions are based on the best scientific evidence. The IOM held a public workshop on February 26, 2010, to examine the state of regulatory science and to

consider approaches for enhancing it."--Publisher's description.