

1. Record Nr.	UNINA9910817967503321
Autore	Boname Morgan L.
Titolo	Advancing the discipline of regulatory science for medical product development : an update on progress and a forward-looking agenda : workshop summary : proceedings of a workshop // Morgan L. Boname, Amanda Wagner Gee, and Anne B. Claiborne, rapporteurs ; Forum on Drug Discovery, Development, and Translation [and three others]
Pubbl/distr/stampa	Washington, District of Columbia : , : The National Academies Press, , 2016 ©2016
ISBN	0-309-43887-X 0-309-43885-3
Descrizione fisica	1 online resource (105 pages) : illustrations
Disciplina	362.17820973
Soggetti	Pharmaceutical policy - United States Drug development - Technological innovations - United States United States
Lingua di pubblicazione	Inglese
Formato	Materiale a stampa
Livello bibliografico	Monografia
Nota di bibliografia	Includes bibliographical references at the end of each chapters.
Nota di contenuto	Introduction -- Characterizing the Implementation science landscape -- Regulatory science applications: using case studies to focus on approaches to advance the discipline -- Regulatory science infrastructure and workforce -- Challenges and opportunities in regulatory science -- Appendix A: Bibliography -- Appendix B: Workshop agenda -- Appendix C: Participant biographies.
Sommario/riassunto	"The field of endeavors known as 'regulatory science' has grown out of the need to link and integrate knowledge within and among basic science research, clinical research, clinical medicine, and other specific scientific disciplines whose focus, aggregation, and ultimate implementation could inform biomedical product development and regulatory decision making. Substantial efforts have been devoted to defining regulatory science and communicating its value and role across the scientific and regulatory ecosystems. Investments are also being made in technology infrastructure, regulatory systems, and

workforce development to support and advance this burgeoning discipline. In October 2015, the National Academies of Sciences, Engineering, and Medicine held a public workshop to facilitate dialogue among stakeholders about the current state and scope of regulatory science, opportunities to address barriers to the discipline's success, and avenues for fostering collaboration across sectors. Participants explored key needs for strengthening the discipline of regulatory science, including considering what are the core components of regulatory science infrastructure to foster innovation in medical product development. This report summarizes the presentations and discussions from the workshop"--Publisher's description.

---