1. Record Nr. UNINA9910785016503321

Titolo	Considerations for ensuring safety and efficacy of vaccines and therapeutic proteins manufactured by using platform approaches [[electronic resource]] : summary of a workshop / / Jeffrey Fox, Marilee Shelton-Davenport, and India Hook-Barnard ; Board on Life Sciences, Division on Earth and Life Studies
Pubbl/distr/stampa	Washington, D.C., : National Academies Press, 2010
ISBN	1-282-66043-8 9786612660436 0-309-15322-0
Descrizione fisica	1 online resource (39 p.)
Altri autori (Persone)	FoxJeffrey (Jeffrey L.) Shelton-DavenportMarilee Hook-BernardIndia
Disciplina	358.38
Soggetti	Vaccination
Lingua di pubblicazione	Inglese
Formato	Materiale a stampa
Livello bibliografico	Monografia
Note generali	Description based upon print version of record.
Nota di contenuto	""Front Matter""; ""PREFACE""; ""ACKNOWLEDGMENTS""; ""CONTENTS""; ""INTRODUCTION/PLATFORMS FOR LARGE-SCALE MONOCLONAL ANTIBODY PRODUCTION/PLATFORMS FOR VACCINE PRODUCTION/SUMMARY OF KEY POINTS ""; ""Appendix A Statement of Task""; ""Appendix B AGENDA""; ""Appendix C Biographies""
Sommario/riassunto	On September 15, 2008, the National Academies held the workshop "Considerations for Ensuring Safety and Efficacy of Vaccines and Therapeutic Proteins Manufactured by Using Platform Approaches". The workshop was planned and organized by an ad hoc planning committee made up of members of the Standing Committee on Biodefense at the US Department of Defense. The charge to the planning committee was to bring together scientists from academe, government, and the biotechnology industry to identify and discuss challenges and ideas related to the Transformational Medical Technologies Initiative's (TMTI) vision of developing countermeasures within a few months after a biologic-warfare agent is identified. The workshop focused on

manufacturing processes and specifically on the development of "manufacturing platforms"--Repeatable components of manufacturing that reduce both development time and risk. An underlying assumption was that demonstrating that integrated platforms can reliably produce safe and efficacious countermeasures might shorten the regulatory approval process. Participants discussed manufacturing-related characteristics of monoclonal antibodies and vaccines. Although the planning committee understood that the TMTI efforts are broader than biologics and that TMTI platform approaches for biologics extend beyond monoclonal antibodies and vaccines, the planning committee believed that focusing on monoclonal antibodies and vaccines could illustrate some of the promise and challenges of platform approaches.