

1. Record Nr.	UNINA9910806999703321
Titolo	Detection and quantification of antibodies to biopharmaceuticals : practical and applied considerations / / edited by Michael G. Tovey
Pubbl/distr/stampa	Hoboken, N.J., : Wiley, c2011
ISBN	9786613203854 9781283203852 1283203855 9781118075678 1118075676 9781118075685 1118075684 9781118075661 1118075668
Edizione	[1st ed.]
Descrizione fisica	1 online resource (442 p.)
Altri autori (Persone)	ToveyMichael G
Disciplina	616.07/98
Soggetti	Immunoglobulins - Analysis Immunoassay
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 and index.
Nota di contenuto	Principals of risk assessment and monitoring of antibody responses to biopharmaceuticals / Eugen Koren, Erik Foehr, and Charles A. O'Neill -- Immunogenicity of therapeutic proteins : a regulatory perspective / Susan Kirshner -- Guidance on immunogenicity assessment of biologically-derived therapeutic proteins : an European perspective / Meenu Wadhwa and Robin Thorpe -- Japanese regulatory perspective on immunogenicity / Takao Hayakawa and Akiko Ishii -- Enzyme immunoassays and radioimmune assays for quantification of anti-TNF biopharmaceuticals and anti-drug antibodies / Klaus Bendtzen and Morten Svenson -- Confirmatory immunogenicity assays / Eric Wakshull and Daniel Coleman -- The use of pharmacodynamics as a surrogate marker for the detection of anti-drug neutralizing antibodies / Florian Deisenhammer -- Cell-based assays for the detection of

neutralizing antibodies to interferon beta (IFN-?) and tumor necrosis factor-alpha (TNF-?) inhibitors / Anthony Meager -- Detection of neutralizing antibodies (NABs) to Interferon-beta by real time RT-PCR / Francesca Gilli and Antonio Bertolotto -- Competitive ligand binding assays for the detection of neutralizing antibodies / Bonnie Wu, George R. Gunn III, and Gopi Shankar --

The use of surface plasmon resonance for the detection and characterization of antibodies / Steven J. Swanson and Daniel Mytych -- Hypersensitivity reactions to biopharmaceuticals : detection and quantification of drug-specific IgE antibodies / Jrgen Dahlstrm and Lennart Venemalm -- Standardization and validation of immunoassays and biophysical assays for the detection of anti-drug antibodies / Daniel Kramer -- Standardization and validation of cell-based assays for the detection of neutralizing anti-drug antibodies / Deborah Finco-Kent and Amy Grenham -- Standardization of neutralizing antibody unitge by bioassay design : constant antigen and constant antibody methodology / Sidney E. Grossberg, Yoshimi Kawade, and Leslie D. Grossberg -- Cut-points and performance characteristics for anti-drug antibody assays / Viswanath Devanarayan and Michael G. Tovey -- Dilutional linearity for neutralizing antibody assays / David Lansky and Carrie Wager -- Detection of neutralizing antibodies to biopharmaceuticals in the presence of high levels of circulating drug / Arno Kromminga and Michael G. Tovey.

Sommario/riassunto

The definitive book on the neutralization of recombinant biopharmaceuticals. Recombinant biopharmaceuticals are an important tool for treating a range of illnesses; however, their efficacy can be severely impaired by their immunogenicity. When introduced into the body, these pharmaceuticals can cause the immune system to produce anti-drug antibodies (ADAs) that neutralize their effects. The first and only book to cover neutralization in connection with biopharmaceuticals and the measurement and application of neutralizing antibodies in modern medicine at any real length, *Detection an*
