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Babiarz, J.C. Pisano, D.J. 2008

Overview of FDA and drug development  
FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices and Biologics  
Pisano, D.J. Mantus, D.S. New York Informa Healthcare USA, Inc1

Regulatory affairs and testing (Chapter 12) - Mechanics of ...

and/or validate specific biomaterials for use in an eventual Advanced Therapy Medicinal Product or Medical Device. Preclinical regulatory affairs would need to be completed taking due account of current good laboratory



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