
Biosimilars And Interchangeable Biologics Strategic Elements

trends in biologic medicine - amgenbiotech - 1 3 2 4 5 introduction facts about biologics biosimilars ≠ generics manufacturing biologics requires planning for and managing variability pharmacovigilance **sopp 8401: administrative processing of original biologics ... - 1 . sopp 8401: administrative processing of original biologics license applications (bla) and new drug applications (nda) version: 8 . effective date **scientific considerations in demonstrating biosimilarity ...** - scientific considerations in demonstrating biosimilarity to a reference product . guidance for industry . u.s. department of health and human services**

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