

- EMA. (2010) Guideline on the investigation of bioequivalence. European Medicines Agency, London, UK.
- FDA. (2001) Guidance on statistical approaches to establishing bioequivalence. Food and Drug Administration, Center for Drug Evaluation and Research, Rockville, MD.
- FDA. (2015a) Scientific considerations in demonstrating biosimilarity to a reference product. Food and Drug Administration, Silver Spring, MD.
- FDA. (2015b) Quality considerations in demonstrating biosimilarity to a reference protein product. Food and Drug Administration, Silver Spring, MD.
- FDA. (2015c) Biosimilars: questions and answers regarding implementation of the Biologics Price Competition and Innovation Act of 2009. Food and Drug Administration, Silver Spring, MD.
- Hsieh TC, Chow SC, Liu JP, et al. (2010) Statistical test for evaluation of biosimilarity of follow-on biologics. *Journal of Biopharmaceutical Statistics* **20**, 75–89.
- Roger SD, Mikhail A. (2007) Biosimilars: opportunity or cause for concern? *Journal of Pharmaceutical Science* **10**, 405–410.
- Schall R, Luus H. (1993) On population and individual bioequivalence. *Statistics in Medicine* **12**, 1109–1124.
- Schellekens H. (2005) Follow-on biologics: challenges of the ‘next generation’. *Nephrology, Dialysis, Transplantation* **20**, 31–36.
- Shao J, Chow SC. (2002) Reproducibility probability in clinical trials. *Statistics in Medicine* **21**, 1727–1742.
- Webber KO. (2007) Biosimilars: are we there yet? Presented at Biosimilars 2007, George Washington University, Washington, DC.
- WHO. (2005) Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability (draft revision). World Health Organization, Geneva, Switzerland.