Suggested Reading List

Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" (2020). US Food & Drug Administration.

Guidance for Industry and FDA Staff: Current good manufacturing practice requirements for combination products. (2017). US Food & Drug Administration.

Guidance for industry vaginal microbicides: Development for the prevention of HIV infection. (2014). US Food & Drug Administration.

ICH guideline M3(R2) on non-clinical safety studies for the conduct of human clinical trials and marketing authorisation for pharmaceuticals. (2013). European Medicines Agency.

ICH guideline S6 (R1) – preclinical safety evaluation of biotechnology-derived pharmaceuticals. (2011). European Medicines Agency.

Guidance for industry nonclinical safety evaluation of drug or biologic combinations. (2006). US Food & Drug Administration.

Nonclinical pharmacology/toxicology development of topical drugs intended to prevent the transmission of sexually transmitted diseases (STD) and/or for the development of drugs intended to act as vaginal contraceptives. (2005). US Food & Drug Administration.