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Q & A Resources

Country	Agency	Contents	Link
EU	EMA	EMA procedural advice for users of the centralized procedure for similar biological medicinal products applications	https://www.ema.europa.eu/documents/regulatory-procedural-guideline/european-medicines-agency-procedural-advice-users-centralised-procedure-similar-biological-medicinal_en-0.pdf
		Biosimilars in the EU (Information guide for healthcare professionals)	https://www.ema.europa.eu/documents/leaflet/biosimilars-eu-information-guide-healthcare-professionals_en.pdf
US	FDA	Questions and Answers on Biosimilar Development and the BPCI Act	https://www.fda.gov/media/119258/download
Canada	Health Canada	Fact Sheet: Biosimilars	https://www.canada.ca/en/health-canada/services/drugs-health-products/biologics-radiopharmaceuticals-genetic-therapies/applications-submissions/guidance-documents/fact-sheet-biosimilars.html
Switzerland	Swissmedic	Questions and answers concerning the authorisation of similar biological medicinal products (biosimilars)	https://www.swissmedic.ch/swissmedic/en/home/legal/legal-basis/administrative-ordinances/questions-and-answers-concerning-the-authorisation-of-similar-bi.html
WHO	WHO	WHO Questions and Answers: similar biotherapeutic products	https://www.who.int/biologicals/expert_committee/QA_for_SBPs_ECBS_2018.pdf?ua=1