Suggested Reading List

Glossary of Regulatory Terms. (2022). WCG Cares.

Inactive Ingredient Search for Approved Drug Products. (Updated 2022). U.S. Food and Drug Administration.

Principles of Premarket Pathways for Combination Products: Guidance for Industry and FDA Staff. (2022). U.S. Food and Drug Administration.

Product Registration Basics for Global Health Program Managers. (Updated 2021). USAID; EECO; WCG Cares; Population Council; Population Services International.

Donation of Contraceptive Products through Special Import Permits: A Case Study in Zambia and Nigeria. Stachowski et al. (2020). International Journal of Drug Regulatory Affairs. DOI: 10.22270/ijdra.v8i4.437

Medical Devices: Application of Risk Management to Medical Devices. (2019). ISO.

Bioanalytical Method Validation Guidance for Industry. (2018). U.S. Food and Drug Administration.

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Learning about Expanded Access and Potential of the Levonorgestrel Intrauterine System (LEAP LNG-IUS): Regulatory Assessment. (2018). FHI360; Population Services International; WCG Cares.

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Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products Guidance for Industry. (2017). U.S. Food and Drug Administration.

Vaginal Microbicides: Development for the Prevention of HIV Infection. (2014). U.S. Food and Drug Administration.

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Information Sheet Guidance for IRBs, Clinical Investigators, and Sponsors: Significant Risk and Nonsignificant Risk Medical Device Studies. (2006). U.S. Food and Drug Administration.

Quality Systems Approach to Pharmaceutical CGMP Regulations. (2006). U.S. Food and Drug Administration.

M4: The Common Technical Document (CTD). (2003). International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH).

Q1A(R2) Stability Testing of New Drug Substances and Products. (2003). U.S. Food and Drug Administration.

Guidance for Development of Vaginal Contraceptive Drugs (NDA). (1998). U.S. Food and Drug Administration.

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