Useful links for education and reading

Please note: this list includes a personal selection of links and materials that some of the PV SIG members deemed useful or interesting. It is not exhaustive and not regularly updated. Feel free to use it to get some insights in the pharmacovigilance world!

Education and e-learning opportunities

- **E-learning modules: medicines (free)**

https://www.gov.uk/government/publications/e-learning-modules-medicines-and-medical-devices/e-learning-modules-medicines-and-medical-devices

- **Regulatory affairs professional society (numerous e-learning opportunities/payable)**

https://www.raps.org

- **International Society of Pharmacovigilance**

https://isoponline.org

- **Pharmaceutical Information & Pharmacovigilance Association (PIPA)**

https://www.pipaonline.org/

- **British Medical Association**

www.bma.org.uk

- **Eu2P European Programme in Pharmacovigilance and Pharmacoepidemiology**

www.eu2p.org

Useful reading (books)

- **Pharmacovigilance Medical Writing: A Good Practice Guide 1st Edition,**

by Justina Orleans-Lindsay (Author)

Pharmacovigilance Medical Writing covers the preparation of pharmacovigilance documents for all stages of the drug development process (i.e. from clinical development through to applications for marketing authorisations to the post-marketing stage). For each document, the

book presents a review of the regulatory framework that governs the content of the document, followed by practical guidance (e.g. scheduling, source data, department/functions involved in document preparation/review, appropriate timelines and planning activities), ending with a generic model document compliant with the current guidelines, which can be modified to meet specific company and product requirements.

https://www.wiley.com/WileyCDA/WileyTitle/productCd-1119967260,descCd-buy.html

- **Adverse Drug Reactions: A Practical Guide to Diagnosis and Management by Christian Benichou (author)**

Reviews the biochemical and physiological abnormalities in each of the body's organ systems, enabling investigators to decide if the problem is of drug–induced origin. Much of the material is presented as a series of observations with accompanying questions which should be addressed in order to make an accurate diagnosis. Includes useful flow charts for the management of adverse drug events and examples of specific report forms.

https://www.amazon.fr/Adverse-Drug-Reactions-Practical-Management/dp/0471942111

- **Cobert's Manual Of Drug Safety And Pharmacovigilance 3nd Edition by Barton Cobert (Author)**

Completely revised and updated, Cobert's Manual of Drug Safety and Pharmacovigilance, Third Edition, is a how-to manual for those working in the fields of drug safety, clinical research, pharmacology, regulatory affairs, risk management, quality/compliance, and in government and legal professions. This comprehensive and practical guide discusses the theory and the practicalities of drug safety (also known as pharmacovigilance), and provides essential information on drug safety and regulations in the United States, Europe Union, and more, including: recognizing, monitoring, reporting, and cataloging serious adverse drug reactions. Cobert's Manual of Drug Safety and Pharmacovigilance, Third Edition, teaches the ins and outs of drug safety in the industry, hospitals, FDA, and other health agencies both in the United States and around the world and presents critical information about what is done when confronted with a drug safety problem.

- https://www.amazon.de/Coberts-Manual-Drug-Safety-Pharmacovigilance/dp/9813278846

Journals and publications

- Drug Safety The Official Journal of the International Society of Pharmacovigilance [ISoP].

- Safety observer

- **Kelly, W.N., Arellano, F.M., Barnes, J. et al. Guidelines for Submitting Adverse Event Reports for Publication. Drug-Safety (2007) 30: 367**. https://doi.org/10.2165/00002018-200730050-00001

  https://link.springer.com/article/10.2165/00002018-200730050-00001#citeas

  The 'Guidelines for Submitting Adverse Events for Publication', published simultaneously in *Pharmacoepidemiology and Drug Safety* (2007; 16: 581–587), is a free-access document, without assigned copyright, and may be republished, copied or quoted, without permission, on the condition that its content remains unaltered. Copyright of the exact format in which the 'Guidelines for Submitting Adverse Events for Publication' appear here belongs to Adis Data Information BV, but this version may be copied without permission for non-commercial purposes.

Other resources (blogs)

- Safety Observer : Regulatory News in Pharmacovigilance blog at https://safetyobserver.blogspot.com
- Cobert's Manual of Drug Safety and Pharmacovigilance 3rd Edition **-->** blog at https://www.c3isolutions.com/category/life-sciences/barts-corner/
- PV blog: https://www.c3isolutions.com/author/bart-c/